
“ANALYSIS OF RISK FACTORS OF LATE PRETERM BIRTH: A CASE
CONTROL STUDY”

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**KLE UNIVERSITY, BELAGAVI,
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LIST OF ABBREVIATIONS USED

WHO	-	World Health Organization
ACOG	-	American College Of Obstetrics and Gynecology
LPB	-	Late preterm birth
HTN	-	Hypertension
PE	-	Pre-Eclampsia
PPROM	-	Preterm Premature rupture of membranes
PROM	-	Premature rupture of membranes
PTB	-	Prior preterm birth
NICU	-	Neonatal Intensive Care Unit
RDS	-	Respiratory Distress Syndrome
TTN	-	Transient Tachypnea of Newborn
PDA	-	Patent DuctusArteriosus
NEC	-	Necrotizing Enterocolitis
AOP	-	Anaemia of Prematurity
IVH	-	Intraventricular Hemorrhage
ADHD	-	Attention Deficit Hyperactivity Disorder

LNMP	-	Last Normal Menstrual period
CI	-	Confidence Interval
LBW	-	Low Birth Weight
VLBW	-	Very Low Birth weight
FLM	-	Fetal Lung Maturity

ABSTRACT

Objective

To identify the risk factors associated with late preterm births.

Methodology

This case control study was conducted in Department of Obstetrics and Gynecology, teaching hospital attached to KLE University's Jawaharlal Nehru Medical College, Belagavi during the period of May 2015- April 2016. A total of 918 women were enrolled, 459 in each group. Women who delivered between 34 – 36⁺⁶ weeks were considered as cases and controls were women who delivered from 37 weeks onwards immediately after a case occurred. Gestational age was confirmed with USG prior to 20 weeks. Data was collected from the history of the patient and the medical records.

Result

Incidence of late preterm birth was found to be 8% among total births. It was found that 55.1% were spontaneous births. The most common risk factor for late preterm birth was Hypertensive disorders of pregnancy (Gestational HTN- 4.8%, Chronic HTN – 5%, PE – 36%, Eclampsia – 4.8%) followed by PPRM (32.7%), History of prior preterm births (19.2%), Gestational diabetes (17.9%), Multifetal gestation (16.6%), Placenta previa (13.5%) and Abruption placenta (9.8%). On analyzing neonatal outcome, Sepsis was found in 25%, Hyperbilirubinemia in 21.9%, RDS in 19%, Transient tachypnoea of newborn in 09% and PDA in 2.9% of the neonates.

Conclusion

The indication for the induction or need for termination should be reevaluated in the late preterm gestation. In order to prevent late preterm birth, identification of the risk factors is necessary and timing of delivery in each risk factor should be reassessed in advance before intended intervention. As LPB constitute majority of preterm births, it is important to limit late preterm deliveries to clear maternal or fetal indication for delivery

Key words: Late preterm birth; Risk factor; Preeclampsia.

CONTENTS

SL. NO.	TOPIC	PAGE NO.
1.	INTRODUCTION	1-4
2.	OBJECTIVES	5-6
3.	REVIEW OF LITERATURE	7-20
4.	METHODS	21-27
5.	RESULTS	28-51
6.	DISCUSSION	52-62
7.	CONCLUSION	63-65
8.	SUMMARY	66-68
9.	BIBLIOGRAPHY	69-76
10.	ANNEXURES	
	ANNEXURE I – CONSENT FORM	77-82
	ANNEXURE II – PROFORMA	83-86
	ANNEXURE III – KEY TO MASTER CHART	87-89

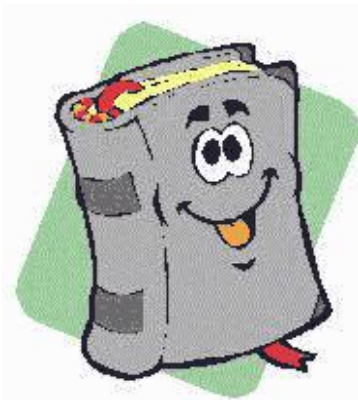
LIST OF TABLES

DESCRIPTION	PAGE NO.
1. Maternal age distribution	30
2. Parity	31
3. Association with PROM	32
4. Association with history of prior preterm births	33
5. Association with Gestational hypertension	34
6. Association with Chronic hypertension	35
7. Association with Severe Pre-eclampsia	36
8. Association with Spontaneous abortion	37
9. Association with Induced abortion	38
10. Association with Eclampsia	39
11. Association with Gestational diabetes mellitus	40
12. Association with Abruption	41
13. Association with Placenta Previa	42
14. Association with multiple gestation	43
15. Association with IUD	44
16. Onset of labour	45
17. Mode of delivery	46
18. Distribution of Gestational age	47
19. Association of birth weight	48
20. Association of Newborn complications	49
21. Distribution of newborn complications	50

LIST OF GRAPHS

DESCRIPTION	PAGE NO.
1. Maternal age distribution	30
2. Parity	31
3. Association with PROM	32
4. Association with history of prior preterm births	33
5. Association with Gestational hypertension	34
6. Association with Chronic hypertension	35
7. Association with Severe Pre-eclampsia	36
8. Association with Spontaneous abortion	37
9. Association with Induced abortion	38
10. Association with Eclampsia	39
11. Association with Gestational diabetes mellitus	40
12. Association with Abruption	41
13. Association with Placenta Previa	42
14. Association with multiple gestation	43
15. Association with IUD	44
16. Onset of labour	45
17. Mode of delivery	46
18. Association of birth weight	48
19. Association of Newborn complications	49
20. Distribution of newborn complications	50

1.
Introduction



Introduction

INTRODUCTION

Preterm birth is a prime cause of infant morbidity and mortality worldwide. The term Preterm birth refers to all births occurring before 37 weeks period of gestation or less than 259 days from the first day of last menstrual period. It is further sub-classified into extreme preterm (<28 weeks gestation), very preterm(28 to <32 weeks gestation), moderate preterm (32 to<34 weeks gestation) and late preterm (34 to <37 weeksgestation).^{1, 2, 3}

Incidence of preterm births in developing countries ranges from 12-18% and India recorded the highest number of preterm births in 2010.¹ Nearly 24% or one in four children born prematurely across the globe in 2010 were from India. Almost 13% of all children born in India were preterm.²

Neonatal mortality and morbidity associated with preterm births is significantly higher than term births. The frequency of adverse neonatal outcomes increases with decreasing gestational age, this trend is also evident in the gestational window of 34 to 36 weeks.^{6,7} Mortality rate is seven times higher in moderately preterm and three times higher in late preterm births as compared to term births.^{6,7}

Late preterm births (LPB), previously tagged as “near-term” babies are the fastest growing population accounting for 75% of all the preterm births and about 8% of the total births.^{4,5} It is a major public health concern due to its rising prevalence and associated neonatal mortality and morbidity. Contrary to our belief that late preterm neonates fare well similar to term babies, they are at a very high risk of immaturity related complications.

A variety of morbidities such as respiratory distress, temperature instability, hypoglycemia, kernicterus, apnea, feeding problems, rehospitalization, neonatal and post neonatal mortality are reported in late preterm births.⁷ Respiratory distress, PDA and sepsis are

Introduction

considered to be common neonatal complications. Furthermore, significantly increased rates of cerebral palsy, mental retardation and other major disabilities in the late-preterm infant compared with term infant should be of great concern because of the profound social burden.^{8,9} Prolonged hospitalization, rehospitalisation and long term sequelae pose great financial and psychological burden on the family.

Late preterm births have not been studied frequently; their developmental biology and functioning of systems are not yet understood completely. Management strategies for these babies are based on general principles, clinical experience and extrapolation from our knowledge of very preterm and term babies. Previous research and available literature on late preterm births focused to cluster the short term and long term outcome. Less is known about the medical indications for late preterm delivery. Late preterm births have been on a drastic rise for many reasons including demographic changes, infertility treatment, increase in maternal age, increasing incidence of multiple pregnancies, increasing rate of caesarean delivery and labour induction.¹³

Recent rise in the LPB rates by 25% raises the question as to whether the indications for these births are justified.^{6,10} Evidence suggested 32% of these deliveries were medically indicated.⁷ It is important to know which medical indication is major contributor in late preterm delivery as the neonatal outcomes likely differ depending upon the underlying pathophysiology of the complication.⁹

The timing of delivery in such cases ought to balance the maternal and newborn risk with the risk of continuation of pregnancy; however evidence to guide the timing of delivery is limited to certain conditions. The ACOG Committee on Obstetric Practice -The Society for Maternal-Fetal Medicine states that patients with placenta previa with suspected accreta,

Introduction

increased placental accretion should be delivered in the late preterm period as the risk of antepartum hemorrhage is 4.7% at 35 weeks, 15% at 36 weeks and 30% at 37 weeks. Patients with prior classical cesarean, Dichorionic-diamniotic twins with concurrent condition like abnormal Doppler and maternal co morbidities (chronic hypertension, preeclampsia etc.) should also be delivered between 34 to 36 completed weeks. Monochorionic–Diamniotic twins with isolated fetal growth restriction also need to be delivered in late preterm gestation as chances of TTTS is 3-4% and fetal death rate rises by 1-2% per week after 32 weeks in monochorionic gestations. Patients with severe pre-eclampsia, pre-gestational well controlled diabetes and PPROM also need to be delivered between 34 to 36 completed weeks.¹⁷

Few indications can be expectantly managed with delivery 37 weeks to decrease the risk of neonatal morbidity and mortality without a significant increase in stillbirth. Thus, in many cases it is possible to prevent LPB without negatively affecting the outcome.^{9, 10} In order to identify these possible preventive measures, a better knowledge of the risk factors leading to LPB is essential. Defining risk factors aids in identifying at-risk women and early initiation of risk specific treatment.

As late preterm births contribute to nearly two-thirds of preterm births, there is a paramount need to evaluate the risk factors leading to the same and identify the associated neonatal morbidities in these seemingly healthy neonates.

2.

Aims and Objectives



Aims and Objectives

AIMS AND OBJECTIVES

The aims and objectives of the present study were

1. To identify the risk factors associated with late preterm births.
2. To determine the perinatal outcome in late preterm births.

3.
Review of Literature



Review of literature

REVIEW OF LITERATURE

BACKGROUND

With respect to gestational age, a newborn may be term, preterm or post term. Preterm birth is a prominent global public health issue. Preterm birth complication is the leading cause of death among children under 5 years of age. It accounts for nearly 1 million deaths each year. World Health Organization (WHO) and the International Federation of Gynecology and Obstetrics (FIGO) in 1976 defined preterm births as newborns delivered before 37 completed weeks (36^{6/7} weeks). Around the year 2005, with recognition of the morbidities associated with infants born at 34 – 36 weeks, this large group was further subdivided into early preterm (<33⁺⁶ weeks) and late preterm (34 weeks to 36⁺⁶ weeks).¹⁶ In 2013, 0.74 million deaths were reported due to preterm birth complications.¹ Premature infants have higher rates of cerebral palsy, sensory deficits, learning disabilities and respiratory illnesses compared with term infants. The morbidity associated with preterm birth often extends to later life, resulting in enormous physical, psychological and economic burden.^{11,12}

DEFINITION

Late Preterm birth is defined as childbirth occurring at 34 weeks onwards to less than 37 completed weeks.^{1,4,5}

INCIDENCE

Late Preterm birth rates have been reported to range from 5% to 7% of live births in some developed countries but are estimated to be substantially higher in developing countries.¹ 70% - 75% of the preterm births are contributed by LPB.⁴ These figures appear to be on the rise.

Review of literature

CAUSES OF LATE PRETERM BIRTH:

LPB is classified into:

- Spontaneous LPB – the onset of labour is spontaneous in nature and accounts for two thirds of late preterm births (75%).¹⁹ Of these , 60% are the result of preterm labour and 40% are due to PPROM.¹⁸
- Induced/ Iatrogenic LPB - where the risk of continuation of pregnancy is of greater risk to mother and baby than the preterm complications. It accounts for 25%.¹⁹ The most common etiology being pregnancy induced hypertension (40%), 4-6% in women with gestational hypertension and 10-11% in women with pre eclampsia, nonreassuring fetal testing (25%), IUGR (10%), ante partumhemorrhage (7%) and fetal death (7%).^{20,21}

The aetiology of LPB is multifactorial. However, the causes of late preterm births can be broadly classified into:

- Maternal causes
- Obstetrical / pregnancy related causes
- Foetal causes

Maternal causes:^{22,23,24}

- ✓ Advanced maternal age
- ✓ Previous preterm birth – strongest risk factor
- ✓ Multifetal gestation
- ✓ Black race

Review of literature

- ✓ Low maternal body mass index
- ✓ Hypertensive disorders of pregnancy
- ✓ Pre-existing maternal medical condition
- ✓ Short interpregnancy intervals
- ✓ Infection and periodontal disease
- ✓ Family history of preterm birth
- ✓ Lifestyle factors
- ✓ Work during pregnancy

Obstetric causes: ^{22,23,24,25}

- ✓ PROM
- ✓ Placenta previa
- ✓ Ante partumhaemorrhage
- ✓ Hypertensive disorders of pregnancy
- ✓ Gestational diabetes mellitus
- ✓ Infection
- ✓ Threatened abortion in first trimester
- ✓ History of prior preterm birth
- ✓ History of previous abortions

Fetal causes: ^{22,23,24,25}

- ✓ Congenital malformations
- ✓ Fetal distress

Review of literature

Approximately 45–50% of late preterm births are idiopathic, 30% are related to preterm rupture of membranes (PROM) and another 15–20% is attributed to medically indicated or elective preterm deliveries.^{26,27} Proper categorization of LPB into spontaneous and induced deliveries helps in determination of global incidence accurately.

COMPLICATIONS ASSOCIATED WITH LATE PRETERM BIRTHS

Little published information exists regarding the diverse morbidities found in late preterm infants; however, the available evidence suggests that compared with term neonates, late preterm newborns are at increased risk for various conditions.³¹

Short term complications²⁸

- ✓ Respiratory distress syndrome (RDS)
- ✓ Transient tachypnea of the newborn (TTN)
- ✓ Intraventricular hemorrhage (IVH)
- ✓ Patent ductus arteriosus (PDA)
- ✓ Necrotizing Enterocolitis (NEC)
- ✓ Pulmonary hypertension
- ✓ Hypothermia, hypoglycemia, hypotension
- ✓ Poor feeding, anemia, jaundice, and sepsis.

