INTRODUCTION

Preterm birth is defined as birth before 37 weeks gestation. The incidence is 6-10% of all births. It is the major cause for neonatal morbidity and mortality. The incidence of spontaneous preterm birth was about three quarters of all preterm births.

Inspite of recent advances in neonatal care, the preterm birth may not be easily predictable from the patient's obstetric history or from routine pervaginal examination. Several studies showed dispropotionate shortening of cervical canal length is a useful predictor of preterm delivery.

The diagnosis of preterm labor remains unreliable, resulting in significant overtreatment. Only fewer than 10% of these women deliver within 1 week.

So, it would be of great clinical importance to find markers which help to find out the pregnant women with preterm uterine contraction, who end up with preterm delivery. They might be benefitted from timely admission and appropriate treatment.

There are many investigations which evaluate many substances that have been found in cervical and vaginal fluids for their ability to predict spontaneous preterm birth.

Insulin-like growth factor binding protein-1 is one of the secretory proteins of decidualised endometrium. It was formerly known as placental

protein 12. It has 2 forms, phosphorylated and dephosphorylated. The phosphorylated isoform predominantly seen in decidual cells and liver

When the delivery is approaching fetal membranes begin to detach from decidua paritalis. The phosphorylated IGFBP-I leaks in to cervical secretion of symptomatic women is a good marker for prediction of preterm delivery

In this study we evaluate , whether patient with preterm labor with intact membranes have phosphorylated IGFBP-I in their cervical secretion and increased level of this marker are associated with an increased risk of preterm delivery within next 7-10 days. Also we evaluate the cervical length measurement and phIGFBP-1 association for predicting preterm delivery.

AIM OF THE STUDY

To assess the efficacy of insulin like growth factor binding protein 1 and cervical length at first admission in symptomatic women with intact membranes for the prediction of impending preterm delivery.

MATERIALS AND METHODS

This is a prospective study of 100 antenatal women, who presented to labor ward, **INSTITUTE OF OBSTETRICS AND GYNECOLOGY,** MMC, CHENNAI in a time period between JAN 2014 To AUG 2014. Ethical committee clearance was obtained from the institution to undergo this study.

After getting the consent all women were examined. Detailed obstetrics history and general examination was done. Per abdominal examination followed by sterile speculum examination done. Any draining pv or signs of infection were noted. We took cervical swab for a quantitative assay of ph-IGFBP-I. The swab was kept in the cervix for 15 seconds.

Then the swab was kept in the test tube containing 0.5 ml of extraction buffer. The specimen was extracted immediately from the swab by swirling the swab vigorously in the solution for 15 secs. Press the swab against the wall of the specimen extraction solution tube. Swab was discarded after that.

Insulin like growth factor binding protein-I was measured in cervical swab Samples obtained using immunoenzymometric assay by bedside kit

Value more than 10 microgram/lit considered as positive. It is shown as two dark line in the bedside kit.The cervical length was measured by transvaginal ultrasound.

Then the patient was followed for next 10 days to till delivery by phone or clinical visit.

INCLUSION CRITERIA

All symptomatic woman with intact membrane, less than 37 weeks of gestation and less than 3 cm cervical dilatation.

EXCLUSION CRITERIA

- Patient refusal
- Multiple gestation
- Previous caesarean section
- Preeclampsia
- Gestational diabetes mellitus
- Anomalous uterus
- Anomalous babies

REVIEW OF LITERATURE

General aspects:

Preterm birth occurs in 6-15 % of all deliveries. It is the most common cause of fetal and neonatal mortality & morbidity. Preterm birth rate increases every year. The incidence of perinatal mortality rate in INDIA varies from 40-150/1000 livebirths. Adverse outcome of preterm birth include cerebral palsy, developmental delay, chronic lung disease and visual and hearing loss.

40 % of preterm birth due to idiopathic preterm labor, 35% due to preterm prelabor rupture of membranes and remainder are iatrogenic, because of obstetrics and medical condition.

Definition and incidence:

Preterm birth is estimated to affect 13 million birth/per annum worldwide. It is defined by WHO as the onset of labor after the viability and before 37 completed weeks or 259 days of pregnancy.

The onset of labor determined by documented uterine contractions atleast one in 10 min and ruptured membranes or documented cervical changes like cervical length of less than 1cm or cervical dilatation of more than 2 cm.Threatenedpreterm labor is defined by documented uterine contractions but no evidence of cervical changes.

The incidence of preterm birth vary widely ranging from 4.4 to 12.7%. The current estimation of preterm delivery is increasing, compared to previous year, because of increased survival of extremely preterm and very low birth weight infants.50% PTD are spontaneous preterm labour,30% all due to preterm premature rupture of membranes and remaining 20% are indicated preterm delivery for maternal & fetal indication[1].

The increasing incidence of spontaneous preterm delivery is due to multiple birth secondary to assisted reproductive techniques, increasing body mass index, and sexually transmitted diseases. preterm labor accounts for 70%neonatal mortality and 50% of long term neurological morbidity. According to CESDI (confidence enquiry into still births and deaths in infancy UK), these are major antecedents of preterm labor.

1. Major placental bleeding 18%
2. Pregnancy induced hypertension 21%
3. Prelabour rupture of membranes 31%
4. Clinical chorioamnionitis 11%
5. Idiopathic preterm labor 55%
6. Cervical incompetence 5%
7. Bacteriuria 7%

Because of this diverse etiology, we should have a diversity of management regimens towards improving neonatal outcomes by trying to prevent delivery before 34 weeks or delaying delivery to optimize the available resources prior to delivery.

Before applying the management regimens we must be aware of the efficiency & inherent risks to mother and baby.

THRESHOLD OF VIABILITY:

The current threshold of viability of a fetus is 26 weeks(ACOG 2002,2008 c). Birth before 26 weeks or birth weight less than 750 g pose a variety of complex medical social & ethical consideration.

According to American academy of pediatrics(branner and co.2000) resuscitation for infants less than 23 weeks or birth weight less than 400 gm is not appropriate.

They are more vulnerable for brain injury, like hypoxic ischemic injury and sepsis.(stoil& associates). Sepsis and hypoxia start a cascade of events which lead to white matter injury& periventricular leukomalacia and later neurodevelopmental impairment. Active brain development occur in second and third trimester. Infants born at 22-25 weeks are more vulnerable to brain injury because of preterm immaturity. Those with birthweights 500-750 g, 55% survived, most of them had complications. Some infants apparently normal at

the time of discharge,but affected by serious developmental impairment by age 8 to 9 years.

Survival increased from 1.7% at 22 weeks to 54% at 25 weeks. Infants born at 22-25 weeks had neurological disability in 25% compared with normal term births. Cognitive scores were lower for infants born at 22-25 weeks

The infants born at 22-25 wks were analysed ,they were undergoing neurodevelopmental testing at 18-22 weeks of age (Tyson and associate 2008).61% died or had profound impairment. Female gender, singleton pregnancy, corticosteroid given for lung maturation and higher gestational age improved the prognosis in these infants born at the threshold of viability. caesarean delivery is controversial to the threshold of viability.it was not associated with a reduction in the short term serious morbidities(Louis and colleagues 2004).

Late preterm birth

It accounts for 75% of all preterm births. Infant born between 34-36 weeks were considered as late preterm births[2]. 80% of late preterm births were due to idiopathic spontaneous preterm labor or prematurely ruptured membranes.another 20% due to complications such as hypertension, placental accidents and IUGR(Mcintire and leveno 2008). Neonatal mortality and morbidity was significantly increased in late preterm infants(tomashek and

coworkers 2007).Neurodevelopment was adversely affected in late preterm infants(petrini and coworkers 2009). So healthcare focus on prematurity should be expanded to late preterm births also[2]. The late preterm deliveries should occur only when there is an accepted maternal and fetal indications (ACOG 2008).