Long term sequelae^{29,30}

- ✓ Cerebral palsy and Neurodevelopment disability
- ✓ Cognitive impairment
- ✓ Bronchopulmonary dysplasia

Review of literature

- ✓ Autism spectrum disorders
- ✓ Periventricular Leukomalacia
- ✓ Attention Deficit Hyperactivity Disorder (ADHD)
- ✓ Retinopathy of prematurity
- ✓ Myopia and hypermetropia

The effect of these complications on long-term neurodevelopment outcome in the late preterm infant is largely unknown but there is growing alarm that these infants are more vulnerable to brain injury and long-term neurological sequelae than previously appreciated.³² The last 6 weeks of gestation is a critical period of growth and development of the fetal brain. Brain weight at 34 weeks is only 65% of that of the term brain and gyral and sulcal formation is incomplete.³¹ Hence, infants born during the late preterm period are at more than 3-fold increased risk of developing cerebral palsy compared with term infants.³¹

The expectation of complications, changes with advancing gestational age through the late preterm period. Complications noted at 34 to 35 week are RDS, sepsis, and patent ductus arteriosus (PDA). Also, at 34 weeks of gestation relatively high rates of neonatal intensive care unit (NICU) admission is noted, whereas the admission rate decreases at 36 weeks of gestation. No overall difference is noted in the incidence of intracranial hemorrhage or necrotizing enterocolitis; however, the rate of these complications is low throughout the late preterm period.¹⁶ Moreover, the number of NICU admissions varies extensively according to the type of facility. In addition to higher risks for serious health complications, the mortality rate for late preterm infants is 3-fold higher than that for term infants (7.7 vs. 2.5 per 1000 live births).³³

Several studies have been conducted on late preterm births. In majority of the available studies risk factors for preterm births are presented. Epidemiological studies have suggested that

Review of literature

sociodemographic and pregnancy specific factors may increase the risk of preterm birth. Obstetric history, diseases and procedures in pregnancy, as well as lifestyle habits such as smoking have been associated with the risk of preterm delivery. Few studies however have considered separately early and late preterm deliveries. Moreover, about 32% of LPB are medically indicated. The characteristics of these cases may differ from spontaneous LPB. It has also been shown that elective Cesarean Section is responsible of the increasing rate of early term births^{3, 4, 5, 6}.

In 1991, a study conducted by Tucker et al to identify the etiology of preterm births quoted that compared to the births <34 weeks, the late preterm births are the result of spontaneous idiopathic preterm labor or PPROM than medical or pregnancy indications.³⁴ A larger proportion of late preterm births in their study were due to spontaneous preterm labor (two-thirds) compared with PPROM (one-third).³⁴ On the other hand, a study conducted by Merlino et al in 2008 suggested that the causes of indicated late preterm births are similar to that for all preterm births including preeclampsia (46%), fetal indications (18%), placental abruption (14%) and other indications (20%).³⁵

ACOG committee in 2003 published a practice bulletin for management of preterm labour which concluded that the relative distribution of etiologies of preterm birth at 34 weeks of gestation were, 30% indicated preterm birth, 30% PPROM and 40% spontaneous preterm labor where as, in late preterm births, the relative distribution of etiologies changes to 20% indicated, 25% PPROM and 55% preterm labor.³⁵

In 2009, Gestational age wise distribution of late preterm births was studied by Lubow et al and the incidence reported was 32.88% for 34 weeks, 33.55% for 35 weeks and 33.55% for 36

Review of literature

weeks. The study also cited spontaneous labour and premature rupture of membranes as the most common indication for the late preterm delivery.³⁶ In another similar study conducted in 2012 by Jain et al, showed similar incidence of late preterm births, 29.8% at 34 weeks, 23.6% at 35 weeks and 46.9% at 36 weeks.³⁷ Results of the Jain et al study were as follows; Preterm labor and PROM accounted for 46.9% cases while maternal/fetal factors such as – PIH, GDM, ante partum hemorrhage, multiple gestation, fetal distress, abnormal Doppler and meconium stained amniotic fluid accounted for 53.5% cases in this study. Incidence of normal vaginal deliveries was 62% and 36% of the late preterm were delivered by lower segment caesarean section. 50.46% of the LSCS were performed for maternal indications and fetal distress was responsible for 49.53% of the LSCS. Incidence of ventouse and forceps delivery was 1 each.³⁷

A variety of factors responsible for late preterm births were described in the previous studies. In a retrospective study conducted in Texas maternal age <17 and >35 increased the risk of late preterm⁷. Study by Melamed et al in 2009, concluded that there was a significant increased prevalence of nullipara among LPB.¹⁵ Another study by Laughton et al in 2010 found an association between the single status and spontaneous LPB and PROM¹¹. However, a study conducted in Italy in 2013 published that there was no association between marital status and preterm births.

In a retrospective cross-sectional analysis using routine delivery data from all births in San Antonio/Bexar County, Texas between 2000 and 2008 and including 259,576 births, variables associated with an increased risk of LPB were black race, age <17, age > 35, gestational hypertension, chronic hypertension, and diabetes¹⁴.

Review of literature

According to a study conducted in Italy hypertension increases the risk of medically indicated LPB while a history of preterm birth or positive vaginal culture was associated with an increased risk of spontaneous and induced LPB³.

A study by Barton et al in 2011 found that 25.5% of patients with mild gestational hypertension without any maternal or fetal complication had iatrogenic elective late-preterm delivery. This practice was also associated with increased rates of neonatal complications and neonatal length of stay⁶.

Another study by Gyamfi et al found that the majority of nonspontaneous late preterm deliveries were non-evidence based. Although women with evidence-based deliveries were more likely to have infants admitted to the NICU, primary factor resulting in NICU admission was early gestational age. Overall, 18.3% of their late preterm cohort was delivered for non-evidence based and potentially avoidable indication.⁴⁵

Thorp et al study in 2003 did not support the suggestion that induced abortions, as performed in Italy during the study period, increased the risk of preterm delivery in subsequent pregnancies. Previous induced abortions did not increase the risk of preterm birth, both in small and normal for gestational age preterm infants⁴⁶.

A Study done by Carreno et al in 2011 with the use of customized birth weight standards found that FGR complicated approximately one-third of all cases of medically indicated LPB. However, the rate of FGR was different for each group (spontaneous, 13%; medically indicated, 32%; elective, 21%; $P = .001$)⁴⁷.

According to a study by Masoura et al, pre eclampsia was responsible for 8% of the late pre term deliveries and rates of caesarean section was higher in the study group with

Review of literature

preeclampsia.³⁸ Shapiro – Mendoza et al found that pregnancy induced hypertension and gestational diabetes mellitus were most frequent maternal complications in late preterm BIRTHS followed by ante partum hemorrhage. In their study, among late-preterm infants with newborn morbidity, 17.9% had no maternal conditions reported, 28.7% had at least 1 maternal condition reported and 36.6% had 2 or more than 2 maternal conditions reported. It was also found that the newborn morbidity rate doubled in infants for each gestational week earlier than 38 weeks.³⁹

In the study by Jaiswal et al, 70.8% of late preterm had at least one of the neonatal morbidities requiring inpatient hospital observation or admission.⁴⁰ In a retrospective study by Wang et al, 77.8% late preterm term babies had at least one clinical problem.⁴¹ Melamed, et al found that compared with full-term infants, spontaneous late preterm delivery was independently associated with an increased risk of neonatal morbidity, including respiratory distress syndrome, sepsis, intraventricular hemorrhage, hypoglycemia, and jaundice requiring phototherapy.¹⁵ Another study by Tomashek et al found that late preterm infants were 1.5 times more likely to require hospital-related care and 1.8 times more likely to be readmitted than term infants.⁴²

Melamed et al found that compared with full-term infants, spontaneous late preterm delivery was independently associated with an increased risk of neonatal morbidity including respiratory distress syndrome, sepsis, intraventricular hemorrhage, hypoglycemia and jaundice requiring phototherapy.¹⁵

Late preterm infants demonstrate specific infection rates, pathogen distribution, and mortality associated with early and late onset sepsis. Recent evidence suggests that late preterm infants (relative to full-term infants) are diagnosed with culture-proven sepsis more frequently and have increased sepsis related mortality and a substantial increased risk for morbidity and mortality. In the study conducted by Jain et al, incidence of sepsis was 9.6%.³⁷ In the study by Wang et al,

Review of literature

36% late preterm babies had sepsis.⁴¹ In the study by Melamed et al incidence of probable sepsis was 19 % and that of confirm sepsis was 0.4%. Max et al found 5.9% incidence of sepsis in late preterm group.^{15,56} In the study by Lubow et al 20% late preterms had respiratory complications.³⁶ Jaiswal et al reported 10.5% incidence of respiratory morbidities in late preterm study group.⁴⁰ In the study by Leone et al, incidence of respiratory distress was 34.7%.⁵² Escobar et al found that 10.7% of the late preterms needed respiratory support while in the study by Rubaltelli et al, 9.6% of late preterm newborns needed respiratory support.^{53,54}

Late Preterm infants are at increased risk of developing hypoglycemia after birth, because they have immature hepatic glycogenolysis and adipose tissue lipolysis, hormonal dysregulation and deficient hepatic gluconeogenesis and ketogenesis.¹⁷ The incidence of hypoglycemia was 8.8% in the study by Jaiswal et al.⁴⁰ In the study by Celik et al, 4% incidence of hypoglycemia was noted.⁵⁵ Melamed et al found that 6.8% of the late preterms had hypoglycemia with higher incidence in the late preterms towards 34 weeks of gestation.¹⁵ Few studies reported higher incidences of hypoglycemia such as Jain et al reported 30% incidence of hypoglycaemia.³⁷ Study by Wang et al showed that 15.6 % of the late pre terms had hypoglycaemia.⁴¹ In the study by Leone et al 14.3 % of the late preterms were hypoglycaemic.⁵²

Pune study found that incidence of hyperbilirubinemia is 13% and was more towards 34 weeks of gestation and the difference was found to be statistically significant. Jain et al found that neonatal hyperbilirubinemia requiring treatment in the form of phototherapy was much higher in late preterm babies as compared to term babies (50.8 vs. 10.4%).³⁷ Their study also revealed that more babies - 67.3% at 34 weeks of gestation required treatment for jaundice as compared to 44 % at 35 and 36 weeks gestation.³⁷ In the study by Jaiswal et al, hyperbilirubinemia was the most common early morbidity in the late preterm group with incidence of 55%.⁴⁰ Wang et al found the

Review of literature

incidence of neonatal jaundice to be 54.4% in the late preterm age group.⁴¹ In the study on late preterms by Melamed et al, incidence of neonatal hyperbilirubinemia was 18 % with higher incidence towards 34 weeks of gestation.¹⁵ Incidence of neonatal hyperbilirubinemia was 47.4 % in the study conducted by Leone et al.⁵² In a prospective study by Celik et al 13.7 % of the late preterms had hyperbilirubinemia.⁵⁵ Max et al found the incidence of neonatal hyperbilirubinemia to be 17.6%.⁵⁶ Lavanya et al found the incidence of hyperbilirubinemia to be 57% in the late preterm population.⁵⁷ They also found that incidence of hyperbilirubinemia was more towards lower gestational age.⁵⁷ The high incidence of significant jaundice in late preterm infants may be attributed to their inability to handle bilirubin load, decreased hepatic UDP glucuronyl transferase enzyme activity, and a slower post natal maturity of hepatic bilirubin uptake. Jaundice in late preterm infants is more prevalent, more pronounced, and more protracted in nature than in their term counterparts.

According to the review article published in 2010 RDS, sepsis and PDA were the three important early morbidities noted.¹⁶ Kalyoncu et al found the incidence of mortality as 2.3% in late preterm births.⁵⁸ The morbidity is significantly higher in late preterm infants than in term ones. Thus, it is not surprising that the survival rate of late preterm infants is significantly reduced. The mortality in the early neonatal (0-6 days), late neonatal (7-27 days) and post neonatal (28-364 days) periods were 6, 3, and 2 times higher respectively in late preterm infants than in term infants in a study conducted by Shapiro – Mendoza et al.³⁷ The common causes of death were congenital malformations, immaturity, sepsis, atelectasis, maternal complications and sudden infant death syndrome (SIDS). SGA are suggested to substantially increase the mortality rate.¹⁷

Iatrogenic prematurity is an underappreciated contributor to the burden of preterm birth. Inaccurate gestational age assessment is the most common cause of unintentional / iatrogenic pre

Review of literature

maturity. ACOG has proposed strict guidelines for gestational age assessment with the intention of minimizing the risk of unintended prematurity. ACOG has also mandated that elective delivery should be planned after 39 weeks of gestation in well-dated pregnancies.⁴³ An earlier elective delivery can only be considered after documentation of FLM (with 2 exceptions in which elective delivery can be performed at 38 weeks without documentation of FLM: HIV and 0 multiple pregnancies).⁴³

In a recent retrospective cohort study of late preterm births (34-37 weeks) at a single tertiary care institution, the authors concluded that less than 10% of late preterm births in this cohort were purely elective and greater than 80% were clearly unavoidable.⁴⁴ These data suggest that the adverse perinatal outcome seen in infants born in the late preterm period may be due to the underlying medical or obstetric condition that prompted the early delivery in the first place, and not due to the gestational age at delivery alone.

With the increase in frequency of late preterm deliveries and its associated increased rate of adverse short and long-term newborn outcomes, recent attention has focused on the etiology of late preterm births and how this may be distinct from very preterm and moderately preterm births. Prior research on late preterm neonates has focused on their physiologic immaturity with associated higher morbidities and mortality compared to neonates born 37 weeks gestation. For obvious reasons, elective preterm deliveries are likely underreported. So how common are elective late preterm births? Stated differently, what proportion of late preterm births is avoidable?

The clinical decision whether to deliver a premature baby is determined by the balance between the risk of death and morbidity associated with prematurity on one hand and the assessment of maternal and fetal well being by termination of pregnancy on the other. There is

Review of literature

now a growing awareness with regard to late preterm birth due to the unanticipated rate of complications this group has demonstrated. There have been many factors found to be associated with late preterm births. Few studies have dealt with factors like hypertension in detail. But none of the studies have included all the above mentioned factors. There are also some conflicting results regarding few factors in previous studies. There is a need to evaluate the indications warranting late preterm delivery, particularly due to the morbidity associated with birth in this gestational age window and still less is known about all the risk factors, which is the aim of my study.

4.

Methods



Methodology

METHODS

The present study was conducted in the Department of Obstetrics and Gynecology, teaching hospital attached to KLE University's Jawaharlal Nehru Medical College, Belagavi.

Study design

The study was a case control study.

Study period

This study was conducted during the period from May 2015- April 2016.

Source of data

Pregnant women with gestational age 34 to 36⁺⁶ weeks who delivered either vaginally or by Cesarean section in the labour room were included in the study as cases. Controls were women who delivered at 37 weeks onwards, immediately after a case occurred.

Sample size

A total of 459 pregnant women delivering late preterm births and 459 who delivered term births were included in the study.

Sampling technique

The sample size was calculated by the following formula

Methodology

$$N = \frac{2(Z_{\alpha} + Z_{\beta})^2 PQ}{(P_0 - P_1)^2}$$

$$(P_0 - P_1)^2$$

Where,

N = number of samples

$$Z_{\alpha} = \text{constant} = 1.96$$

$$Z_{\beta} = 0.84$$

$$P = \frac{P_0 + P_1}{2}$$

$$Q = 100 - P$$

With type I error rate $\alpha = 0.05$ and

Type II error rate $\beta = 0.02$ with a power of 80%

Considering the above formula the minimum sample size was calculated as 280 (140 in each group). However during the study period 459 women who delivered in late preterm gestation were assessed for eligibility and the same were included in the study as cases. Equal numbers of controls were included.

Methodology

Selection criteria

Inclusion Criteria:

Selection of cases:

- Women delivering between 34 weeks to 36 weeks 6 days period of gestation (gestational age assigned by ultrasound before 20th week of gestation).

Selection of controls:

- Women delivering 37 weeks onwards and period of gestation assigned by ultrasound before 20th week of gestation.