High risk factor for preterms

In History

- Previous history of abortions (spontaneous/induced)
- Previous history of preterm delivery
- Pregnancy followed by artificial reproductive technology
- Recurrent UTI/Asymptomatic bacteriuria
- Smoking,low socioeconomic and nutritional status
- Maternal stress

In present pregnancy

MATERNAL

Pregnancy complications

- Preeclampsia
- Antipartum hemaorrhage
- Preterm premature rupture of membranes

- Polyhydramnios

UTERINE ANOMALIES

- Cervical incompetence
- Malformations of uterus

MEDICAL AND SURGICAL ILLNESS

- Acute fever
- Acute pyelonephritis
- Diarrhea
- Acute appendicitis
- Toxoplasmosis

CHRONIC DISEASE

- Hypertension
- Nephritis
- Diabetes mellitus
- Severe anemia
- Decompensated heart disease

GENITAL TRACT INFECTIONS

- Bacterial vaginosis

- Beta hemolytic streptococcus infection
- Chlamydial infection
- Mycoplasma

FETAL

- Multiple pregnancy
- Congenital malformations
- Intrauterine death

PLACENTA

- Infarction
- Thrombosis
- Placenta Previa
- Abruptio Placentae

IATROGENIC –due to medical and obstetric complications

IDIOPATHIC- 50% cause of preterm births are not known. Premature activation of some systems involved in initiation of labor at term

Etiopathogenesis:

1. Activation of fetal HPA axis.
2. Choriodecidual bacterial colonization[1]

- Increased TNF, increased IL 1,6,8

3.Pathological uterine enlargement

- Increased mechanical stretch, increased IL 8
- Increased Gap junction, increased PG synthesis.

CHORION /AMNION/ AND DECIDUA

- Increased PGE 2,F2 alpha, increased TxA2
- Increased prostaglandin dehydrogenase
- Increased collagenase
- ↑Leukocyte elastase

- ↑myometrial contraction
- ↑cervical ripening
- ↑cervical insufficiency

Leads to

Preterm labor and preterm delivery

ANTECEDANTS AND CONTRIBUTING FACTORS:

1.THREATENED ABORTION:

First trimester vaginal bleeding were associated with subsequent preterm labor ,placental abruption and subsequent pregnancy loss less than 24 weeks(Weiss and associates 2004)

2.LIFE STYLE FACTORS:

- Cigarette smoking
- Inadequate maternal weight gain
- Illicit drug use
- Overweight women(Ehrenberg and colleagues 2009)

  Specially prenatal weightgain is associated with preterm labor(hickey and colleagues 1995)
- Young and advanced maternal age
- Poverty
- Short stature
- Vitamin deficiency
- Prolonged walking or standing
- Strenuous work

- Psychological factors like depression, anxiety and chronic stress(merces 2002 and their associates)(neggers and coworkers 2004)

3. RACIAL AND ETHINIC DISPARITY:

Compared to white, blacks are more prone to preterm birth(Goldenberg and colleagues 2008b) especially recurrent preterm delivery Other association include low socio economic status and educational status(Kistka and colleagues2007)

4.GENETIC FACTORS:

The recurrent and familial nature of the preterm birth has led to that genetics may play a role. Involvement of immunoregulatory genes in potentiating chorioamnionitis in case of preterm delivery was analysed in various study(Gihson 2007, Hampton 2006)

5.PERIODANTAL DISEASE:

Gum infection was significantly associated with preterm birth (Goepfert and coworkers 2004). But studies found that treatment of

periodontal disease during pregnancy did not significantly alter the rates of preterm birth.

6. INTERVAL BETWEEN PREGNANCIES:

Short interval less than 18months and longer than 59 months between pregnancy were associated with increased risk of pretermbirth (Conde-Agudelo and coworkers 2006)

7.PRIOR PRETERM BIRTH:

Prior preterm deliveries one of the main risk factor.(Bloom and associates 2001). The risk was increased 3 fold following one preterm delivery. Incidence was 5-15% following one preterm delivery and increased to 41% following two preterm delivery. But this may contribute to only 10% of preterm delivery. So 90% of preterm births cannot be predicted with the history of previous preterm births.

8.INFECTION:

Intrauterine infection trigger the preterm labour. Inflammatory cytokines released by the microorganisms stimulate the production of prostaglandins and matrix degrading enzymes. Interluekins and TNF

were involved in this process. These prostaglandins stimulate the uterine contractions. Preterm rupture of membranes occur due to degradation of extracellular matrix in the fetal membranes. Incidence of intrauterine infections in preterm labor was 25-40%.The two microorganisms involved in preterm labor were ureaplasma urealyticum and mycoplasmahominis(Goldenberg and colleagues 2008a).Short cervix was associated with microbial invasion due to the ascent from the genital tract. Antimicrobial treatment was tried to reduce the rate of preterm labour. But it did not reduce the rate of preterm birth or chorioamnionitis (histological).(Tita and coworkers 2007)

Bacterial vaginosis:

The lactobacillus predominant vaginal flora replaced by anaerobes like gardenellavaginalis, mobiluncus& mycoplasma hominis.

It is associated with spontaneous abortion, preterm rupture of membrane, preterm labour and chrioamnionitis(hillier 1995, leitich 2003a). women with bacterial vaginosis and susceptible TNF alpha

genotype had 9 fold increased risk of preterm birth(macones and colleagues 2004)

But screening and treatment of bacterial vaginosis did not prevent preterm birth (okun and associates 2005)

RISK OF PRETERM BIRTHS

MATERNAL RISK

GENERAL RISK:

Most common maternal complication is postpartum endometritis but it responds rapidly to antibiotics

RISK DUE TO TOCOLYTIC AGENTS:

Beta sympathomimetics were associated with adverse maternal effect like chest pain(10%), dyspnea, tachycardia, palpitation(48%), tremor (39%), hypokalemia, hyperglycemia, nausea(20%) and headache(21%)(Cochrane review, gyetvai and colleagues) Pulmonary edema is life threatening adverse effect. It is more common in multiple gestation and who receiving corticosteroid for lung maturity. Other contributory factor was combination of tocolytic agents

unrecognized chrioamnionitis and fluid overload. An infrequent but serious maternal complication is myocardial ischemia due to myocardial micronecrosis.

Non steroidal antiinflammatory inhibits cox enzymes. Which plays main role in the initiation and maintenance of labor . Side effect of NSAID were peptic ulcer, GI bleed, PPH, renal failure and thrombocytopenia. Comparison of non selective COX inhibitors versus COX2 inhibitor did not show any difference in maternal side effects(king and associates)

Calcium channel blockers produce pulmonary edema, maternal hypotension& hepatotoxicity. caution is advised if magnesium sulphate is used concurrently because of potentiation of the side effect.(king and associates)

FETAL RISK:

The effect of preterm birth on the fetus depending on the gestational age at the time of birth and birth weight. Prematurity is classified into three groups

- Severe prematurity < 30 wks
- Intermediate prematurity 30-34 weeks
- Late or mild prematurity 34-37 weeks

All obstetrical resources should be used to avoid severe and intermediate permaturity. These births should occur in tertiary center with adequate neonatal intensive care facilities. Mild prematurity can be managed in level 2 nurseries(hagen et al 1993)

CONSEQUENCES IN FETUS:

- Neonatal Respiratory Distress Syndrome
- Intraventricular haemorrhage
- Bronchopulmonary Dysplasia
- Necrotising enterocolitis
- Cerebral palsy

These complication are common before 28 weeks and extends in to 30-32 weeks(mol et al 1999)

SCREENING METHODS

The symptoms and signs of preterm labor vary only a little from the normal physiololgical symptoms and signs of pregnancy, so early detection of preterm labor or preterm rupture of membranes in routine antenatal care is often problematic. The diagnostic criteria for preterm labor is defined by the onset of frequent uterine contractions with progressive effacement and dilatation of cervix. It can be assessed once the uterine contractions occur every 10 mins and 80% of cervical effacement & 3 cm cervical dilatation. But most of the patients present with mild symptoms and signs of labor. When the thresholds for contraction and cervical changes lowers, it will affect the sensitivity and positive predictive value for detection of preterm labor.

The screening test, which predicts the preterm birth would have high sensitivity and high negative predictive value. The available screening tools did not decrease the incidence of preterm birth. Now wide variety of screening tools have been evaluated in research.(fonseca and associates 2007).