Exclusion Criteria:

- Women without an ultrasound before 20th week of gestation.
- Women who refused to consent

Ethical clearance

Prior to the commencement of the study ethical clearance was obtained from the Institutional Ethical committee, Jawaharlal Nehru Medical College, Belgaum. Letter no: MDC/DOME/171 dated 17/11/2014

Informed Consent

All pregnant women who met the inclusion criteria of cases and controls, admitted to the labour room were screened for eligibility by detailed history, routine antenatal examination and investigations by trained residents in the department of obstetrics and gynecology. Those

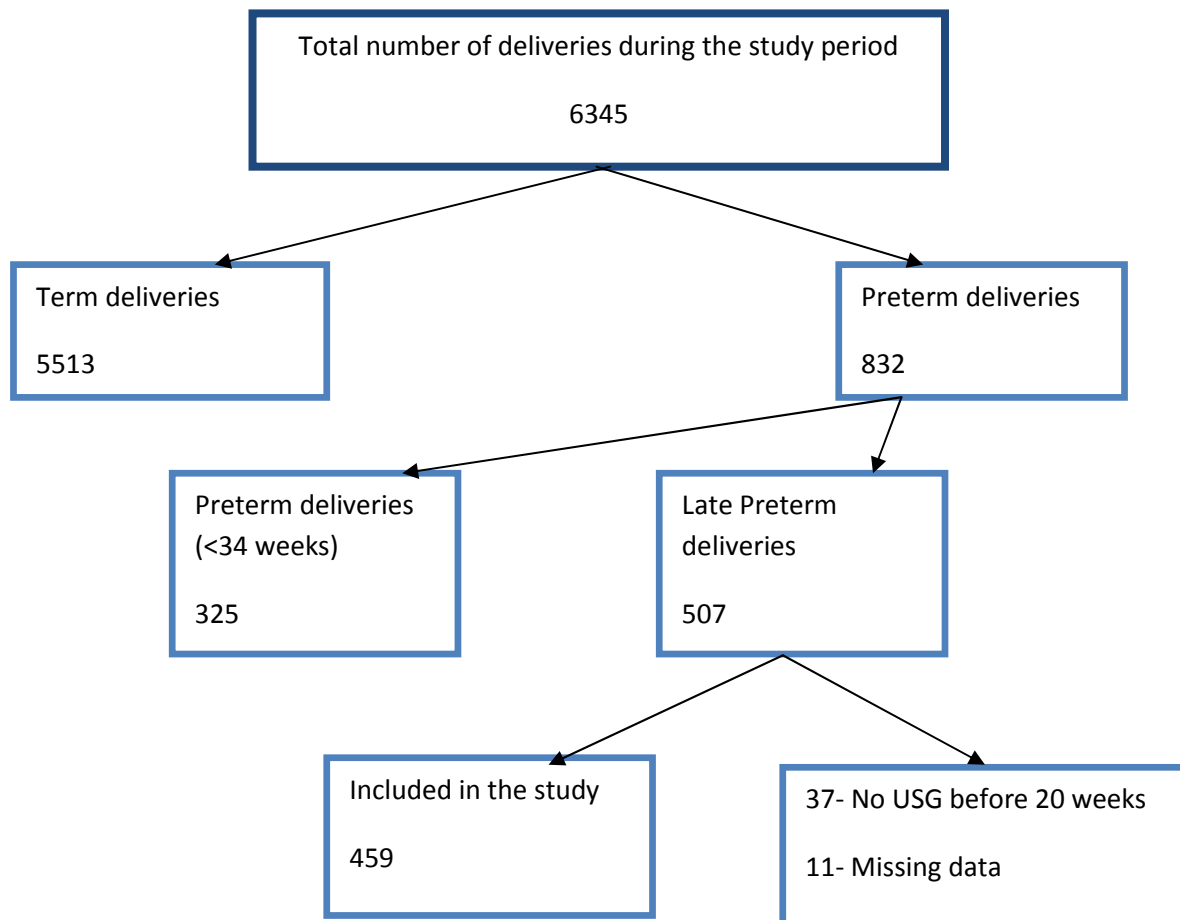
Methodology

fulfilling the selection criteria were explained about the purpose of the study. A written informed consent was obtained from all the participants before the enrollment (Annexure I).

Method of collection of data

After enrollment demographic data, obstetric history, current pregnancy details, information on labour, mode of delivery was obtained. Routine obstetric examination was carried out. Neonatal outcome after delivery was obtained. The data was recorded on a predesigned and pretested data collection instrument (Annexure II).

CONSORT Flow diagram



Methodology

During this one year period, total 6345 deliveries occurred, among which 832 were preterm (13.11%). Among these 832 preterm births, 507 were late preterm ones (61%). However, 459 women who met the inclusion criteria were included as cases.

Procedure

Cases and controls who met the inclusion criteria were identified and data was collected by direct interviewing with women and their relatives and from the records. Information regarding the neonate was collected at the time of discharge from the records.

A data collection instrument was designed which consisted information regarding following; (Annexure II)

1. Sociodemographic data;
2. Maternal characteristics;
3. Current pregnancy;
4. Mode of delivery;
5. Newborn condition and complications.

During the period of one year, total preterm births were noted to be 832. 507 among these preterm deliveries were late preterm deliveries. However, 459 met the inclusion criteria as 37 of them did not have a documentation of USG before 20th week and 11 cases had incomplete data.

Methodology

Statistical analysis

The data obtained was coded and entered into Microsoft Excel Worksheet. The data was analysed using chi-square test and Fischer's exact test. Association of each risk factor with LPB was obtained by chi square test. A probability value ('p' value) of less than or equal to 0.05 was considered as statistically significant. Univariate logistic regression analysis was done to identify one to one relationships between each risk factor and LPB and measure of association was calculated by unadjusted odds ratio with corresponding 95% confidence interval

All statistical calculations were done with the use of the computer programs Microsoft Excel 2013 and SPSS version 17 for Microsoft windows

5.
Results



Results

RESULTS

This Case Control study was conducted in the Department of Obstetrics and Gynecology, teaching hospital attached to KLE University's Jawaharlal Nehru Medical College Belgaum, during the period from May 2015- April 2016.

A total of 918 pregnant women were included in the present study. 459 women who delivered late preterm births(34 to 36⁺⁶ weeks gestation) were included in the study as cases. Controls were the women who delivered at term immediately after a case occurred.

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

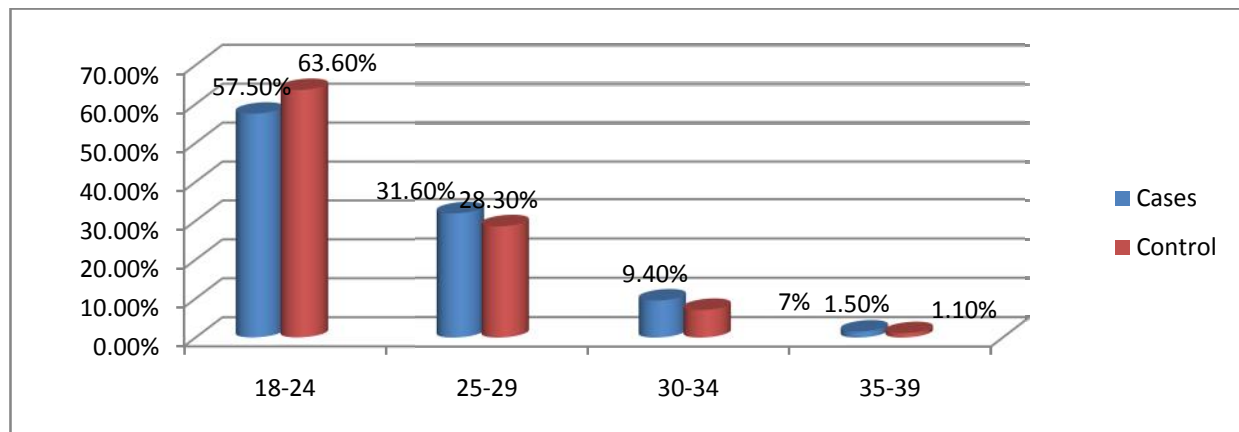
Results

Table 1: Maternal Age distribution

Age group (Years)	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
18-24	264	57.5%	292	63.6%
25-29	145	31.6%	130	28.3%
30-34	43	9.4%	32	7%
35-39	07	1.5%	05	1.1%
Total	459	100.00	459	100.00

Chi square value = 5.138 DF= 3 p= 0.273

Graph 1: Age distribution



Majority of pregnant women, 57.5% in cases and 63.6% women in control group were aged between 18 to 24 years. 31.6% women in the cases and 28.3% in the control group were between 25 – 29 years. P value = 0.273 was not statistically significant. Hence, in this study there was no statistically significant association between maternal age distribution in both cases and controls.

Results

Table 2: Parity

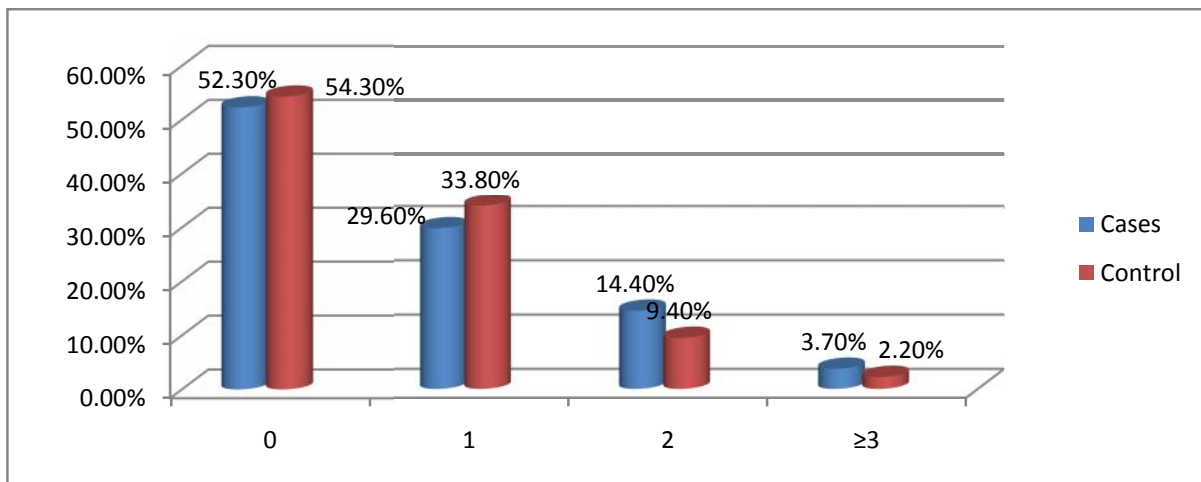
Parity	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
0	240	52.3%	251	54.3%
1	136	29.6%	155	33.8%
2	66	14.4%	43	9.4%
≥3	17	3.7%	10	2.2%
Total	459	100.00	459	100.00

Chi square value = 8.155

DF= 3

p = 0.043

Graph 2: Parity



52.3 % of the pregnant women among cases and 54.3 % of the pregnant women in control group were primigravida. 33.8% of controls and 29.6% of cases had parity status one. P value (P = 0.043) was statistically significant. Parity status has an association with the late preterm births.

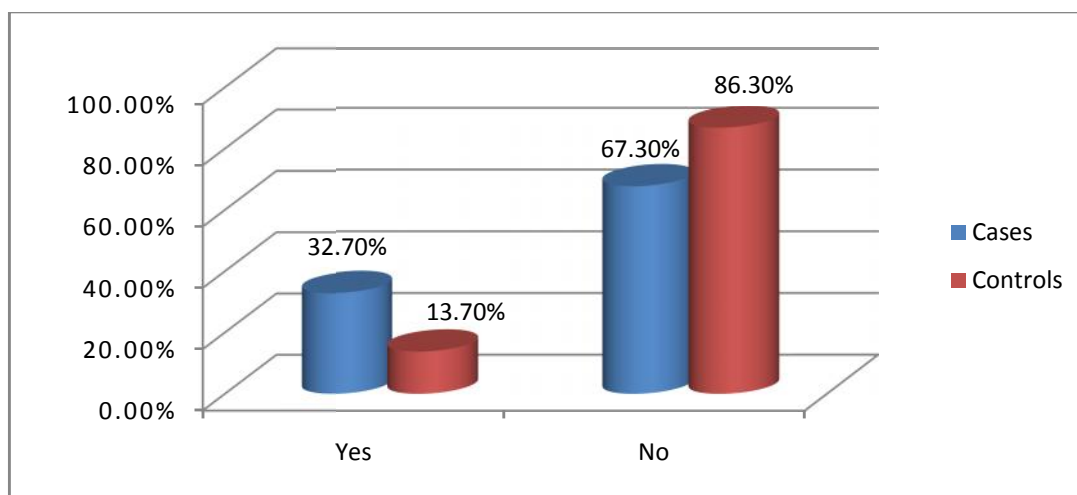
Results

Table 3: Association with PPRM

PPROM	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
Yes	150	32.7%	63	13.7%
No	309	67.3%	396	86.3%
Total	459	100.00	459	100.00

Chi square value = 46.271 p <0.001 OR = 3.05 (95%CI – 2.2-4.2)

Graph 3: Association with PPRM



The study showed significant association of PPRM with LPB as 32.7% of cases and 67.30% controls had PPRM. P value (<0.001) was statistically significant. Odds ratio was found to 3.05.

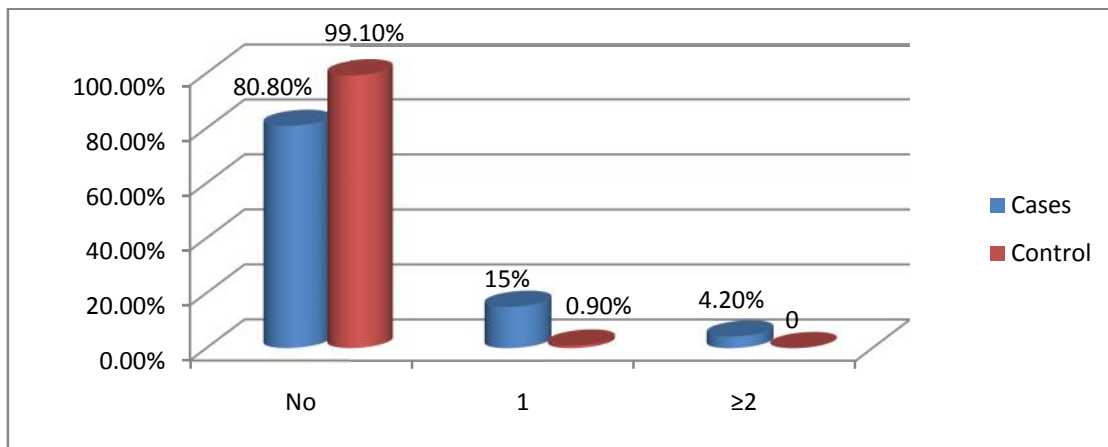
Results

Table 4: Association with history of prior preterm births

	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
No	371	80.8%	455	99.1%
1	69	15%	4	0.9%
≥2	19	4.2%	0	0
Total	459	100.00	459	100.00

Chi square value = 85.419 DF = 2 p <0.001 OR = 26.98 (95%CI -9.8-73.47)

Graph 4: Association with history of prior preterm births



The present study showed that prior one preterm birth was found in 15% of cases where as only 0.9% of controls had prior one preterm birth. Prior 2 preterm births was seen in only in cases (4.2%). P value (<0.001) was statistically significant. There was a statistically significant association with Odds ratio being 26.98

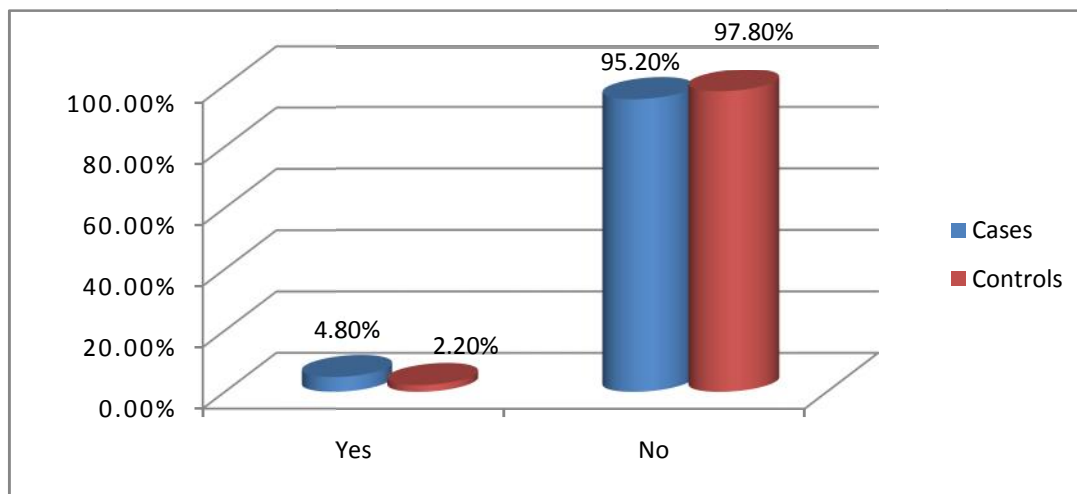
Results

Table 5: Association with Gestational hypertension

Gestational HTN	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
Yes	22	4.8%	10	2.2%
No	437	95.2%	449	97.8%
Total	459	100.00	459	100.00

Chi square value = 19.667 p <0.001 OR = 2.35 (95%CI -1.1-4.9)

Graph5: Association with Gestational hypertension



4.80% of cases had gestational hypertension and only 2.20% had the risk factor among controls. P value was statistically significant (p <0.001). The association with gestational hypertension was statistically significant with odds ratio of 2.35

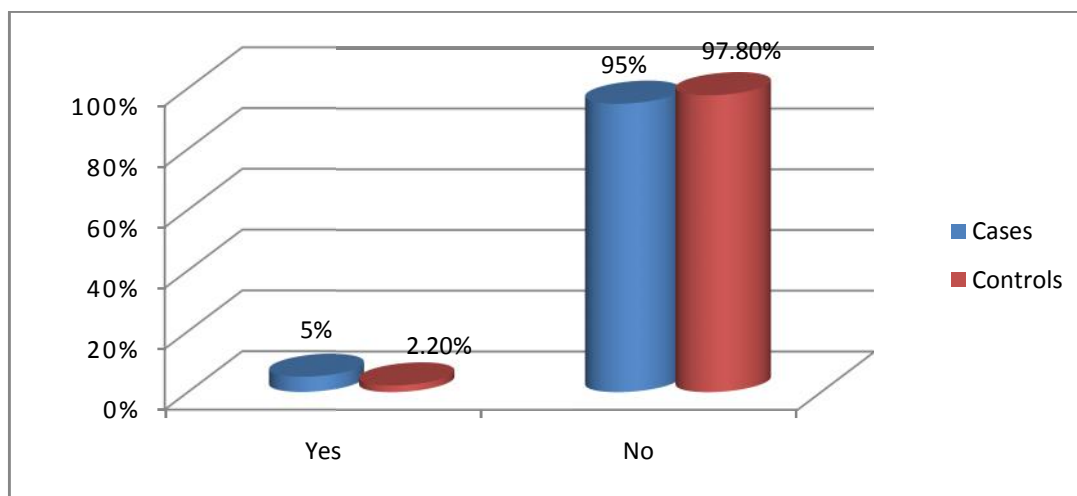
Results

Table 6: Association with Chronic hypertension

Chronic HTN	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
Yes	23	5%	10	2.2%
No	436	95%	449	97.8%
Total	459	100.00	459	100.00

Chi square value = 20.11p <0.001 OR = 2.4 (95%CI -1.1-5)

Graph 6: Association with Chronic hypertension



In the present study, 5% of cases had chronic hypertension and only 2.20% had the risk factor among controls. P value was statistically significant (p <0.001). The association with chronic hypertension was statistically significant with odds ratio of 2.4

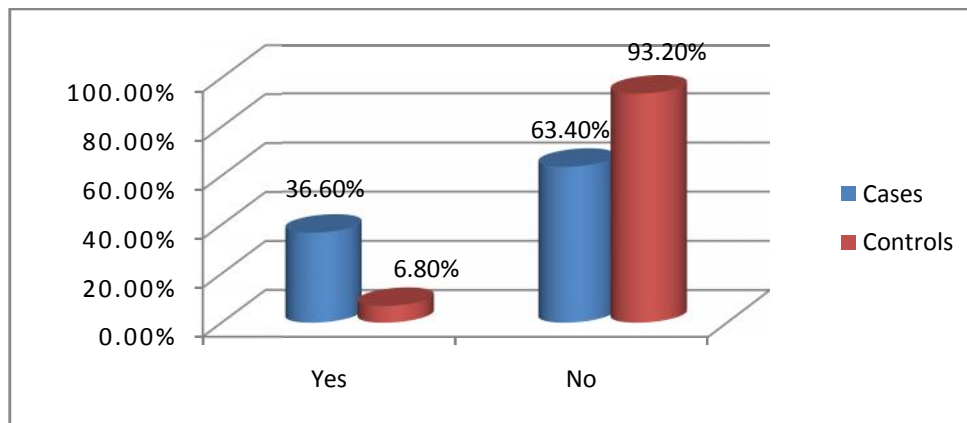
Results

Table 7: Association with Severe Pre-eclampsia

Severe PE	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
Yes	168	36.6%	31	6.8%
No	291	63.4%	428	93.2%
Total	459	100.00	459	100.00

Chi square value = 120.42 DF=1 p <0.001 OR = 8 (95%CI -5.3-12)

Graph 7: Association with Severe Pre-eclampsia



Majority of the severe pre-eclamptics were seen in the cases group (36.6%) and a few of them in control group (6.8%). P value was statistically significant (p <0.001). The association with severe pre-eclampsia was statistically significant with odds ratio of 8.

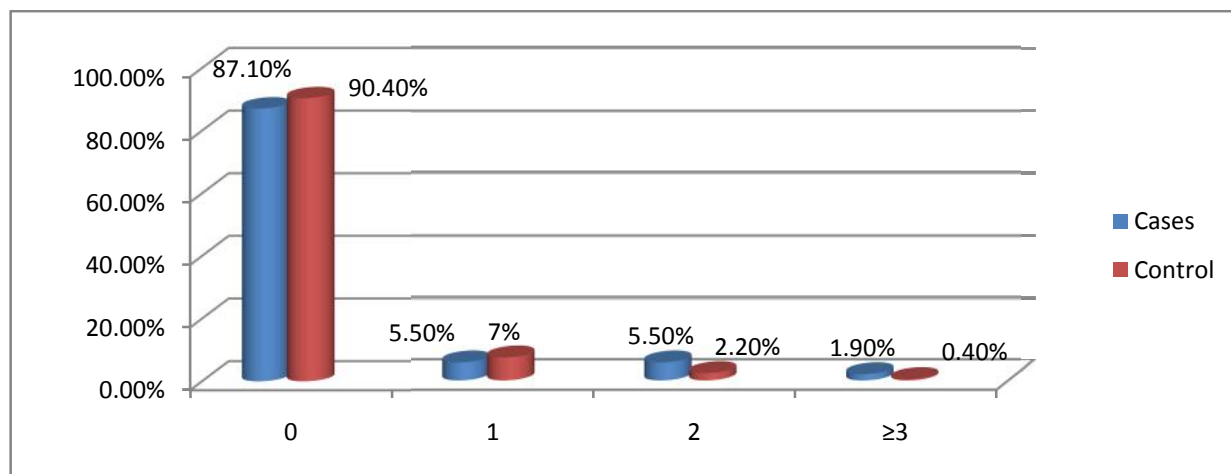
Results

Table 8: Association with Spontaneous abortion

Spontaneous abortion	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
0	398	87.1%	415	90.4%
1	25	5.5%	32	7%
2	25	5.5%	10	2.2%
≥3	09	1.9%	02	0.4%
Total	459	100.00	459	100.00

Chi square value = 12.094 DF= 3 p = 0.007

Graph 8: Association with Spontaneous abortion



In the present study, a larger part of the cases had 1 or 2 spontaneous abortion (5.5% each) and 1.9% of cases had more than 3 spontaneous abortion. P value (P = 0.007) was statistically significant.

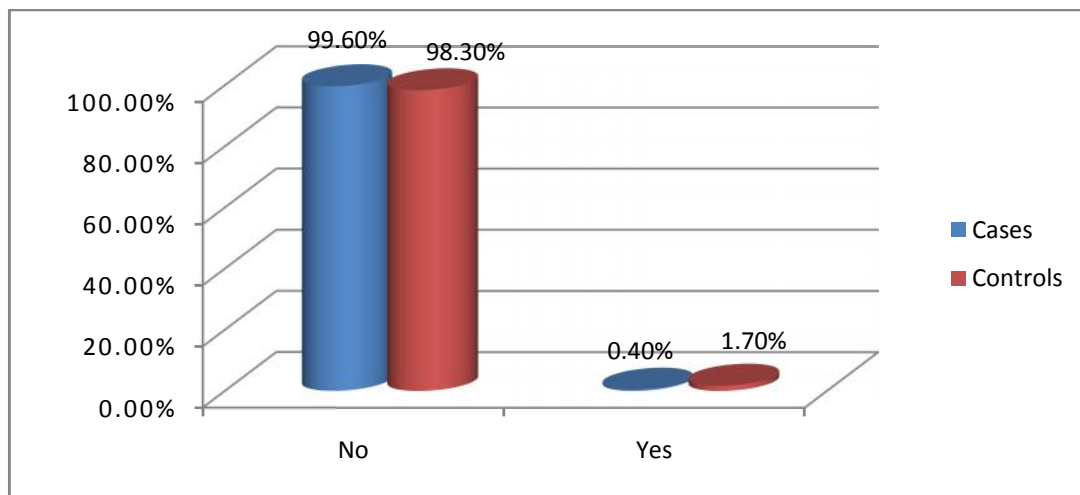
Results

Table 9: Association with Induced abortion

Induced abortion	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
No	457	99.6%	451	98.3%
Yes	02	0.4%	08	1.7%
Total	459	100.00	459	100.00

p = 0.107

Graph 9: Association with Induced abortion



0.4% of cases and 1.70% of controls had induced abortions. However, no significant association was found with the induced abortion as p value was 0.107

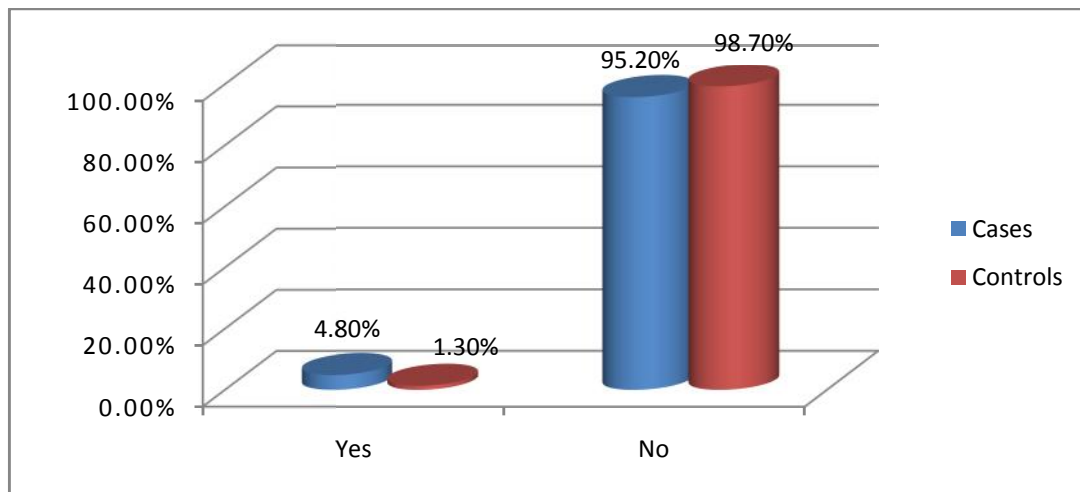
Results

Table 10: Association with Eclampsia

Eclampsia	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
Yes	22	4.8%	61	1.3%
No	437	95.2%	453	98.7%
Total	459	100.00	459	100.00

Chi square value = 9.43 DF=1 p = 0.002 OR = 3.8 (95%CI -1.5-9.4)

Graph 10: Association with Eclampsia



In the present study, 4.85 of cases had Eclampsia and only 1.3% among controls had Eclampsia. P value was statistically significant (p = 0.002). The association with Eclampsia was statistically significant with odds ratio of 3.8.

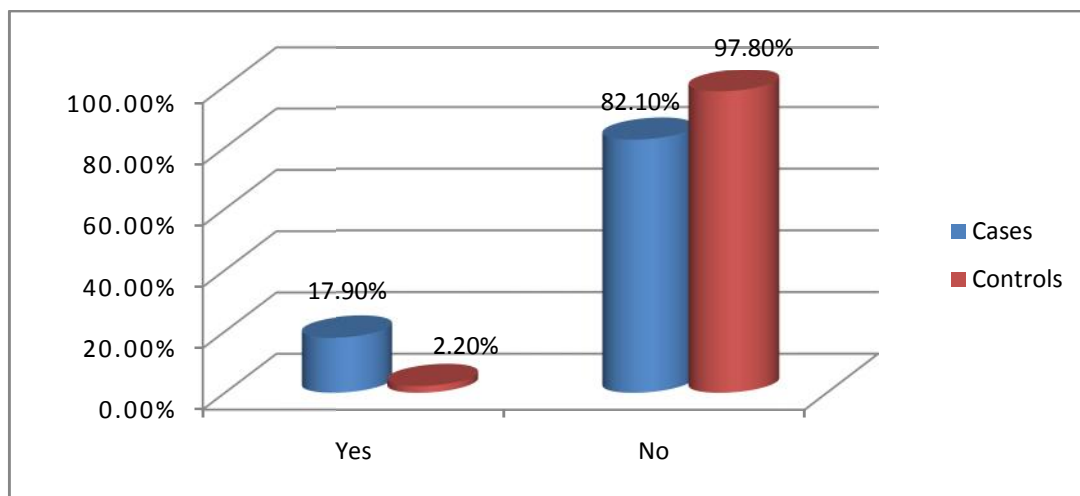
Results

Table 11: Association with Gestational diabetes mellitus

GDM	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
Yes	82	17.9%	10	2.2%
No	377	82.1%	449	97.8%
Total	459	100.00	459	100.00

Chi square value = 62.624 DF=1 p < 0.001 OR = 9.8 (95%CI – 5-19.2)

Graph 11: Association with Gestational diabetes mellitus



In the present study, majority of the gestational diabetics were cases (17.90%) and a few of them were among controls(2.2%). P value was statistically significant ($p < 0.001$). The association with gestational diabetes was statistically significant with odds ratio of 9.8.