MONITORING UTERINE ACTIVITY:

Simplest method to monitor the uterine activity is to teach the patient about the uterine contractions and how to palpate and record her own contraction. Patient should monitor the contraction for 1 hour twice a day[3]. This technique is easy and non expensive, but it is completely subjective and known to have poor sensitivity. It will also increase the patient anxiety which in turn increase the risk of preterm labor.

Another method of monitoring is tocography monitoring. Several studies showed that preterm delivery rate was reduced in the monitored group, but sensitivity and specificity of tocometer vary. It depend on the tension of the belt and the thickness of the maternal abdominal wall. It is also expensive and time consuming. So it is not suitable for low risk mother,but better for high risk mother.

CERVIACAL SCREENING:

Normally the cervical effacement starts at 32 weeks of pregnancy. This process begins in 16-24 weeks in patients affected by preterm labor. This effacement usually begins at the internal os. It can be seen as cervical shortening and cervical funneling. It can be detected by trans vaginal USG.

USG assessment of cervix is used to improve the accuracy of the diagnosis of preterm labor and to predict the women who enter in to preterm labor.

Several studies shows assessment of cervical length& funneling either alone or in combination is useful in predicting spontaneous preterm labor in asymptomatic women.

DIGITAL MEASUREMENT OF THE CERVIX:

Studies show that digital assessment of the cervix is highly subjective. It does not correlate with transvaginal assessment.

USG MAESUREMENT OF CERVIX:

Cervix is measured by ULTRASONOGRAM by 3 routes[4]

- Trans abdominal
- Trans vaginal
- Trans perineal

Cervix is a dynamic structure. Cervical measurements are affected by abdominal pressure and bladder filling.

After emptying the bladder a transvaginal probe is introduced in to the anterior fornix of the vagina. Avoid undue pressure on the cervix. It will distort the anatomy. In sagittal section the whole length of the endocervical mucosa is identified. The distance between external os to internal os is measured. Minimum 3 measurements are made and the shortest length is reported[4].

Transabdominal and transperineal assessment is used, in the situation in which vaginal examination ideally would be avoided like pre term prelabor rupture of membrane. In trans abdominal route the shortening of cervix is identified in 13 % of the cases. If the bladder is

full it is easy to access the length of the cervix but it may be associated with the increase in length of the cervix.

In sagittal section, the curvature of the endocervical canal affect the measurement .So there would be a potential for false positive reports.

Cervical funneling is an independent predictive value for preterm delivery. It can be measured by dilatation of the internal os and endo cervical canal length. Combination of these factors gives a cervical index. Funneling was defined as if the width at the internal cervical os greater than 5 mm.

CERVICAL ASSESSMENT IN HIGH RISK ASYMPTOMATIC PATIENT:

HIGH RISK MOTHER:

- Previous Preterm Labor
- History of Previous Preterm Prelabor Rupture Of Membranes
- Previous Cervical Surgery
- Uterine Anomaly

In high risk patients there is a strong association between short cervix and preterm labor[6].

Several studies showed that a single examination at 16-19 weeks of gestation with cervical length of 25 mm or less is associated with increased risk of preterm labor at 35 weeks. The negative predictive value of this cutter is 96 %. If cervical examination was done up to 24 weeks a single measurement of less than 25 mm is associated with preterm delivery about 4.2 times.

CERVICAL ASSESSMENT IN LOW RISK ASYMPTOMATIC PATIENT:

Significant preterm deliveries occur in low risk population with no historical risk factor.(Iams and coworkers) Studies shows evaluation of cervical length seems to be similar predictive value in low risk patient also. Till recently scanning in low risk patient was not useful, because the effective intervention to improve pregnancy outcome was not documented.

One randomized trail shows, screening the cervical length between 20-25 weeks& effective intervention for those with cervical length of less than 15 mm with progesterone up to 34 weeks will reduce the risk of preterm labor. But it did not show reduction of perinatal mortality and morbidity(Fonseca and associates 2007)

Final conclusion is the screening test like, transvaginal assessment of length of cervix should be offered to all women[5]. It should be done at the time of routine anomaly scan. It can identify high risk women who need close monitoring & corticosteroid need.

CERVICAL ASSESSMENT IN SYMPTOMATIC PRETERM LABOR:

Early diagnosis of preterm labor is essential to reduce the risk of preterm labor or to optimize the condition for premature neonate. The cervical assessment by digital examination is important. But it has interobserver error. The USG assessment is essential in symptomatic women, for earlier treatment of the patient with cervical changes and also reducing the unnecessary treatment for patient who are not in preterm labor[6].

CERVICAL SCREENING IN TWIN PREGNANCY:

Approximately 5-10% of twins deliver before 33 weeks of gestation. The preterm delivery is increased to 6 fold in multiple gestation. Several studies show insufficient data about cervical length in twin pregnancy to predict preterm delivery.

INCOMPETENT CERVIX:

Cervical incompetence is a clinical diagnosis. It is recurrent painless cervical dilatation and spontaneous mid trimester birth in the absence of spontaneous rupture, bleeding and infection.

CERVICOVAGINAL FETAL FIBRONECTIN:

It is a glycoprotein. It is found in decidua, placenta and amniotic fluid. It is important for implantation and placental and uterine attachment.(Leeron and colleagues 1996). It is found in cervical screening in 16-18 weeks of gestation because in early weeks the fusion of fetal membranes and decidua is incomplete. Again the fibronectin is found at the time of onset of labor. In between 22- 37 weeks it is not found in cervical screening[12]. If chronic decidual disruption occur due to infection in 2 nd and early part of 3 rd trimester (lockwood and co workers 1991)it will leak into the cervical secretion.

ELISA assay has been developed as bed side test to detect total fibronectin. Digital examination , sexual intercourse, PPROM, and vaginal bleeding affect the test result.so it produces false positive results. It has a sensitivity of 53% and specificity of 89% value more than 50 ng/ml is positive. Negative result associated with fewer admission and decreased hospital stay[13].(love and asoociates).

The combination of ultrasound assessment of cervical length and fibronectin had better prediction of preterm labor[21](Rizzo and co workers). Several studies show that fetal fibronectin assessment after cervical length assessment was more specific[21](Schmitz and associates)

SCREENING FOR BACTERIAL VAGINOSIS ;

Bacterial vaginosis is an over growth of mixture of many microbes-Like Gardenellavaginalis, mobiluncus and mycoplasma hominis. Its role in preterm labor is poorly described. But the risk is double with bacterial vaginosis. Early pregnancy infection greater risk than late pregnancy infection.(Leitich and co workers). Screening and subsequent treatment of bacterial vaginosis remains controversial[16]. Treatment of bacterial vaginosis with antibiotics did not reduce the risk of preterm birth.(Cochrane collaboration). But it reduce risk of PPROM screening and treatment of bacterial vaginosis has benefit only in high risk women, but more studies are required.

RECOMMENDED SCREENING STRATEGIES TO PREVENT PRETERM BIRTH(ACOG 2001,2008 A)

- Screening For Preterm Labor In Low Risk Population Is Not Beneficial
- Currentdata Not Supporting The Home Uterine Activity Monitoring And Bacterial Vaginosis Screening.
- Cervical Length Assessment And Fetal Fibronectin May Be Useful, But Only their Negative Predictive Value Is Valuable.

INSULIN LIKE GROWTH FACTOR BINDING PROTEIN-I

INSULIN LIKE GROWTH FACTOR BINDING PROTEIN-I is one of the major protein, found in human decidua & amniotic fluid. Its concentration is 10-100 times higher in amniotic fluid than serum[17]. Amniotic fluid contains non phosphorylated forms, decidua contains phosphorylated form.

INSULIN LIKE GROWTH FACTOR system contains **INSULIN LIKE GROWTH FACTOR-I and INSULIN LIKE GROWTH FACTOR-II** receptors and binding protein. It has a control mechanism in fetal and placental growth and development.

INSULIN LIKE GROWTH FACTOR BINDING PROTEIN was formerly known as placental protein-II. It was isolated 15years ago, radio immune assay was developed measuring both is form of phIGFBP-1

In PPROM and preterm labor, **INSULIN LIKE GROWTH FACTOR BINDING PROTEIN-I** found in cervical secretions, commercial strip is available to detect it presence.

Its Sensitivity iwas94- 96%, specificity is 95%, but in clinical application 74% sensitivity has been documented.(kekki et al). It has high negative predictive value 92%,its positive predictive value was 63%. Its concentration I of at least 10 micro gram/liter in Cervical swab indicates 10 fold increase the risk of preterm delivery[18] kekki et al).

Some studies compare the value of cervical phIGFBP-1 with cervical length measurement[20]. The cervical length at 22-24 weeks and **INSULIN LIKE GROWTH FACTOR BINDING PROTEIN-I** measurement were useful to detect preterm delivery.(bitter et al)

Many other protein like , FFN , IL 1[19] ,IL 8 and TNF alpha also be evaluated as biochemical predictor for threatened preterm delivery. FFN produced by chorion. It is detected by monoclonal antibody FDC 6. FFN is cervical secretion test vary in their sensitivity, specificity and their predictive value in different studies. Because of the multifactorial etiology of preterm birth its prediction never become 100 % so combination of markers may help to come to diagnosis very closely.

Infection can activate the cytokine pathway. It trigger the production of extracellular matrix degradation proteases in decidua and fetal membrane, it also increases prostaglandin production.It leads to uterine contraction and cervical changes. It also releases the chorionic or decidual proteins from the interface of decidua and chorion, so decidual isoform IGFBP 1 also released in cervico vaginal secretion[17]. In contrast to FFN only small amount of IGFBP 1 is present in urine and seminal plasma. So recent intercourse does not affect the test results. But preterm premature rupture of membranes gives false positive result.

OTHER PREDICTORS OF PRETERM LABOUR[20]:

- Placental Corticotropin Releasing Hormone And Its Hinding Protein
- Salivary Estriol
- Inflammatory Cytokines And Prostaglandins
- Cervical Ferritin
- Non Invasive Cutaneous Cardiovascular Dynamics

But these markers are not reliable marker of preterm labour[23].

PREVENTION OF PRETERM LABOR

PER PREGNANCY PREVENTIVE MEAUSRES:

Pre pregnancy counseling regarding recurrence of preterm delivery, because previous preterm birth is most significant risk factor.(ashamed and colleagues). One previous preterm delivery had 15% recurrence and 2 previous preterm delivery had 41% recurrence. Counsel the women living remote from a perinatal center and suggest relocating during the critical period. Advice regarding avoidance of heavy manual labor, mental stress, smoking , alcohol, and chemical dependency.

PRENATAL PREVENTION:

1) **ASSESSMENT OF RISK**:

Risk assessment done by proper history taking and clinical examination. Scoring system (creasy and anouales) which uses socio economic factor, medical history and habit of women was tried, but Scoring system predictive value is low(17- 34%)

2) **EDUCATION OF PATIENT**:

Patient education about signs and symptoms of preterm labor is useful. Some signs and symptoms of preterm labor were menstrual like cramps, pelvic pressure sensation, dull head ache, perception of contraction and a show. If these symptoms are present a through cervical assessment by USG is essential.

ANTENATAL CARE:

If patient is high risk for preterm labor the antenatal assessment need to be more frequent in the second trimester because, early and frequent antenatal care can detect some of the maternal and fetal conditions like anemia, GHT, asymptomatic bacteuria (Bowes and associates)

PRIMARY PREVENTIVE STRATEGIES OF PRETERM LABOUR:

PROGESTERONE:

According to csapo 1956,progesterone maintain the uterine quiescence and block the labour initiation.A study conducted by NICHD Maternal Fetal Medicine units network at 2003,they used injection 17-hydroxy progesterone caproate weekly from 16 weeks to 36 weeks[15]. The rate of preterm delivery was reduced significantly. But the study conducted by carities and associates 2009 shows no improvement with progesterone. Progesterone vaginal suppositories 200mg were associated with decrease in preterm birth before 34 weeks(fonseca and collegues 2003,2007) It also reduce preterm delivery in patients with short cervix. According to ACOG 2008, progesterone therapy should be limited to women who had previous preterm birth. But further studies are needed.

CERVICAL ENCIRCLAGE

The early second trimester USG can identify the asymptomatic cervical changes like shortening of length and funneling of cervix.

According to RCOG trial,the Mc Donald suture significantly reduces the preterm birth before 33 weeks but there was no improvement in preterm birth before 37 weeks , still birth, and neonatal death. 1 out of 30 will be benefited by cervical encirclage[6]. Cerclage had limited risk in low and moderate risk of preterm delivery. (Cochrane review by drakely and co workers)

3 indications of cervical encerclage:

1. Previous history of recurrent 2nd trimester losses and diagnosed as cervical incompetence
2. Short cervix which was identified byUSG
3. Rescue cerclage- done as an emergency procedure

TREATMENT FOR VAGINAL INFECTION

Currently there is insufficient evidence available for prophylactic antibiotics during pregnancy to prevent preterm delivery (Cochrane review by Othman and associates)

Principles of management of preterm labour:

- Glucocorticoids
- Bed rest
- Hydration and sedation
- Antenatal transfer
- Tocolytic agents- in appropriate situations
- Antibiotics- if needed
- Careful intrapartum monitoring
- Route of delivery

Bed Rest:

According to some studies, they concluded that the available evidence neither supported nor refused the use of bedrest in preterm labour (Cochrane database sosa and associates 2004)

Corticosteroids:

Corticosteroids accelerate the lung maturation of fetus.Its lowers the incidence of respiratory distress syndrome and neonatal mortality rates (liggins and Howie 1972). Dexamethasone given as 6mg im

every 12hrly for 48 hrs.Betamethasone given as 12 mg every 24hrs for 2 doses.

Antenatalcorticosteroids reduce the neonatal death due to respiratory distress syndrome with respiration support[14] and decreases the neonatal intensive care admission and neonatal cerebroventricularhemorrhage (Roberts and Dalziel). But no demonstrated increased risk to the mother as chorioamnioitis or puerperal sepsis. Some clinicians administered steroids at weekly interval. But some trials show 4 or more courses of steroids[7] increase the incidence of cerebral palsy or neonatal death (NICHD trial of Wagner and Australasian collaborative trial of repeat doses of steroids). Behavioral problems like ADHD, emotional reactivity is increased in repeated course group. (crowther and colleagues). In some studies, the neonatal growth parameters was reduced due to repeated courses of steroids (Murphy and associates- MACS-multiple courses and antenatal corticosteroids for preterm birth trial).

According to ACOG and NIH (national Institute of Health) , one course of betamethasone (12 mg, 2 doses, 24 hoursapart) should be

given in preterm labour. Rescue dose is not allowed. Many investigation are under way regarding the use of different types of corticosteroids. According to Mittendorf and co workers, if high exposure to Magnesium in Preterm labour occurs, betamethasone may be less effective to prevent intra ventricular hemorrhage.

RCOG Guidelines

It would be indicated in all women who is in high risk of preterm labour in between 24-34 weeks. If there is pulmonary immaturity it should be given in more than 34 weeks.

It should be given still after 37 weeks in neonates born by elective cesarean. It significantly reduces RDS and transient tachypnea of newborn. Corticosteroid therapy should be started immediately in high risk women, unless delivery is imminent.

Betamethasone is the steroid of choice because it reduces the risk of deathof neonates than dexamethasone and also reduces the risk of periventricular leucomalacia(Lee study) Antenatal corticosteroids is contraindicated in maternal systemic infections like tuberculosis. In chorioamnionitis, caution is recommended. In GDM patients close

monitoring is essential in the first 3 days to avoid transient hyperglycemia. Usually, steroid effect begins after 12 hours of first dose and it lasts for 5 days.

TOCOLYTICS

1.β ADRENERGIC AGONISTS

It reduces intracellular calcium level and prevents myometrial contractile protein activation.

- Ritodrine[8]

It resulted in serious maternal and fetal side effects.Tocolysis is third most common cause of acute respiratory distress and death in pregnant woman because of pulmonary edema. Because beta agonist cause water and sodium retention that leads to volume overload.(Hankins and colleagues 1988).It is not used nowadays.