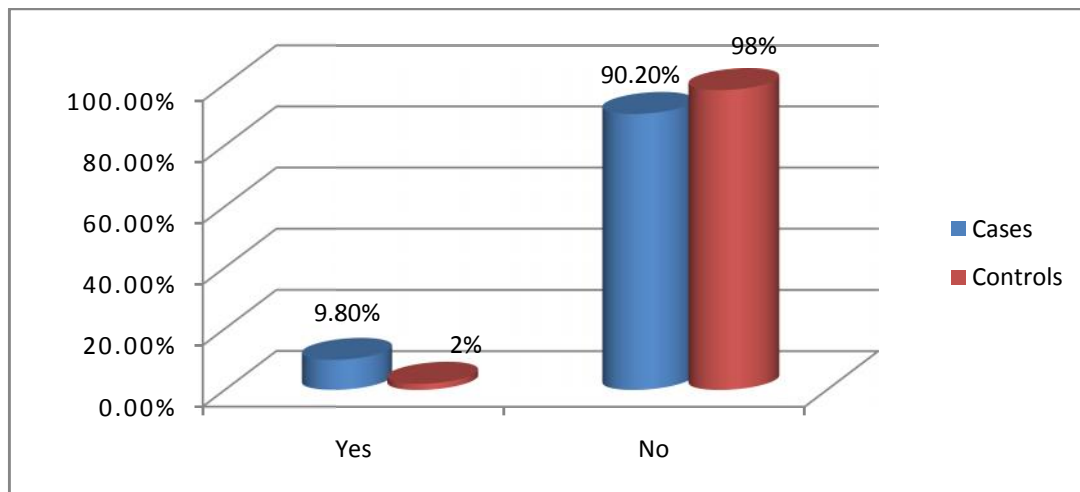
Results

Table 12: Association with Abruptio

Abruptio	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
Yes	45	9.8%	09	2%
No	414	90.2%	450	98%
Total	459	100.00	459	100.00

Chi square value = 25.5 DF=1 p< 0.001 OR = 5.4 (95%CI – 2.6-11.2)

Graph 12: Association with Abruptio



9.8% of cases had abruptio where as only 2% of controls presented with abruptio. P value was statistically significant (p<0.001). The association with abruptio was statistically significant with odds ratio of 5.4.

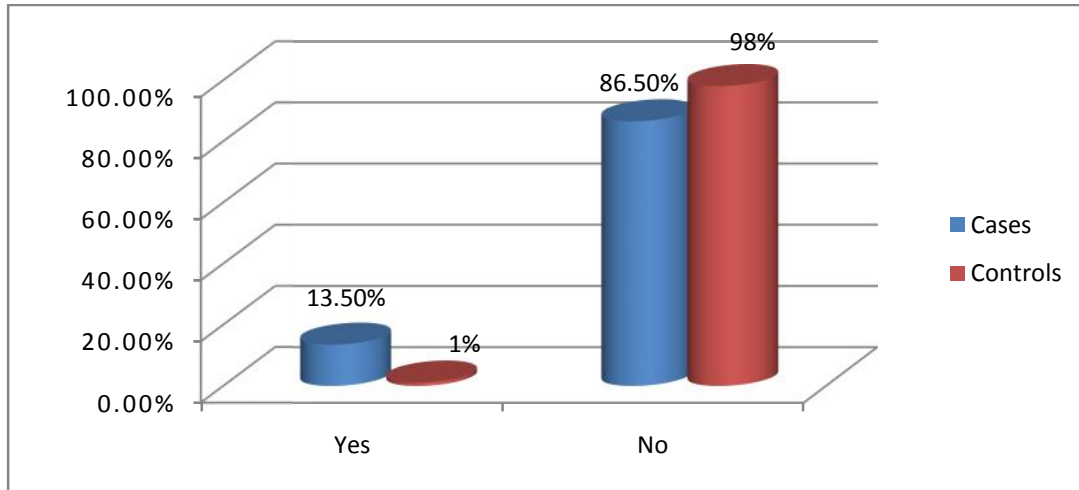
Results

Table 13: Association with Placenta Previa

Placenta previa	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
Yes	62	13.5%	05	1.1%
No	397	86.5%	454	98.9%
Total	459	100.00	459	100.00

Chi square value = 52.30 DF=1 p < 0.001 OR = 14.1 (95%CI – 5.6-35.7)

Graph 13: Association with Placenta Previa



In the present study, a greater part of women who had placenta previa were among the cases (13.5%) where as only 1.1% of the controls had placenta previa. P value was statistically significant (p<0.001). The association with placenta previa was statistically significant with odds ratio of 14.

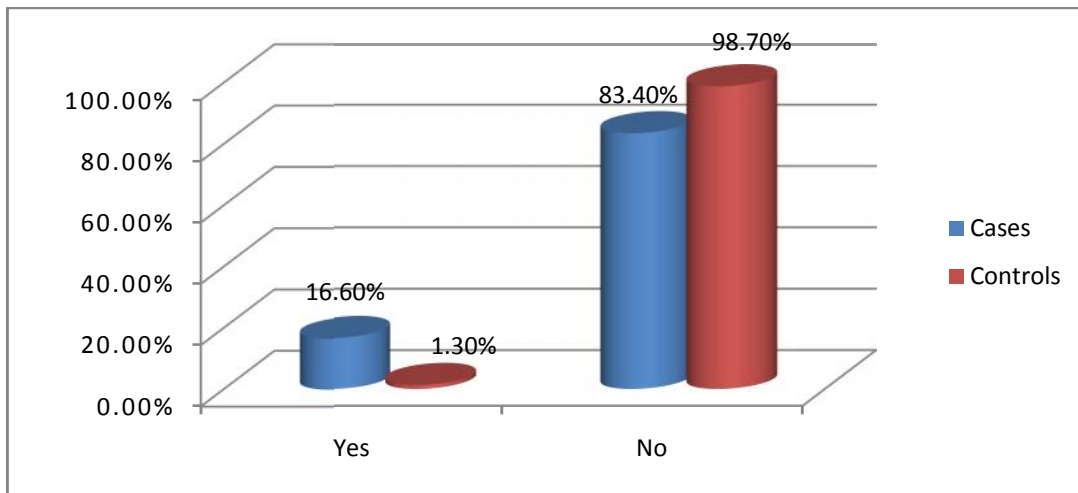
Results

Table 14: Association with multiple gestations

Placenta previa	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
Yes	76	16.6%	06	1.3%
No	383	83.4%	453	98.7%
Total	459	100.00	459	100.00

Chi square value = 65.61 DF=1 p < 0.001 OR = 14.9 (95%CI – 6.4-34.5)

Graph 14: Association with multiple gestations



A greater part of women who had multiple gestations were among the cases (16.6%) where as only 1.3% of the controls had multiple gestations. P value was statistically significant ($p < 0.001$). The association with multiple gestations was statistically significant with odds ratio of 14.9.

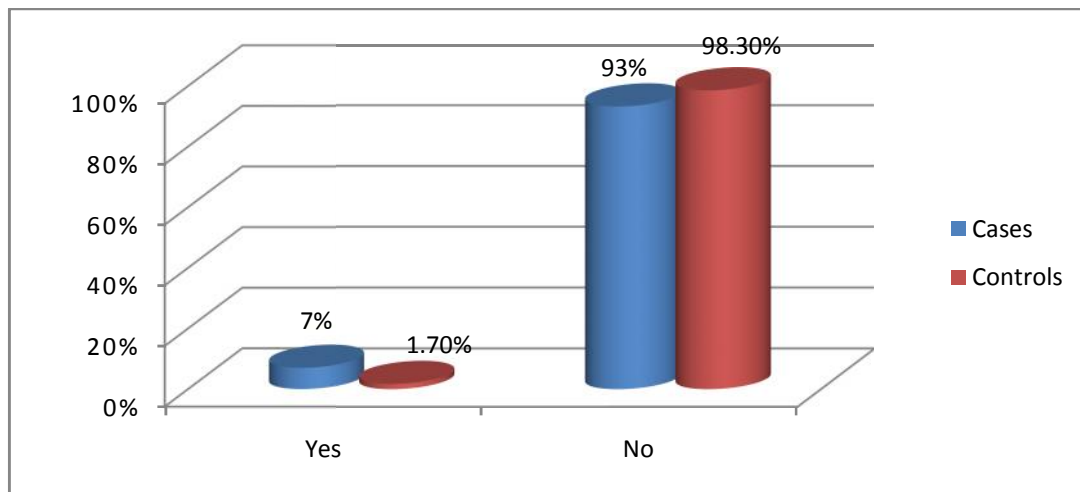
Results

Table 15: Association with IUD

IUD	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
Yes	32	07%	08	1.7%
No	427	93%	451	98.3%
Total	459	100.00	459	100.00

Chi square value = 10.056 DF=1 p < 0.001 OR = 4.2 (95% CI – 1.9-9.2)

Graph 15: Association with IUD



In the present study, 7% were cases among the ones with IUD and 1.7% were among controls. P value was statistically significant ($p < 0.001$). The association with IUD was statistically significant with odds ratio of 4.2.

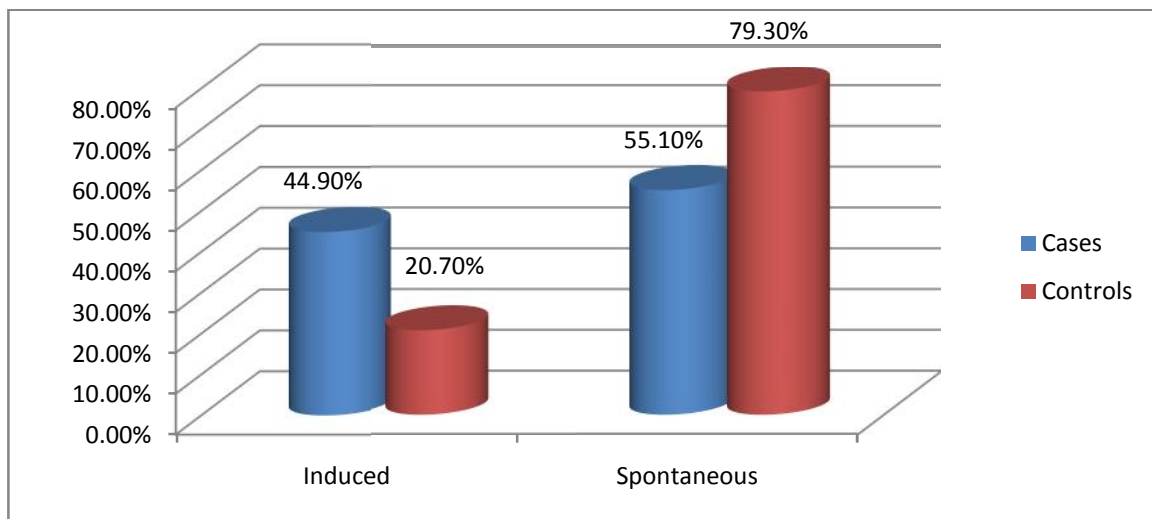
Results

Table 16: Onset of labour

	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
Induced	206	44.9%	95	20.7%
Spontaneous	253	55.1%	364	79.3%
Total	459	100.00	459	100.00

Chi square value = 114.074 DF=1 p < 0.001 OR = 4.7 (95% CI – 3.5-63)

Graph 16: Onset of labour



In the present study, labour was spontaneous in 55% cases and 79.30% controls where as 44.9% of cases were induced for one or other maternal, fetal or obstetric indications described above. P value was statistically significant ($p < 0.001$). Hence, majority of the cases were induced with odds ratio of 4.7.

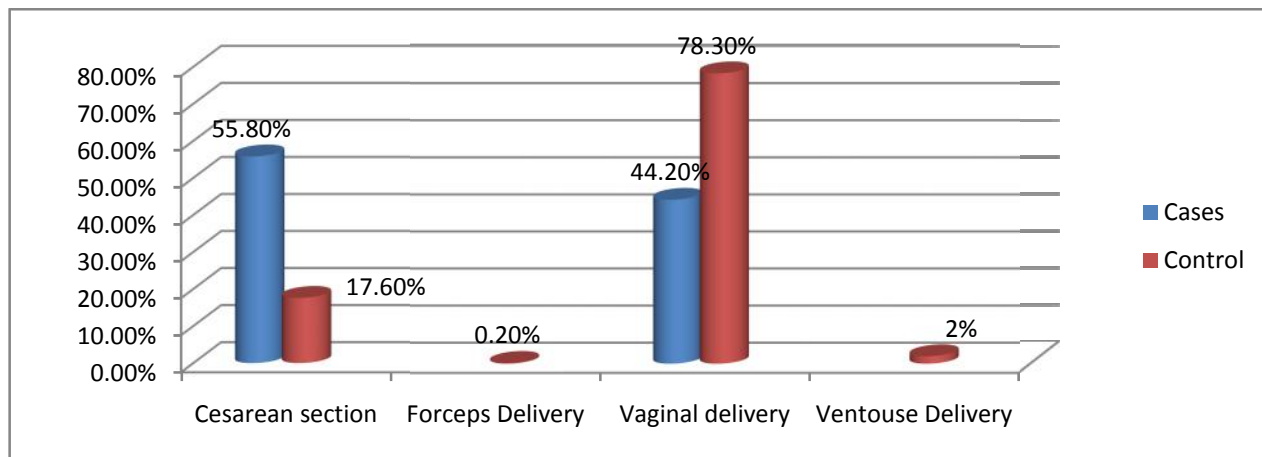
Results

Table 17: Mode of delivery

Mode of delivery	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
Cesarean section	256	55.8%	81	17.6%
Forceps Delivery	0		1	0.2%
Vaginal delivery	203	44.2%	364	78.3%
VentouseDelivery	0		13	2%
Total	459	100.00	459	100.00

p<0.001

Graph 17: Mode of delivery



In the present study, among 459 cases, 55.8% underwent cesarean section where as the remaining 44.2% delivered vaginally. Majority of controls delivered vaginally (78.3%) and 17.6% of controls underwent cesarean section and remaining 2.8% and 0.2% underwent ventouse and forceps delivery respectively. P value was statistically significant (p<0.001).

Results

Table 18: Distribution of Gestational age

Gestational Age	Cases and controls
34	100
35	159
36	200

Among the cases, majority of them delivered at gestational age of 36 weeks (200) and remaining 159 delivered at 35 weeks gestational age and rest 100 delivered at 34 weeks period of gestation.

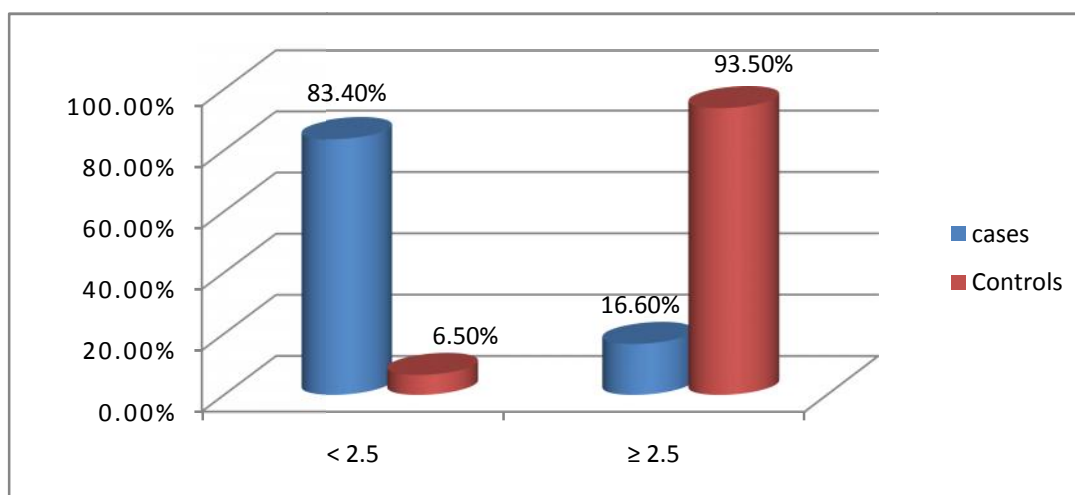
Results

Table 19: Association of birth weight.