- Terbutaline:

Continuous use of terbutaline is not advised. It also causes pulmonary edema,sudden maternal death and neonatal myocardial necrosis(fletcher and colleagues).Oral therapy is also not effective

- Calcium channel blockers:

It inhibits calcium channels in the cell membrane thereby reducing the myometrial activity[10].Nifedipine is the most commonly used since it safe and more effective than beta agonist (king and colleagues 2003).Nifedipine is given as 20 -30 mg STAT followed by 10-20 mg tds for 48hrs.It will not prolong the pregnancy when used concurrently with MgSO4. The combination is most dangerous because Nifedipine enhances the neuromuscular blocking effects of magnesium[9]. Thus it interferes with cardiac and pulmonary function(Kurtzman and associates).

- Prostaglandin Inhibitor:

Prostaglandin synthase is involved in conversion of arachidonic acid to prostaglandin.Because prostaglandins are involved in the mechanism of labor. The drugs that block the prostaglandin production like acetyl salicylate and indomethacin were used to prevent preterm labour(Zukerman and associates 1974).It can be given 50-100 mg at 8hrs interval. Not to exceed 200 mg in 24hrs interval.But it produces oligohydraminos and it will be reversible.

Several studies show that it will produce neonatal necrotizing enterocolitis(Muench and coworkers 2001).

- MgSO4:

High concentration of ionic magnesium decreases the myometrial activity.It is a calcium antagonist.But close monitoring of magnesium sulphate toxicity is essential(samol and lambers 2005).

MgSO4 produces neuroprotective effectin neonates especially in 24-28 weeks[11].Because it stabilizes the intracranial tissue,decreases the fluctuation in cerebral blood flow ,reduces the synthesis of cytokines and bacterial endotoxins and decreases the effect of inflammation(Nelson Aslanyan And colleauges 2007,crowther and colleagues 2003 Rouse and colleagues 2008).

- Atosiban:

It is a oxytocin antagonist .But in Randomized clinicaltrails, shows it improves neonatal outcome and also it was associated with neonatal morbidity. (moutquis&co workers 2000)

1.Nitrous oxide donors:

It is smooth muscle relaxant, but it was not effective than other tocolytics. Maternal hypotension is common side effects.

These tocolytics are used to stop preterm labor temporarily. But it doesnot prevent preterm labor. It is used for antenatal corticosteroid therapy & antenatal transfer of patients to tertiary care hospital where the NICU facilities are available. It does not improve neonatal outcome (berkman and associates 2003)

ANTIBIOTICS:

Antibiotics use in preterm labor does not improve the neonatal outcome(ORACLE II trail). This study shows increased cerebral palsy rate in treated groups. The mechanism is, sub clinical infection must provoke labor was suppressed with antibiotics, but not eliminated. It will cause continues exposure of fetus to toxic environment & perinatal infection and neurological impairment. But overt infection should be treated with antibiotics.

MANAGEMENT OF WOMEN WITH THREATENED OR ESTABLISHED PRETERM LABOR:

Once preterm diagnosis is made, start the clinical appraisal and appropriate investigation about the maternal and fetal condition. USG is used to assess the fetal weight, fetal biometry, presentation and liquor volume, placental site, and cervical length. Doppler asscessment for fetal well being.Vaginal and urine culture & sensitivity to ruleout infective etiology.Complete blood count. and C reactive protein also important. Amniocentesis is used for fetal lung maturity assessment, gram stain and culture. IL 6 estimation may be considered.

The outcome was poor in 20-24 weeks, it will be discussed with before starting tocolytics. in this situation parents should be allowed to choose the options regarding delivery . In 24 – 34 weeks give corticosteroids and tocolytics , it will facilitate inutero transfer of fetus to tertiary care level and fetal lung maturity. Calcium channel blocker is the first line tocolytics because of cheaper cost , easy administration and fewer maternal side effects than beta

sympathomimmetics[23]. It should be continued for 48 hours. Use of tocolytics more than 48 hours doesnot prevent preterm delivery. If it is not tolerable, alternative agent should be used. Intrauterine infection is the main cause of tocolysis failure, so it should be used with caution. Give antibiotics if there is overt maternal infection. Emergency cerclage is limited value.

LABOR AND DELIVERY:

If Preterm delivery is inevitable , the mode of delivery will be discussed with the parents by multidisciplinary team. Before 24 weeks vaginal delivery should be anticipated. In 24 – 34 weeks the management of labor not differ from beyond 34 weeks. If there is signs of intrauterine infection, antibiotic therapy should be started to prevent maternal morbidity. Group b streptococcal infections are also dangerous to preterm neonates. Prophylactic outlet forceps and episiotomy doesnot improve the neonatal outcome. They should be used only in obstetric indication. Vacuum delivery is contraindicated before 34 weeks.

In extreme preterm { 24- 28 weeks} EN CAUL method of delivery is associated with higher cord ph because intact amniotic membrane helps to product the fetus from mechanical forces during vaginal birth. The delivery should be done in tertiary level care where neonatologist and neonatal intensive care facility is available.

PRINCIPLE OF MANAGEMENT IN PRETERM LABOR:

1. FIRST STAGE OF LABOR:

- Bed rest – to avoid early rupture of membrane
- Adequate fetal oxygenation
- Epidual analgesia
- Labor should be carefully monitored with continuous electronic fetal monitoring
- Caesarean delivery- for obstetric indication only

SECOND STAGE OF LABOR

The birth should be gentle and slow to avoid rapid compression and decompression of the head

- Episiotomy
- Cord should be clamped immediately after birth to avoid hypervolemia and hyperbilirubinemia
- Shift the neonates to the intensive care unit under the care of neonatologist

POST NATAL MANAGEMENT

MOTHER:

- Encouragement of parent and infant bonding
- Breast feeding should be encouraged
- Continues psychological support to the mother is important

NEONATE:

Premature neonates should adopt the extra uterine life because the different organ system undergo continues functional and structural development and maturation (lee and colleagues). Lung

immaturity is the major cause of respiratory distress syndrome, and poorly developed respiratory control may lead to recurrent apnea. Due to patent ductus arteriosus, congestive cardiac failure may occur. Liver immaturity is likely to be associated with severe neonatal jaundice(morris and Tyson).

In extremely premature infants chronic lung disease and retinopathy are long term complication. In hypoxic ischemic encephalopathy, head cooling method is used to improve the neurological morbidity of preterm neonates (Jacobs and associates). Maturity of lung is the main factor in determining the prognosis of preterm infants.

Minimizing the severity and incidence of respiratory distress syndrome is the major factor for the improvement of neonatal mortality and morbidity. Perinatal care, selective use of tocolytics and maternal corticosteriod administration all are enhance the lung maturity. Prophylactic use of exogenous surfactant & rescue use of surfactant in mechanically ventilated neonates are reduce the respiratory morbidity.

1.MINNAMAIJA KEKKIAND ASSOCIATES (2001)

IGFBP-1 in cervical secretion as a predictor of preterm delivery

This is a prospective study analyzing 63 women with PTL. Aim of this study was to identify the accuracy of phosphorylated isoform of IGFBP-1 in cervical secretion in symptomatic women with intact membrane in predicting increased risk of PTD.

7 of 17 (41%) positive women delivered as preterm before 35 weeks.3 0f 46 (7%) negative women delivered as preterm before 37 weeks .In control population, 3 out of 58(5%) women had positive results, but none of these women delivered as preterm

In this study the median number of weeks between the first presentation with preterm contraction to delivery was 10.2 in negative group and 5.1 in positive group.

2.DERYA EROGLU & ASSOCIATES (2006)

Prediction of PTD among women with threatened preterm labour

Aim of this study was to analyse the predictive value of fetal fibronectin and Ph IGF-BP-1 in cervical secretion and transvaginal USG measurement of cervical length for preterm delivery less than 35weeks.

51 women with 24-35 weeks gestationand preterm pains were included in this study. Ph IGFBP- 1 and fetal fibronectin were analysed in cervical secretion. Cervical length was measured with transvaginal USG.

Positive predictive value of fetal fibronectin was 50%, Ph IGFBP-1 was 58.3% and cervical length< 20 mm- 100%, cervical length was <25 mmm- 66.7%. Negative predictive values for fibronectin- 91.9%, for Ph IGF-BP-1- 92.3%, cervical length less than 20 mm-91.1% and cervical length, less than 25mm- 90.5%

In this study group, preterm birth rate was 19.6%. When the three tests were combined, positive predictive value of each test was increased.

The study shows that Ph IGF-BP-1 and fibronectin are equally good in predicting the PTD

3.DEVLETA BALIC & ASSOCIATES (2008)

IGFBP- 1 in cervical secretion as a predictor of preterm delivery

This was a prospective study. It was conducted in a OBG clinic at Tulsa. 80 patients between 24-34 weeks gestation were included in this study. After taking proper history, all women underwent IGFBP-1 measurement in cervical secretion using Actimpartus kit. The bishop's score was determined by per vaginal examination. Rates were compared by Spearman Rank co-relation kit, standard deviation, student's t test

8 patients in the study group had positive Ph IGFBP-1 test. 6 patients delivered as preterm. The negative predictive value of this test was 98.59%.Positive predictive value of this test was 94.43%.

Bishop's score specificity and sensitivity were 83.78% and 50%. Bishop's score positive predictive value was 20%, negative predictive value was 95.36%. But there was no correlation between IGFBP-1 and bishop's score.

Conclusion of this study was IGF-BP-1 is <10µg/L (negative test) in asymptomatic women, the risk of PTD is low. The IGF-BP-1 test could be used as a screening test in asymptomatic women

4.H.METE TANVIR & ASSOCIATES

Cervical Ph IGF-BP-1 for the prediction of preterm delivery in symptomatic cases with intact membrane

It is a prospective and observational study. This study evaluate the predictive value of IGF-BP-1 test in symptomatic women with PTL, at 24-37 weeks gestation, with intact membrane and less than 3 cms dilatation are included in this study.

68 cases were included in this study most of the test positive cases has high bishop's score and low gestational age at delivery(P=0.001). Sensitivity was 70%, specificity was 74%, positive predictive value was 48%, Negative predictive value was 88%. The

test is based on the immunochromatographic qualitative analysis of PhIGFBP-1. All cases are evaluated by mother's demographic characteristics and neonatal outcome.

Conclusion of this study was that the test had high negative predictive value to predict PTD less than 34 weeks and within 7 days. It is useful to reassure the patient and avoid unnecessary intervention.

The author also concluded that there was a strong association between gestational age at delivery and cervical length in test positive Patient.

5.ANELA LATIFAGIC& ASSOCIATES

IGFBP-1 in cervical secretion in women with symptoms of preterm delivery

Aim of this study was to evaluate the value of IGFBP-1 in cervix in symptomatic preterm pain patients and also correlation of this test with bishop's score. 30 pregnant women were included. All of these women were between 24-34 weeks of pregnancy. The concentration of IGFBP-1 was estimated by ActimPartus test. The test is considered positive is IGFBP-1 concentration was >10 μg/L.

Statistical importance was determined at the variation level of 5% and 1%. 20 patients in the study group had positive test (66.67%) and 15 women had preterm delivery.

Sensitivity and specificity was 80% and 53.33% respectively.Positive predictive value was 33.33% and negative predictive value was 80%.

In Bishop score, the sensitivity was 93.33% and specificity was 33.33%.Positive and negative predictive values was 58.33% and 83.33% respectively.

In the study group correlation between Actimpartus and Bishop score was positive ($p<0.05$). Bishop score was a better predictive value regarding the prediction of Preterm Delivery than Actim Partus test. Statistical significance was good ($p=0.003$).

In other studies, the comparison of Foetal Fibronectin and IGFBP 1, sensitivity of IGFBP 1 is better (78%) than Foetal Fibronectin(76%).By using this test, we could be able to avoid unnecessary intervention and cost of treatment significantly.

This study's conclusion was IGFBP 1 in Cervical Secretion can be used as a predictor of Preterm Delivery. But Bishop score more than 4 is better predictor than IGFBP 1 in symptomatic preterm women.

6. K.KWEK et al(2004)

Evaluation of a bedside test for phosphorylated insulin like growth factor binding protein- in preterm labour

This study's objective was to assess the efficacy of bedside kit for IGFBP- 1 in the diagnosis of Preterm Labour. It is a prospective study. 47 women with 24-34 weeks of gestation were included in the study. Corticosteroid and tocolytics were given to all patients.

In 47 patients, 29 women had negative test (61.7%) and 18 women had positive test (38.3%). The positive group had median cervical dilation of 1cm ($p<0.05$). There was no statistical significance of these 2 groups. Tocolytic therapy, stay in the labour ward and median duration of hospitalization were longer in test positive group ($p<0.05$) (34.5hour, 56 hour, 5 day).

In test negative group, 91.7% of the women had preterm delivery after seven days of onset of contraction . In positive group 44.4% women had delayed delivery after seven days.

Sensitivity& specificity of bedside test for phIGFBP-1 were 73.77% and 82.6%. The positive and negative predictive value were 77.8% and 79.2%. Small sample size was the drawback of this study.

Conclusion of this study was, if there is suspected preterm labor a negative test could exclude the diagnosis. So it avoid unnecessary obstetric intervention like tocolysis and inutero transfer.

7.LEMBET ET AL

It was a prospective study .In this study 36 symptomatic patient between 20 to 36 weeks gestation was included. 18 patients had positive actimpartus test, other 18 had negative test. Among the 18, one delivered at term. 17 patients delivered less than 37 weeks. In 18 negative patient, 2 delivered as preterm($p<0.005$). Sensitivity was 89.5%, specificity was 94.1%, positive predictive valuewas 94.4%, negative predictive value was 88.9%

8.RICARDO GOMEZ AND ASSOCIATES;

Cervicovaginal fibronectin improves the prediction of preterm delivery based on sonographic cervical length in patient with preterm labor

Aim of this study was to assess the efficacy of USG measurment of cervical length and vaginal FFN to predict the preterm labor. It is a prospective study.214 patient with preterm contraction (22 to 35 weeks) and cervical dilatation less than 3 cm were included in this study.

Outcome was assessed in terms of delivery within the 48 hours, 7 days, 14 days of admission and delivery less than 32 and 35weeks. Admission to delivery interval was also calculated.

This study was conducted in soterodelrio hospital, chile in1998 to 2002. Transvaginal usg was used to assess the cervical length. Fluid in posterior fornix was collected for fetal fibronectin assessment. It was collected before digital examination and transvaginal examination. The concentration of 50 microgram per ml was indicative of positive test.

Statistical analysis was done by chisquare test, logistic regression and survival analysis. Results shows preterm delivery less than 35 weeks was twenty percent, preterm delivery within 48 hours was 7.9 percent, within 7 days-13 %, within 14 days was 15.8%, ROC curve analysis shows there was a significant relationship between the preterm delivery and cervical length and fetal fibronectin. { $p< 0.01$ }. The prediction of preterm delivery was improved by adding FFN test with cervical length.

9.O.OLCITSU ETAL { 1992 }:

Early prediction of preterm delivery by transvaginal ultrasonography:

In his study use of transvaginal usg in the evaluation of cervix length was assessed. 130 high risk and 129 control patient was evaluated. Shortening of cervix by -1.5 sd or more was associated with increased risk of preterm delivery { $p < 0.01$ } .Dilated internal os more than 5 mm was associated with preterm delivery{ $p < 0.01$}

10.HUA SIENG TING AND ASSOCIATES:

Comparision ofbedside test for prediction of preterm labor.ph igfbp-1 and fetal fibronectin.

Aim of this study was to compare the effectiveness of bedside kits for both phIGFBP-1 and FFN for predicting preterm delivery. Patient with symptoms of preterm labor was included (24 to34 weeks). Both tests were performed. Antenatal corticosteroid and tocolytics were continued. 108 patient were included in this study. Among 108 , 95 patient had complete data for analysis.