	Cases (n=459)		Control (n=459)	
	Number	Percent	Number	Percent
< 2.5	383	83.4%	30	6.5%
≥ 2.5	76	16.6%	429	93.5%
Total	459	100.00	459	100.00

Chi square value = 548.467DF=1p <0.001 OR = 72.1 (95%CI – 46.2 – 112.4)

Graph18: Association of birth weight.



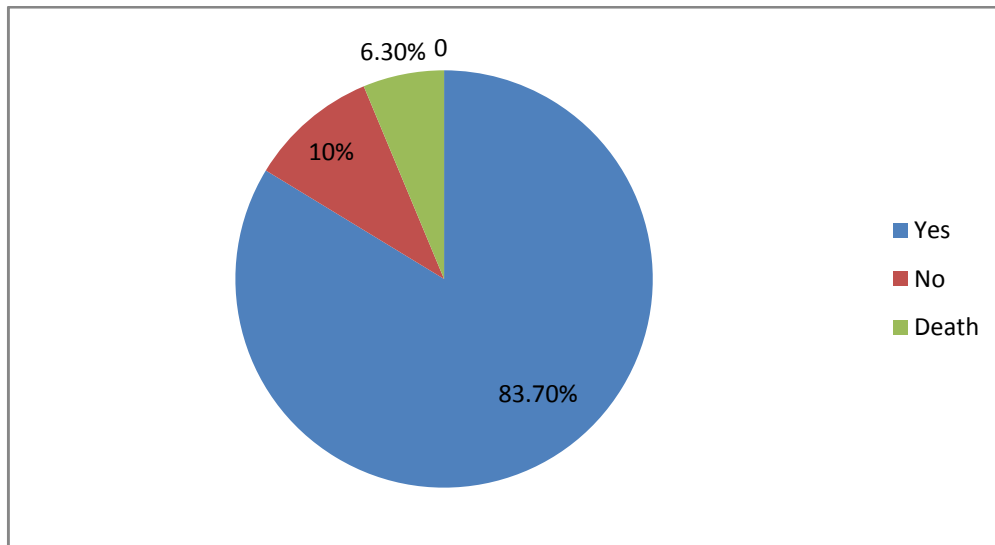
In the present study, 83.4% of low birth weights were among the cases and only 6.5% were controls. P value was statistically significant ($p < 0.001$). There was a significant association with low birth weights and the cases with odds ratio of 72.1.

Results

Table 20: Association of Newborn complications

	Cases (n=427)	
	Number	Percent
Yes	358	83.7%
No	42	10%
Death	27	6.3%
Total	427	100.00

Graph 19: Association of Newborn complications



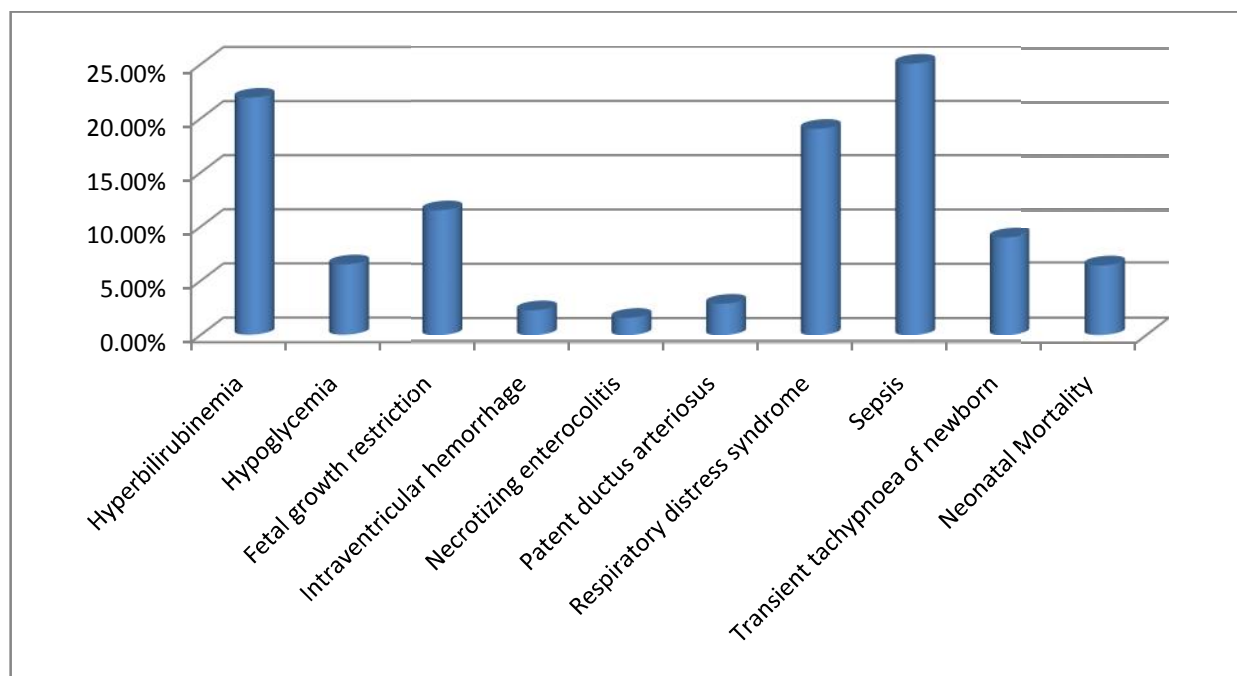
Majority of the newborns among cases (83.7%) had a newborn complication. Mortality was seen in 6.3%. 32 cases of IUD were excluded while analyzing the newborn complications.

Results

Table 21: Distribution of newborn complications

Complications	Total	Percentage
Hyperbilirubinemia	84	21.9%
Hypoglycemia	25	6.5%
Fetal growth restriction	44	11.5%
Intraventricular hemorrhage	09	2.3%
Necrotizing enterocolitis	06	1.6%
Patent ductusarteriosus	11	2.9%
Respiratory distress syndrome	51	19%
Sepsis	96	25%
Transient tachypnoea of newborn	58	09%
Neonatal Mortality	29	6.3%

Graph 20: Distribution of newborn complications



Results

As cited above 25% of them had sepsis and 21.9% had hyperbilirubinemia, 09% and 19% had TTN and RDS respectively. 2.9% had patent ductus arteriosus and 2.3 had IVH. 83.4 % of cases delivered newborns with birth weight <2.5 kg. Along these lines, Sepsis, Hyperbilirubinemia and RDS were the frequent complication in this gestational window. Neonatal mortality was found to be 6%.

6.

Discussion



Discussion

DISCUSSION

Late preterm birth is a major public health issue and delivery in this gestational period is a matter of controversy in most of the conditions. Several studies have been conducted to identify the short term and long term morbidities of late preterm birth. Few studies have also tried to consider the factors leading to these seemingly healthy late preterm infants. Majority of the factors are subdivided widely into 2 groups, factors causing spontaneous LPB or Induced/Iatrogenic LPB. Iatrogenic LPB is an underrated contributor of late preterm birth. Due to this very reason ACOG mandated elective deliveries strictly at 39 weeks and if preterm deliveries were to occur then a clear documentation of the FLM and indication for the delivery need to be mentioned.⁴³

Despite the evidence and recommendations, there is reluctance in the obstetrical community to adopt the practice of planned / elective deliveries at 39 weeks.¹⁶ This is not only inappropriate but it is potentially dangerous because it can lead to unintentional late preterm birth with its accompanying complications. ACOG suggested that a significant number of reductions in late preterm births would be seen following this practice.⁴³

Majority of studies in the past have studied risk factors for preterm births. Previous research on late preterm neonates focused on their physiologic immaturity with associated higher morbidities and mortality compared to neonates born 37 weeks gestation. Present study analyzed the risk factors for late preterm birth, a population much different from the over all preterm births.

The present study was undertaken to identify the risk factors leading to late preterm births which was my primary objective. The secondary objective was to assess the neonatal conditions and complications that occurred in these infants.

Discussion

This case control study was conducted in the Department of Obstetrics and Gynecology, teaching hospital attached to KLE university's JNMC Belgaum during the period of May 2015 to April 2016. A total of 459 pregnant women between 34 weeks to 36 weeks 6 days period of gestation admitted to the labour room and delivering preterm babies were included in the study. Controls were the women who delivered at term (>37 weeks) immediately after a case occurred. Cases and controls who met the inclusion criteria were identified and data was collected. A data collection instrument was designed which consisted information regarding sociodemographic data, maternal characteristics, current pregnancy, mode of delivery, newborn condition and complications. Details regarding the neonate were collected at the time of discharge from the record. Data was entered in the Microsoft excel sheet and statistical analysis was done.

The incidence of late preterm birth varies from country to country and in current study, incidence was 8% of total births consistent with the review article published on late preterm birth in 2010.¹⁴ The percentage distribution of LPB in the present study were 21.78%, 34.64% and 43.57% at 34, 35, 36 weeks respectively similar to an Indian study conducted at Pune in 2015.¹⁵

A retrospective study conducted in Texas concluded, maternal age <17 and >35 increased the risk of late preterm where as, present study did not show any significant association between maternal age and late preterm birth.¹² In contrast to this, a study conducted by Laughon et al on precursors of late preterm birth in 2010 published that women who had a spontaneous preterm birth and preterm PROM had a higher percentage of maternal age < 18 years old, BMI < 25.0 kg/m² and single status than women with indicated or unknown precursors or women who delivered at term.¹¹

Current study showed significant association was found with parity one, in contrast to results of a case control study in Italy which quoted no association between parity and Late

Discussion

preterm birth.⁷ Laughon et al study and an Indian study which considered finding an association between parity status and late preterm birth showed similar findings.^{10,11} In contrast to the above mentioned studies, Study at Melamed concluded that there was a significant increased prevalence of LPB among nullipara.^{5,15}

In agreement with other available studies, History of previous preterm birth was seen in 19.2% of cases, 15% had previous one PTB and 4.2% had previous 2 PTB and it was one of the strongest risk factors (OR- 26.98) for LPB.⁵ A case control study conducted in Italy analyzed 305 women where history of prior preterm births was associated to be a prime factor in Late preterm deliveries.⁵ In 2007, Spong et al described prior preterm birth as a major risk factor for late preterm infants.⁴⁸ Various studies also found that history of one prior preterm birth accounts for 15% of risk to preterm delivery where as, history of prior 2 preterm births accounts for 30% risk.^{48,49} But in present study, the number of prior 2 PTB were only 4.2% as there were less number of women with parity status more than 2.

In the present study, PPRM was found in 32.7% and it was found that 55.1% were spontaneous births and 44.9 % were induced/ iatrogenic late preterm births. The 2010 Laughon et al study reported that Spontaneous preterm birth, including spontaneous labor and preterm premature rupture of membranes, accounted for approximately two thirds of all late preterm births, while another third had an indicated precursor.¹¹ Similar findings were seen in study by Lubow et al that spontaneous labour and premature rupture of membranes were the most common indication for the late preterm delivery.³⁶ The high number of induced deliveries in the study correlates with the number of cases of hypertensive disorders and other risk factors described.

In accord to a study conducted in Italy which reported hypertension to be strongly associated with LPB, hypertensive disorders of pregnancy were another strong risk factor in the present

Discussion

study with PE (OR-8) and Eclampsia(OR- 3.8) comprising major input.⁵ Similar results were noted in various studies.^{4,8,9,15} In the study by Masoura et al, pre eclampsia was responsible for 8% of the late pre term deliveries.³⁸ Shapiro – Mendoza et al found that pregnancy induced hypertension was the most frequent maternal complication in late preterms.³⁹ This study also concluded that gestational diabetes to be another important maternal complication leading to late preterm births.³⁹

In a retrospective cross-sectional analysis which analyzed routine delivery data from all births in San Antonio/Bexar County, Texas variables associated with an increased risk of LPB were black race, age <17, age 35, gestational hypertension, chronic hypertension, and diabetes¹². Current study had similar results with gestational hypertension, chronic hypertension and diabetes as risk factors. This study did not show any association between previous history of induced abortion and LPB in contrast to Thorp et al study which suggested that induced abortions increased the risk of preterm delivery in subsequent pregnancies.⁴⁶

Multifetal pregnancy, placenta previa and abruptio placenta have been recognized as a risk factor for preterm births, the same is evident even in late preterm gestation. This study had 16.6% of multifetal gestation, 13.5% of Placenta previa and 9.8% of Abruptio placenta. Each of them had a trivial association with late preterm births comparable to the conclusion of Pune 2015 study and review article 2010.^{14,15} Multifetal gestation was seen in 7% of women in Laughon et al study.¹¹ Incidence of placental abruption was reported to be 14% in 2008 Merlion et al study.⁵⁰ Placenta previa and abruption have been considered as major factors responsible for delivery in late preterm gestation by various studies.⁵¹ Shapiro – Mendoza et al study found that ante partum hemorrhage was the second common causative factor in late preterm delivery after hypertensive disorders.³⁹

Discussion

With regard to the mode of delivery, in the present study among 459 cases, 55.8% underwent cesarean section whereas the remaining 44.2% delivered vaginally. Majority of controls delivered vaginally (78.3%) and 17.6% of controls underwent cesarean section and remaining 2.8% and 0.2% underwent ventouse and forceps delivery respectively. Similar findings were noted by the Laughon et al study, where rate of cesarean section was doubled in late preterm gestation compared to term.¹¹ In contrast to this, an Indian study conducted in Pune concluded that incidence of normal vaginal deliveries was higher with 62% of the late pre terms delivered by this route and 36% of the late preterm delivered by lower segment caesarean section.¹⁷ Similar to present study, instrumental delivery in their study was reported as 1% in both ventouse assisted and forceps delivery. In the study by Jain et al, 86.8% late preterm babies were delivered by caesarean section while only 10.5% were delivered by vaginal route and 2.6% by assisted vaginal deliveries.³⁷ However they also quoted that caesarean rates in their study were higher because a majority of them were referred for antenatal problem.³⁷ Incidence of deliveries conducted by caesarean section was 67.8% in the study by Jaiswal et al⁴⁰. In their study 32.2% late preterms were delivered by normal vaginal delivery. In the study by Masoura et al, rates of caesarean section was higher in the study group with pre eclampsia.³⁸ In the study by Melamed et al, incidence of caesarean section in late preterm group was 27.7%.¹⁵ Thus, compared to other Indian studies, incidence of caesarean deliveries was higher in present study group. High rates of c-section in this study can be attributed to the majority of women who were referred with an anticipated antenatal problem as this is a tertiary care centre and also the number of eclamptics and pre eclamptics noted and the number of cases induced in view of such complications.