If both test was negative,the median gestational age at delivery was3 7.4 weeks. If phIGFBP-1 and FFN both were positive the median gestational age at delivery was 32.4 to 34.2 weeks ($p<0.001$) . If any one of the test was positive the admission delivery interval was shortened.

If phIGFBP-1 test was positive the admission delivery interval 2.8 weeks shorter than negative group(2.3weeks compared with 5.1 weeks).($p<0.001$). but if FFN test is positive ,the median delivery intervals 1.8 weeks shorter than negative test result(3.3 weeks

compared with 5.1 weeks)(p=0.002). Both test had high negative predictive value in predicting delivery within 48 hrs, 7 and 14 days(1.00,0.92,0.92 and 0.97,0.89,0.89)

Conclusion of this study was both phIGFBP-1 and FFN were effective bedside test to predict the preterm delivery in symptomatic women. But phIGFBP-1 has higher negative predictive value of 1.00 in predicting the risk of delivery within 48 hrs.

11. LOOKWOOD ET AL

Association between ffn in preterm labor patient &preterm delivery

This study showed that negative result would ruleout labor within 7 days. Negative predictive value was 97-99.5%.positive predictive value was 15-25%. So a positive test should not be interpreted as an indicator of labor.

12.D-PATERNOSTER ET AL(2001)

Sonographic cervical length and ph igfbp-1 in cervical secretion inthe prediction of spontaneous preterm delivery

Aim of this study is to evaluate the efficacy of phIGFBP-1 test for predicting preterm delivery. It is a prospective study. 210 women were included (24 to 35 weeks) in this study. They were underwent phIGFBP-1 test and transvaginal cervical length measurement. A multivariate logistic regression model was used to analysis the statistics. The prevalence of preterm delivery in symptomatic women was 16%.

The ROC curve showed that 26mm of cervical length was the best cutoff value for predicting preterm delivery.(sensitivity 86.4%, specificity 71.9%,positive predictive value34.5%, negative predictive value 96.8%).

If cervical length less than 26mm, 34.5% patient was delivered as preterm. But only 3.2% patient delivered as preterm if cervical length more than 26mm ($p<0.0001$).The odds ratio was very high.

In phIGFBP-1 test the sensitivity was 52.9%, specificity was 89.2, PPV -48.7%& NPV-90.8%. The logistic regression of phIGFBP-1 was statistically significant in predicting preterm delivery.($p<0.0001$). The odds ratio was 9.29%.

Multivariate analysis shows , the two variable were independent , so useful in combination to predict preterm delivery($p<0.0001$). The specificity of cervical length <26mm was increased in the presence of positive phosphorylated IGFBP-1-test (96%).

Conclusion of this study was her TVS of cervical length of >26mm and exposure to phosphorylated IGFBP 1 in symptomatic patient shows a low risk for preterm delivery. So we avoid unnecessary intervention.

13. AIDAY AND COLLEAGUES

Predicting PTL: evaluation of ILGFBP 1 as a bedside test

It is a prospective study conducted in kotamarudu hospital, O&G department. All symptomatic women (28-37 weeks) were included. 50 patients were recruited .Finally 44 were included.39 had

negative results.5 had positive results. Among 39, 6 delivered within 7 days. Among 5,3 delivered within 7 days. The sensitivity, specificity ,PPV, NPV were 33%,94%,60%and 80% in predicting pre term delivery within 7 days.

The conclusion of this study was that the bedside test had high specificity & NPV. So it could be used as predictor in PTL within 7 days of symptoms .

It help to decide in utero transfer of this patients in local settings.

14.ARDA LAMBET & ASSOCIATES(2002):

New rapid bed side test to predict preterm delivery: phosphorylated insulin like growth factor binding protein in cervical secretion.

It is a prospective study . 36 symptomatic women (20 -36 weeks) were included. The presence of cervical phosphorylated insulin like growth factor binding protein was assessed by immuno chromatography(new rapid bedside test kit).

Out of 36, 18 had positive and 18 had negative results. In 18 positive & 17 delivered as preterm, among 18 negative cases 2 delivered as preterm ($P< 0.05$). The sensitivity, specificity, positive predictive value and negative predictive value in preterm labor were 89.5,94.1,94.4, 88.9%. But the test was used to detect delivery within 7 days the sensitivity, specificity positive predictive value, negative predictive value were 93.8 ,85%,83.3, 94%.

Conclusion of his study was cervical detection of phosphorylated insulin like growth factor binding protein- I by immune chromatography is a rapid &highly applicable test to predict preterm delivery in symptomatic high risk.

AGE GROUP * PRETERM

TABLE I a

			PRETERM		
			0	1	Total
AGE GROUP	Less than 20 years	Count	10	8	18
		% within AGE GROUP	55.6%	44.4%	100.0%
		% within PRETERM	16.1%	21.1%	18.0%
		% of Total	10.0%	8.0%	18.0%
	20 to 30 years	Count	45	28	73
		% within AGE GROUP	61.6%	38.4%	100.0%
		% within PRETERM	72.6%	73.7%	73.0%
		% of Total	45.0%	28.0%	73.0%
	More than 30 years	Count	7	2	9
		% within AGE GROUP	77.8%	22.2%	100.0%
		% within PRETERM	11.3%	5.3%	9.0%
		% of Total	7.0%	2.0%	9.0%
	Total	Count	62	38	100
		% within AGE GROUP	62.0%	38.0%	100.0%
		% within PRETERM	100.0%	100.0%	100.0%
		% of Total	62.0%	38.0%	100.0%