On the subject of Neonatal outcome, current study showed momentous difference between the neonatal outcome of term and late preterm births. While analyzing the results of newborn

Discussion

complications, 32 cases of IUD were excluded from the analysis. Incidence of early morbidities in the late preterms was 83% in present study. Similar findings were reported in following studies. In the study by Jaiswal et al 70.8% of late preterm had at least one of the neonatal morbidities requiring admission to neonatal intensive care unit.⁴⁰ In a retrospective study by Wang et al, 77.8% late preterm term babies had at least one clinical problem.⁴¹ Another study by Tomashek, et al found that late preterm infants were 1.5 times more likely to require hospital-related care and 1.8 times more likely to be readmitted than term infants.³⁹ Shapiro - Mendoza, et al found that the newborn morbidity rate doubled in infants for each gestational week earlier than 38 weeks.³⁹

Melamed, et al found that compared with full-term infants, spontaneous late preterm delivery was independently associated with an increased risk of neonatal morbidity, including respiratory distress syndrome, sepsis, intraventricular hemorrhage, hypoglycemia, and jaundice requiring phototherapy.¹⁵ Similarly, in present study amid a range of neonatal morbidities studied, sepsis (25%), hyperbilirubinemia (21.9%), RDS (19%) and TTN (09%) were noteworthy with major contribution. Patent ductus arteriosus (2.9%), IVH (2.3%) were other morbidities noted. Sepsis, Hyperbilirubinemia and RDS were of a greater magnitude. Comparable results were reported in available studies.^{2,7,14,15}

Incidence of sepsis was 25% in this study. In the study conducted by Jain et al, incidence of sepsis was 9.6%.³⁷ In the study by Wang et al, 36% late preterm babies had sepsis.⁴¹ In the study by Melamed et al incidence of probable sepsis was 19 % and that of confirm sepsis was 0.4%. Max et al found 5.9% incidence of sepsis in late preterm group.^{15,56} Late preterm infants demonstrate specific infection rates, pathogen distribution, and mortality associated with early and late onset sepsis. Recent evidence suggests, however, that late preterm infants (relative to

Discussion

full-term infants) are diagnosed with culture-proven sepsis more frequently, have increased sepsis related mortality, and have a substantial increased risk for morbidity and mortality.

Incidence of Respiratory distress syndrome (RDS) in the present study was 19%. In the study by Lubow et al 20% late preterms had respiratory complications.³⁶ Jaiswal et al reported 10.5% incidence of respiratory morbidities in late preterm study group.⁴⁰ In the study by Leone et al, incidence of respiratory distress was 34.7%.⁵² Escobar et al found that 10.7% of the late preterms needed respiratory support while in the study by Rubaltelli et al, 9.6% of late preterm newborns needed respiratory support.^{53,54}

Late Preterm infants are at increased risk of developing hypoglycemia after birth, because they have immature hepatic glycogenolysis and adipose tissue lipolysis, hormonal dysregulation, and deficient hepatic gluconeogenesis and ketogenesis.¹⁷ In the present study, incidence of hypoglycemia was found to be 6.5% similar to Indian study done in Pune where the incidence was 7%.¹⁷ The incidence of hypoglycemia was 8.8% in the study by Jaiswal et al.⁴⁰ In the study by Celik et al 4% incidence of hypoglycemia was noted.⁵⁵ Melamed et al found that 6.8% of the late preterms had hypoglycemia with higher incidence in the late preterms towards 34 weeks of gestation.¹⁵ Few studies reported higher incidences of hypoglycemia such as, Jain et al reported 30% incidence of hypoglycaemia.³⁷ whereas study by Wang et al showed that 15.6 % of the late pre terms had hypoglycaemia.⁴¹ In the study by Leone et al 14.3 % of the late preterms were hypoglycaemic.⁵²

The incidence of hyperbilirubinemia was 21.9%, in current study. Pune study found that incidence of hyperbilirubinemia 13% and was more towards 34 weeks of gestation and the difference was found to be statistically significant. Jain et al found that neonatal hyperbilirubinemia requiring treatment in the form of phototherapy was much higher in late

Discussion

preterm babies compared to term babies (50.8 vs. 10.4%).³⁷ Their study also revealed that more babies - 67.3% at 34 weeks of gestation required treatment for jaundice as compared to 44 % at 35 and 36 weeks gestation.³⁷ In the study by Jaiswal et al, hyperbilirubinemia was the most common early morbidity in the late preterm group with incidence of 55%.⁴⁰ Wang et al found the incidence of neonatal jaundice to be 54.4% in the late preterm age group.⁴¹ In the study on late preterms by Melamed et al, incidence of neonatal hyperbilirubinemia was 18 % with higher incidence towards 34 weeks of gestation.¹⁵ Incidence of neonatal hyperbilirubinemia was 47.4 % in the study conducted by Leone et al.⁵² In a prospective study by Celik et al 13.7 % of the late preterms had hyperbilirubinemia.⁵⁵ Max et al found the incidence of neonatal hyperbilirubinemia to be 17.6%.⁵⁶ Lavanya et al found the incidence of hyperbilirubinemia to be 57% in the late preterm population.⁵⁷ They also found that incidence of hyperbilirubinemia was more towards lower gestational age.⁵⁷ The high incidence of significant jaundice in late preterm infants may be attributed to their inability to handle bilirubin load, decreased hepatic UDPglucuronyl transferase enzyme activity, and a slower post natal maturity of hepatic bilirubin uptake. In this study incidence of hyperbilirubinemia was lower as compared to most other studies.¹⁷ Jaundice in late preterm infants is more prevalent, more pronounced, and more protracted in nature than in their term counterparts.

According to the review article published in 2010 RDS, sepsis and PDA were the three important early morbidities noted.¹⁶ In the present study sepsis was seen in 25%, RDS in 19% and patent ductus arteriosus in 2.9%. Mortality rate in this study was 6.3% where as Kalyoncu et al found the incidence of mortality as 2.3% in late preterm births.⁵⁸ The morbidity is significantly higher in late preterm infants than in term ones, thus it is not surprising that the survival rate of late preterm infants is significantly reduced. The mortality in the early neonatal (0-6 days), late

Discussion

neonatal (7-27 days) and post neonatal (28-364 days) periods were 6, 3, and 2 times higher respectively in late preterm infants than in term infants in a study conducted by Shapiro – Mendoza et al.³⁷ The common causes of death were congenital malformations, immaturity, sepsis, atelectasis, maternal complications and sudden infant death syndrome (SIDS). SGA are suggested to substantially increase the mortality rate.¹⁷

Thus, LPB are associated with significantly increase of newborns morbidity and mortality, early and late as well as compared to full term births. In order to prevent LPB the identification of the risk factors is fundamental. The present study is an attempt to obtain actual data on latepreterm births and associated neonatal morbidities from India. Risk factors found to be statistically significant in association with late preterm births in the present study were Hypertensive disorders of pregnancy (Gestational HTN- 4.8%, Chronic HTN – 5%, PE – 36%, Eclampsia – 4.8%) followed by PROM (32.7%), History of prior preterm births (19.2%), Gestational diabetes (17.9%), Multifetal gestation (16.6%), Placenta previa (13.5%), Abruption placenta (9.8%).

On analyzing neonatal outcome, Sepsis was found in 25%, Hyperbilirubinemia in 21.9%, RDS in 19%, Transient tachypnoea of newborn in 09% and PDA in 2.9% of the neonates. As the present study was designed to asses early neonatal morbidities, rehospitalisation, length of follow up and longterm risks to which these infants are exposed have not been studied. The study population is derived from tertiary care referral centre where significant proportions of mothers are referred for antenatal problems. Therefore a higher incidence of morbidities was observed in these late preterm populations.

The above findings also suggest that the adverse perinatal outcome seen in infants born in the late preterm period may be due to the underlying medical or obstetric condition that prompted

Discussion

the early delivery in the first place and not due to the gestational age at delivery alone. A reduction in the number of newborns exposed to unnecessary risks due to elective delivery in the later preterm period would have great societal benefit. In an era where both the quality and cost of care are of paramount importance, we must reassess the clinical opinions about timing of delivery. Because published data reveal that some harm may occur as a result of unnecessary late preterm births, the practice of preterm delivery without a clear indication merits strict reevaluation.

8.

Summary



Summary

SUMMARY

This case control study was conducted in Department of Obstetrics and Gynecology, teaching hospital attached to KLE University's Jawaharlal Nehru Medical College, Belagavi during the period of May 2015 to April 2016. The present study was undertaken to identify the risk factors leading to late preterm births in our hospital which was my primary objective. The secondary objective was to assess the neonatal conditions and complications that occurred in these infants.

During this one year period, total 6345 deliveries occurred, among which 832 were preterm (13.11%). Among these 832 preterm births, 507 were late preterm ones (61%). However, 459 women who met the inclusion criteria were included as cases. A total of 459 pregnant women delivering between 34 weeks to 36 weeks 6 days period of gestation admitted to the labour room were included in the study. Controls were the women who delivered at term (>37 weeks) immediately after a case occurred. Cases and controls who met the inclusion criteria were identified and data was collected. A data collection instrument was designed which consisted information regarding sociodemographic data, maternal characteristics, current pregnancy, mode of delivery, newborn condition and complications. Details regarding the neonate were collected at the time of discharge from the record. Data was entered in the Microsoft excel sheet and statistical analysis was done.

Risk factors found to be statistically significant in association with late preterm births in the present study were Hypertensive disorders of pregnancy (Gestational HTN- 4.8%, Chronic HTN – 5%, PE – 36%, Eclampsia – 4.8%) followed by PROM (32.7%), History of prior preterm births (19.2%), Gestational diabetes (17.9%), Multifetal gestation (16.6%), Placenta previa

Summary

(13.5%), Abruption placenta (9.8%). More than one complication was noted in many of the cases. On analyzing neonatal outcome, Sepsis was found in 25%, Hyperbilirubinemia in 21.9%, RDS in 19%, Transient tachypnoea of newborn in 09% and PDA in 2.9% of the neonates.

7.

Conclusion



Conclusion

CONCLUSION

It is evident from this study that following were the risk factors of late preterm births, history of prior PTB, gestational hypertension, chronic hypertension, PE, GDM, Eclampsia, multifetal gestation, abruption, placenta previa and IUD. History of prior preterm births and hypertensive disorders of pregnancy were major contributors. Neonatal mortality and morbidity is higher in LPTB compared to term births. Sepsis, hyperbilirubinemia and RDS were the frequent morbidities noted.

The indication for the induction or need for termination should be reevaluated in the late preterm gestation. In order to prevent late preterm birth, identification of the risk factors is necessary and timing of delivery in each risk factor should be reassessed in advance before intended intervention. However, further research is considered necessary evaluating genitourinary infections leading to PROM and spontaneous LPB. Survey for infections followed by treatment provides a scope to prevent LPB. As LPB constitute majority of preterm births, it is important to limit late preterm deliveries to clear maternal or fetal indication for delivery.

These findings also suggest that the adverse perinatal outcome seen in infants born in the late preterm period may be due to the underlying medical or obstetric condition that prompted the early delivery in the first place and not due to the gestational age at delivery alone. A reduction in the number of newborns exposed to unnecessary risks due to elective delivery in the later preterm period would have great societal benefit. In an era where both the quality and cost of care are of paramount importance, we must reassess our clinical opinions about timing of delivery. Because published data reveal that some harm may occur as a result of unnecessary late

Conclusion

preterm births, the practice of preterm delivery without a clear indication merits strict reevaluation.

9.

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10.

Annexure I



Information sheet for women participating in the Research:

Annexure I

Analysis of Risk factors of late preterm births: A case control study

Name of the Institution: KLE University's Jawaharlal Nehru Medical College, Women's & Children's Health Research Unit, Belgaum

Purpose:

We are conducting a research study to analyse all the risk factors for late preterm births defined as infants born at 34 0/7 – 36 6/7.

Procedure:

If you agree to participate, you will be asked to sign a consent form.

We will be collecting all the data regarding your sociodemographic data, results of the investigations done during your hospital stay and the details regarding your child.

Benefits:

We want to let you know that there may be no benefits to participating in this study. By participating you will be helping to ensure that women in future get the best available treatment at delivery.

Side Effects, Risks & Discomforts:

Annexure I

There are no side effects to participating in this study.

Confidentiality:

Any information you provide during the study will be kept confidential. Your full name will not appear on any study document and only staff participating in the study will have access to the information you provide.

Right to Refuse or Withdraw:

You are free to choose whether or not you wish to participate. You are also free to withdraw from the study at any time should you wish to do so for any reason. We hope you will participate and thank you if you do.

CONSENT

Annexure I

Analysing Risk factors for late preterm birth: A case control study

IP number:

Name:

Age:

Address:

Phone number:

I have (been) read the information sheet concerning this study and I understand what is required of me if I take part in the study. All my questions and doubts have been answered by you. I understand that I can withdraw from the study at any time I wish without giving a reason and this will not affect the normal health care I receive.

I agree to take part in this study.

Annexure I

Woman's signature or thumb print.....

Date.....

Signature of the Investigator:

If the consenting woman is illiterate: ask the woman to print her thumb under "Woman's signature or thumb print" and print the Name of an Independent Literate Witness, the date and the signature of the Witness (if possible, this person should be selected by the participant and should have no connection to the research team) after the below statement:

I was present while the benefits, risk and procedures were read to the volunteer. All questions she had were answered and she has agreed to participate in the study.

Witness's name.....

Annexure I

Witness's signature.....

Date.....

Signature of the Investigator:

ಸಂಶೋಧನೆಯಲ್ಲಿ ಭಾಗವಹಿಸುತ್ತಿರುವ ಮಹಿಳೆಯರ ಮಾಹಿತಿ ಪತ್ರ

ಕೊನೆಯಲ್ಲಿ ಪ್ರಸವ ಪೂರ್ವ ಜನನದ ಅಪಾಯಕಾರಿ ಅಂಶಗಳ ವಿಶ್ಲೇಷಣೆ ಒಂದು ಕೇಸ ನಿಯಂತ್ರಣದ ಅಧ್ಯಯನ

ಸಂಸ್ಥೆಯ ಹೆಸರು :

ಕೆ.ಎಲ್.ಇ. ವಿಶ್ವವಿದ್ಯಾಲಯ, ಜವಾಹರಲಾಲ ನೆಹರೂ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ಮಹಿಳೆಯರ ಮತ್ತು ಮಕ್ಕಳ ಆರೋಗ್ಯ ಸಂಶೋಧನಾ ಘಟಕ ಬೆಳಗಾವಿ.

ಉದ್ದೇಶ

ನಾವು 36 6/7 ಹಾಗೂ 34 0/7 ನಲ್ಲಿ ಜನಿಸಿದ ಶಿಶುಗಳ ಕೊನೆಯಲ್ಲಿ ಪ್ರಸವ ಪೂರ್ವ ಜನನದ ಕುರಿತು ಎಲ್ಲ ಅಪಾಯಕಾರಿ ಅಂಶಗಳನ್ನು ವಿಶ್ಲೇಷಿಸಲು ಸಂಶೋಧನಾ ಅಧ್ಯಯನ ನಿರ್ವಹಿಸುತ್ತಿದ್ದೇವೆ.

ವಿಧಾನ ಒಂದು ವೇಳೆ ನೀವು ಭಾಗವಹಿಸಲು ಒಪ್ಪಿದ್ದೇ ಆದರೆ ನಿಮ್ಮಿಂದ ಒಂದು ಸಮೃತ್ತಿಯ ನಮೂನೆಗೆ ಸಹಿ ಕೇಳಲಾಗುತ್ತದೆ.

ನಾವು ತಾವು ಆಸ್ಪತ್ರೆಯಲ್ಲಿ ತಂಗಿದ್ದಾಗ ತಮ್ಮ ಮಗುವಿನ ಬಗ್ಗೆ ನಿಮ್ಮ ಸೊಸಿಯೋಡೇಮೋಗ್ರಾಫೀಕ್ ಡಾಟಾ, ಅಲ್ಲದೇ ಫಲಿತಾಂಶ ಮತ್ತು ಸಂಶೋಧನೆಗಳ ಕುರಿತು ಮಾಹಿತಿಯನ್ನು ಕಲೆ ಹಾಕುತ್ತೇವೆ.

ಪ್ರಯೋಜನೆಗಳು

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವವರಿಂದ ಇರುವ ಪ್ರಯೋಜನೆಗಳು

ಸದರಿ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವ ಮೂಲಕ ನೀವು ಭವಿಷ್ಯದಲ್ಲಿ ಮಹಿಳೆಯರು ಅತ್ಯುತ್ತಮ ಚಿಕಿತ್ಸೆ ಮತ್ತು ಹೆರಿಗೆ ವ್ಯವಸ್ಥೆಯ ಕುರಿತು ಪ್ರಯೋಜನ ಪಡೆಯಬಹುದಾಗಿದೆ.

...2

ಅಡ್ಡ ಪರಿಣಾಮಗಳು, ಅಪಾಯಗಳು ಮತ್ತು ಅಸೌಕರ್ಯಗಳು

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವವರಿಂದ ಯಾವುದೇ ರೀತಿಯ ಅಡ್ಡ ಪರಿಣಾಮಗಳು, ಅಪಾಯಗಳು ಮತ್ತು ಅಸೌಕರ್ಯಗಳು ಉಂಟಾಗುವದಿಲ್ಲ.

ಗೌಪ್ಯನೀಯತೆ

ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನೀಡಲಾಗುವ ಎಲ್ಲ ಮಾಹಿತಿಗಳನ್ನು ಗೌಪ್ಯವಾಗಿಡಲಾಗುವುದು ನಿಮ್ಮ ಪೂರ್ಣ ಹೆಸರು ಅಧ್ಯಯನದ ಯಾವುದೇ ದಾಖಲೆಗಳಲ್ಲಿ ದಾಖಲಾಗುವದಿಲ್ಲ. ಮತ್ತು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವ ಯಾವುದೇ ಕರ್ಮಚಾರಿಗಳು(ನೌಕರರು) ಅಧ್ಯಯನದ ಕುರಿತು ನೀವು ನೀಡುವ ಯಾವುದೇ ಮಾಹಿತಿಯನ್ನು ಯಾರಿಗೂ ತಿಳಿಸುವದಿಲ್ಲ.

ತಿರಸ್ಕರಿಕೆ ಅಥವಾ ಹಿಂತೆಗೆದುಕೊಳ್ಳುವಿಕೆ

ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆ ಅಥವಾ ಭಾಗವಹಿಸದಿರುವುದು ನಿಮ್ಮ ಸ್ವಾತಂತ್ರ್ಯಕ್ಕೆ ಬಿಟ್ಟಿದ್ದು.

ಒಂದು ವೇಳೆ ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಿದಲ್ಲಿ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಹಾಗೂ ಯಾವುದೇ ಕಾರಣಕ್ಕೂ ತಾವು ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯಬಹುದಾಗಿದೆ.

ನೀವು ಭಾಗವಹಿಸಲು ಆಶಿಸುತ್ತೇವೆ ಮತ್ತು ನಿಮಗೆ ಧನ್ಯವಾದ

ಸಂಪರ್ಕಿಸಿ ತಮಗೆ ಯಾವುದಾದರೂ ಪ್ರಶ್ನೆಗಳಿದ್ದಲ್ಲಿ ತಾವು ಕೂಡಲೇ ಅಥವಾ ಹೆರಿಗೆ ನಂತರ ಕೇಳಬಹುದು ಒಂದು ವೇಳೆ ತಾವು ನಂತರ ಪ್ರಶ್ನೆ ಕೇಳಲು ಬಯಸಿದ್ದೇ ಆದರೆ ತಮ್ಮ ಹೆರಿಗೆ ವೇಳೆಯಲ್ಲಿ ತಮ್ಮನ್ನು ಪರೀಕ್ಷಿಸಿದ ನೂರಿತ ವೈದ್ಯರನ್ನು

ಸಮ್ಮತಿ

ಕೊನೆಯಲ್ಲಿ ಪ್ರಸವ ಪೂರ್ವ ಜನನದ ಅಪಾಯಕಾರಿ ಅಂಶಗಳ ವಿಶ್ಲೇಷಣೆ ಒಂದು ಕೇಸ ನಿಯಂತ್ರಣದ ಅಧ್ಯಯನ

ಐಪಿ ಸಂಖ್ಯೆ :
ಹೆಸರು :
ವಯಸ್ಸು :
ವಿಳಾಸ :
ದೂರವಾಣಿ ಸಂಖ್ಯೆ :

ನಾನು ಈ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಮಾಹಿತಿಯ ವಿವರಗಳನ್ನು ಸಂಪೂರ್ಣವಾಗಿ ಓದಿದ್ದೇನೆ. ಮತ್ತು ನನಗೆ ಈ ಅಧ್ಯಯನದ ಅವಶ್ಯಕತೆ ಇದ್ದು ನಾನು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವ ಅವಶ್ಯಕತೆ ಇರುವುದೆಂದು ಅಂದುಕೊಂಡಿದ್ದೇನೆ. ನನ್ನ ಎಲ್ಲ ಪ್ರಶ್ನೆಗಳಿಗೆ ಮತ್ತು ಸಂಸೆಗಳಿಗೆ ತಮ್ಮಿಂದ ನನಗೆ ಉತ್ತರ ದೊರಕಿದೆ. ನಾನು ಅಧ್ಯಯನದಿಂದ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಕೂಡ ಯಾವುದೇ ಕಾರಣ ನೀಡದೇ ಹಿಂದೆ ಸರಿಯಬಹುದಾಗಿದೆ ಎಂಬುದನ್ನು ತಿಳಿದುಕೊಂಡಿದ್ದೇನೆ. ಇದರಿಂದ ನನ್ನ ಸಾಮಾನ್ಯ ಆರೋಗ್ಯದ ಮೇಲೆ ಯಾವುದೇ ಪರಿಣಾಮ ಆಗುವದಿಲ್ಲವೆಂದು ಅರಿತಿದ್ದೇನೆ.

ನಾನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಕೊಳ್ಳುತ್ತೇನೆ.

ಮಹಿಳೆಯ ಸಹಿ ಮತ್ತು ಹೆಚ್ಚರಳು ಮುದ್ರಣ _____ ದಿನಾಂಕ _____

ಪರೀಕ್ಷಕರ ಸಹಿ_____

ಒಪ್ಪಿಗೆ ಸೂಚಿಸಿದ ಮಹಿಳೆಯು ಅಶಿಕ್ಷಿತಳಾಗಿದ್ದಲ್ಲಿ ಮಹಿಳೆಯ ಸಹಿ ಮತ್ತು ಹೆಚ್ಚರಳು ಮುದ್ರಣವನ್ನು ಪರೀಕ್ಷಿಸಲು ಆಕೆ ಆಯ್ಕೆ ಮಾಡಬಹುದು. ಸಾಧ್ಯವಿದ್ದಲ್ಲಿ (ಒಬ್ಬ ಸ್ವತಂತ್ರ ಸುಶಿಕ್ಷಿತ ಸಾಕ್ಷಿದಾರ ದಿನಾಂಕ ಮತ್ತು ಸಾಕ್ಷಿದಾರನ ಸಹಿ, ಹೆಸರು ಮುದ್ರಣ ಪಡೆಯಲು ಮಹಿಳೆ ಭಾಗಿಯಾದಲ್ಲಿ ಹಾಗೂ ಈ ಕೆಳಗಿನ ವಿಧಾನ ಮಾಡಿದ ನಂತರ ಸಂಶೋಧಕರ ಸಂಪರ್ಕ ಇರುವುದು ಅವಶ್ಯಕವಿರುತ್ತದೆ).

ಲಾಭ, ಅಪಾಯ ಮತ್ತು ಕಾರ್ಯಪದ್ಧತಿ ಸ್ವತಃ ನನ್ನ ಉಪಸ್ಥಿತಿಯಾಗಿ ಓದಲಾಯಿತು ಅವುಗಳೆಂದರೆ ಎಲ್ಲ ಪ್ರಶ್ನೆಗೂ ಉತ್ತರ ಮತ್ತು ಆಕೆ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಗೆ ನೀಡಿದ್ದಾಳೆ.

ಸಾಕ್ಷಿದಾರನ ಹೆಸರು _____

ಸಾಕ್ಷಿದಾರನ ಸಹಿ _____ ದಿನಾಂಕ : _____

ಪರೀಕ್ಷಕರ ಸಹಿ _____

संशोधन सहभागी स्त्रियांचा माहिती पत्रक :

उशीरा मुदतपूर्व जन्म धोक्याचे घटक विश्लेषण: अ केस नियंत्रण अभ्यास

संस्थेचे नाव :

के.एल.ई. विद्यापिठ,
जवाहरलाल नेहरु वैज्ञकीय कॉलेज, महिला व मुलांचा आरोग्य संशोधना विभाग,
बेळगाव.

हेतू :

३६ ६/७ आम्ही ३४ ०/७ जन्म अर्भकाची व्याख्या उशीरा मुदतपूर्व जन्म सर्व जोखीम घटक विश्लेषण एक संशोधन अभ्यास आयोजित आहेत.

कार्यपध्दती :

आपण सहभागी सहमत असल्यास, आपण एक संमती फॉर्म साइन इन करण्यास सांगितले जाईल.

आम्ही आपल्या मुलाला संबंधित आपक्या सोशीयोडर्मोग्राफिक डेटा, तुमच्या रुग्णालयात निवास दरम्यान पूर्ण तपास परिणाम आणि संबंधित सर्व माहिती गोळा केले जातील.

फायदे :

आम्ही आपल्याला या अभ्यासात सहभागी नाही फायदे असू शकते की कळवू इच्छित.
सहभागी करुन आपण भविष्यात महिला प्रसुती उत्कृष्ट उपलब्ध उपचार मिळेल, याची खात्री करण्यासाठी मदत केली जाईल.

वाईट परिणाम, धोके व असौकर्य

या अभ्यासाचे काही वाईट परिणाम, धोके व असौकर्य नसतील.

गोपनीयतेच्या :

आपण अभ्यास दरम्यान प्रदान केलेली कोणतीही माहिती गुप्त ठेवले जातील. आपले पूर्ण नाव प्रदान माहिती प्रवेश असेल अभ्यासात सहभागी कोणत्याही अभ्यास दस्तऐवज कुठेही दाखल नाही होत आणि अध्ययनमध्ये भाग घेतलेले कोणतेही कर्मचारी आपल्या माहितीबद्दल कोणालाही माहिती देणार नाहीत.

उजव्या नकार किंवा माघारीचा :

आपण सहभागी होऊ इच्छित किंवा नाही हे निवडू मुक्त आहोत. तुम्ही कोणत्याही कारणास्तव तसे करण्याची इच्छा पाहिजे आपण कोणत्याही वेळी अध्ययनपासून माघार घेऊ शकता. आम्ही आपण सहभागी होईल अशी आशा बाळगतो आणि जर का आपला आभार.

श्री रोग व प्रसुती विभाग,

संमती

उशीरा मुदतपूर्व जन्म धोक्याचे घटक विश्लेषण: अ केस नियंत्रण अभ्यास

आयपी नंबर :

नावं :

वय :

पत्ता :

फोन नंबर :

मी (केले) या अभ्यासात यासंबंधी माहिती पत्रक वाचले आणि मला अभ्यासात भाग घेऊ
तर मी मला आवश्यक आहे ते समजून माझी सर्व प्रश्न आणि शंका आपण उत्तरे दिली
आहेत. मी एक कारण न देता इच्छा कोणत्याही वेळी अभ्यास पासून काढू शकतात आणि
हे मी प्राप्त सामान्य आरोग्य काळजी परिणाम करणार नाही हे मला समजते.

मी या अभ्यासात भाग घेणे सहमत.

स्त्रीच्या स्वाक्षरी किंवा थंब प्रिंट..... दिनांक.....

संशोधकाचे स्वाक्षरी.....

संमती स्त्री अशिक्षित असल्यास: "बाई स्वाक्षरी किंवा थंब प्रिंट" अंतर्गत तिच्या थंब प्रिंट
आणि या व्यक्तीने निवडले पाहिजे, शक्य असल्यास (एक स्वतंत्र सुशिक्षित साक्षीदार
तारीख आणि साक्षीची स्वाक्षरी नाव मुद्रित करण्यासाठी स्त्री विचारु सहभागी आणि
खालील विधान केल्यानंतर संशोधन संघ संपर्क) असणे आवश्यक आहे :

फायदे, धोका आणि कार्यपध्दती स्वयंसेवक वाचून आल्या मी उपस्थित होते. ती होती
सर्व प्रश्नांची उत्तरे होते आणि ती अभ्यासात सहभागी करण्याचे मान्य केले आहे.

साक्षीदार नाव.....

साक्षीदारांची स्वाक्षरी..... दिनांक

संशोधकाचे स्वाक्षरी :

11.

Annexure III



PROFORMA

1. Patient details :

a. Name:
b. IP number :
c. Age :
d. Full address:
e. Contact number:
f. Occupation:
g. Height :
h. Weight :
i. BMI:

2. Parity :

1	2	3	≥ 4
---	---	---	----------

3. History of prior preterm birth :

Yes	No
-----	----

Annexure II

4. History of abortions :

Spontaneous			Induced		
0	1	≥ 2	0	1	≥ 2

5. Abruption:

Yes	No
-----	----

6. Placenta Previa:

Yes	No
-----	----

7. Chronic hypertension :

Yes	No
-----	----

8. PIH:

Yes	No
-----	----

9. Eclampsia :

Yes	No
-----	----

10. GDM:

Yes	No
-----	----

11. Multifetal gestation:

Yes	No
-----	----

Annexure II

12. IUD

Yes	No
-----	----

13.PROM:

Yes	No
-----	----

14. Delivery :

Spontaneous	Induced
-------------	---------

15. Mode of delivery:

Vaginal	LSCS
---------	------

16. NICU admission:

Yes	No
-----	----

17. Newborn complication:

Yes	No
-----	----

18.Mention neonatal complication:

19. Birth weight :

20. Gestational age:

13.

Annexure III



Annexure III

Keywords for master chart

Y - yes

N - no

CS - cesarean section

V - vaginal delivery

S - spontaneous

I -Induced

VN - Ventouse

F - Forceps

HTN - Hypertension

PE - Pre-Eclampsia

PROM - Premature rupture of membranes

PTB - Prior preterm birth

NICU - Neonatal Intensive Care Unit

RDS - Respiratory Distress Syndrome

TTN - Transient Tachypnea of Newborn

Annexure III

PDA	-	Patent Ductus Arteriosus
NEC	-	Necrotizing Enterocolitis
IVH	-	Intraventricular Haemorrhage
GDM	-	gestational diabetes