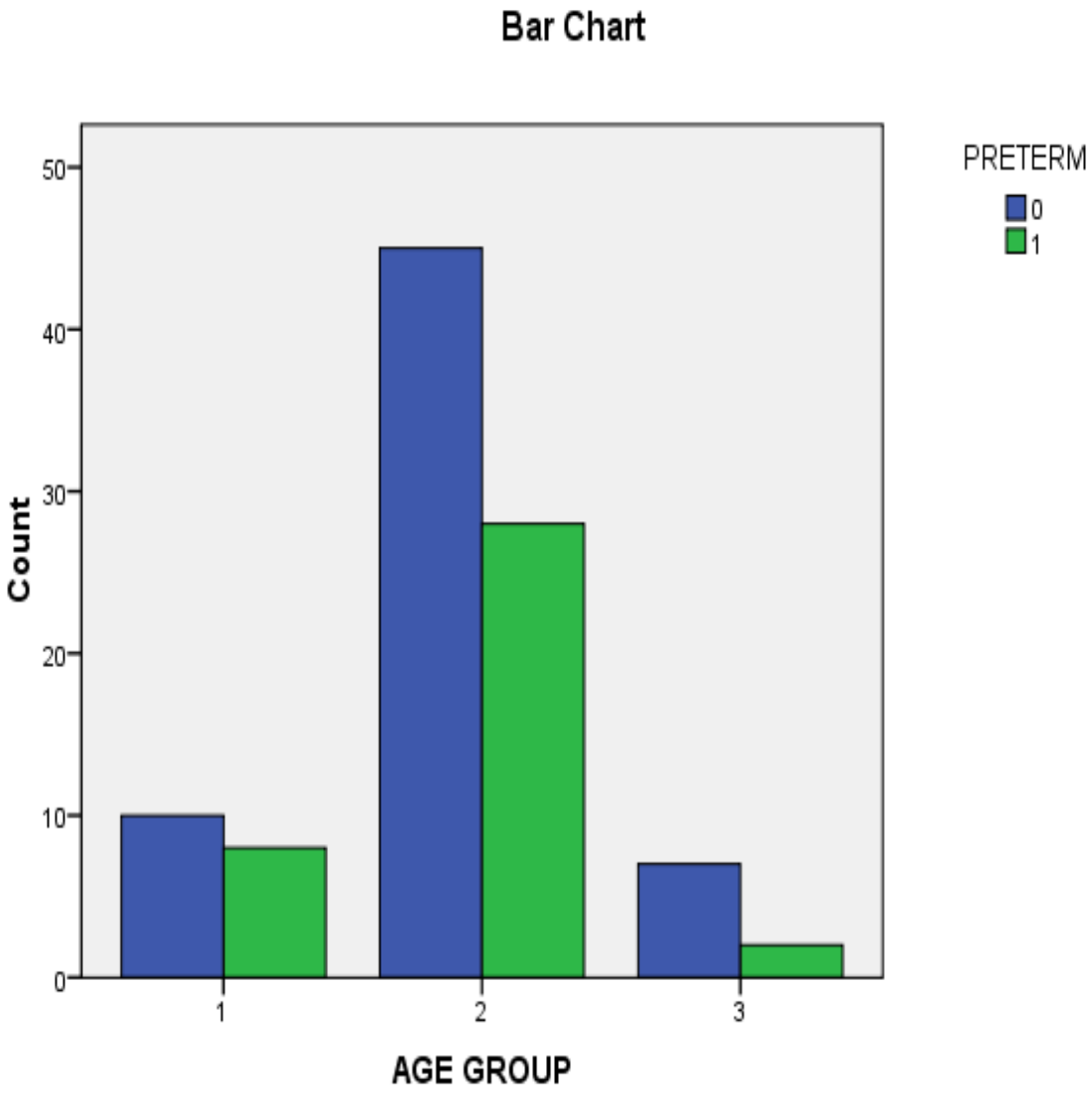
Chi-Square Tests

TABLE I b

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	1.272[a]	2	.529
Likelihood Ratio	1.343	2	.511
Linear-by-Linear Association	1.068	1	.301
McNemar-Bowker Test	-	-	.[b]
N of Valid Cases	100		

INTERPRETATION

In 100 study patient, 18 patient belongs to <20 yrs. 73Patients belongsto 20 to 30 years of age. Most of the preterm (73.7%) Occurs in 20 to 30 years of age groups. P value was 0.529. So there was no statistical association between the age group and preterm in this study.



The same result was shown as bar diagram.

OBSTETRIC SCORE * PRETERM

TABLE II a

			PRETERM		
			0	1	Total
OBSTETRIC SCORE	primi	Count	35	22	57
		% within OBSTETRIC SCORE	61.4%	38.6%	100.0%
		% within PRETERM	56.5%	57.9%	57.0%
		% of Total	35.0%	22.0%	57.0%
	multi	Count	27	16	43
		% within OBSTETRIC SCORE	62.8%	37.2%	100.0%
		% within PRETERM	43.5%	42.1%	43.0%
		% of Total	27.0%	16.0%	43.0%
	Total	Count	62	38	100
		% within OBSTETRIC SCORE	62.0%	38.0%	100.0%
		% within PRETERM	100.0%	100.0%	100.0%
		% of Total	62.0%	38.0%	100.0%

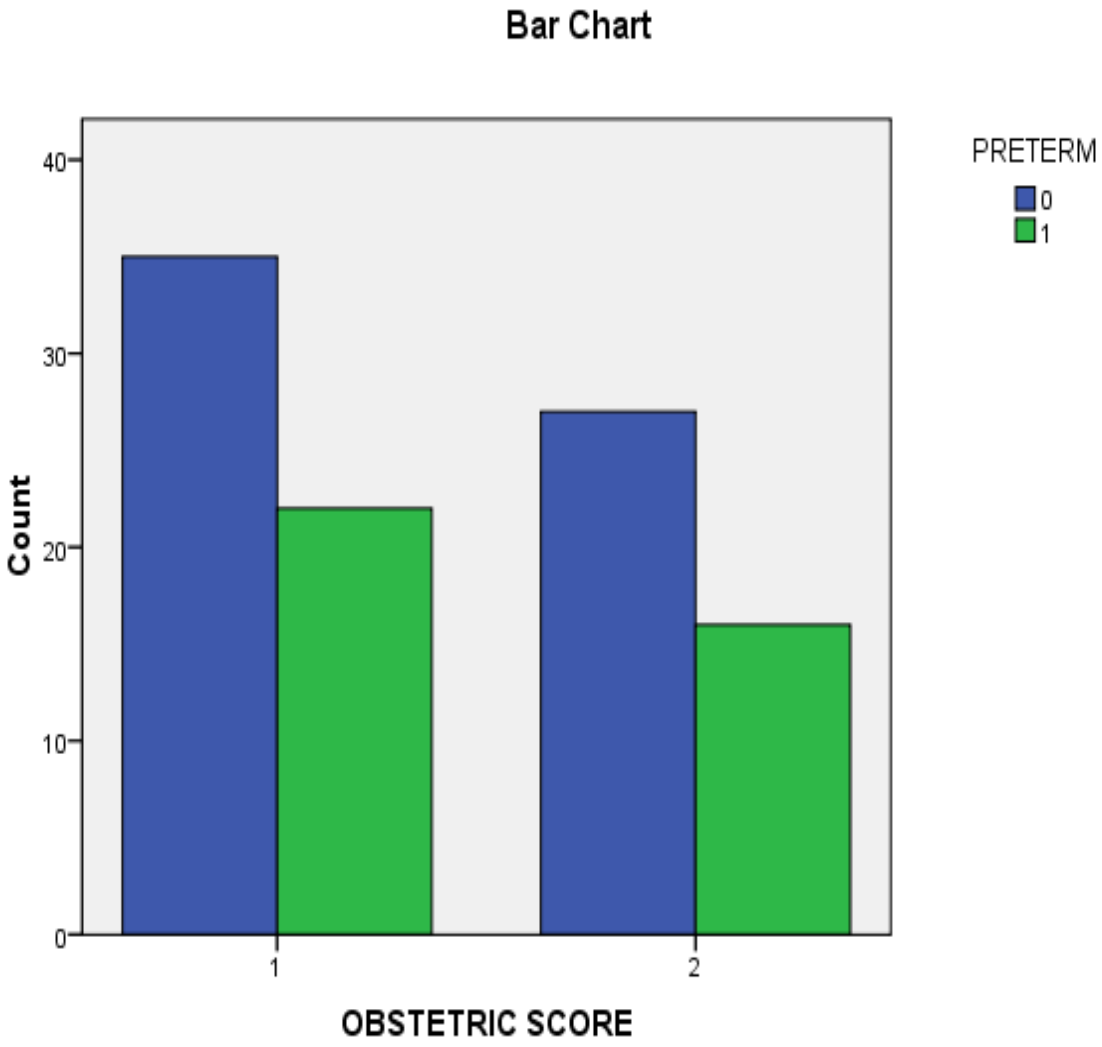
Chi-Square Tests

TABLE II b

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.020[a]	1	.887		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.020	1	.887		
Fisher's Exact Test				1.000	.527
Linear-by-Linear Association	.020	1	.888		
McNemar Test				.[c]	
N of Valid Cases	100				

INTERPRETATION;

In 100 patients, 57 patient were primi. 43 patients were multi. Primi constitutes 57.9% of preterm , multi constitutes 42.1% of preterm. P value was 0.527. There was no statistical significance between obstetric score and preterm in this study.



The bar chart shows the association between obstetrics score and preterm.

CERVICAL DILATATION * PRETERM

TABLE III a

			PRETERM		
			0	1	Total
CERVICAL DILATATION	Nil	Count	24	1	25
		% within CERVICAL DILATATION	96.0%	4.0%	100.0%
		% within PRETERM	38.7%	2.6%	25.0%
		% of Total	24.0%	1.0%	25.0%
	1cm	Count	27	18	45
		% within CERVICAL DILATATION	60.0%	40.0%	100.0%
		% within PRETERM	43.5%	47.4%	45.0%
		% of Total	27.0%	18.0%	45.0%
	2cm	Count	10	19	29
		% within CERVICAL DILATATION	34.5%	65.5%	100.0%
		% within PRETERM	16.1%	50.0%	29.0%
		% of Total	10.0%	19.0%	29.0%
	3cm	Count	1	0	1
		% within CERVICAL DILATATION	100.0%	.0%	100.0%
		% within PRETERM	1.6%	.0%	1.0%
		% of Total	1.0%	.0%	1.0%
	Total	Count	62	38	100
		% within CERVICAL DILATATION	62.0%	38.0%	100.0%
		% within PRETERM	100.0%	100.0%	100.0%
		% of Total	62.0%	38.0%	100.0%

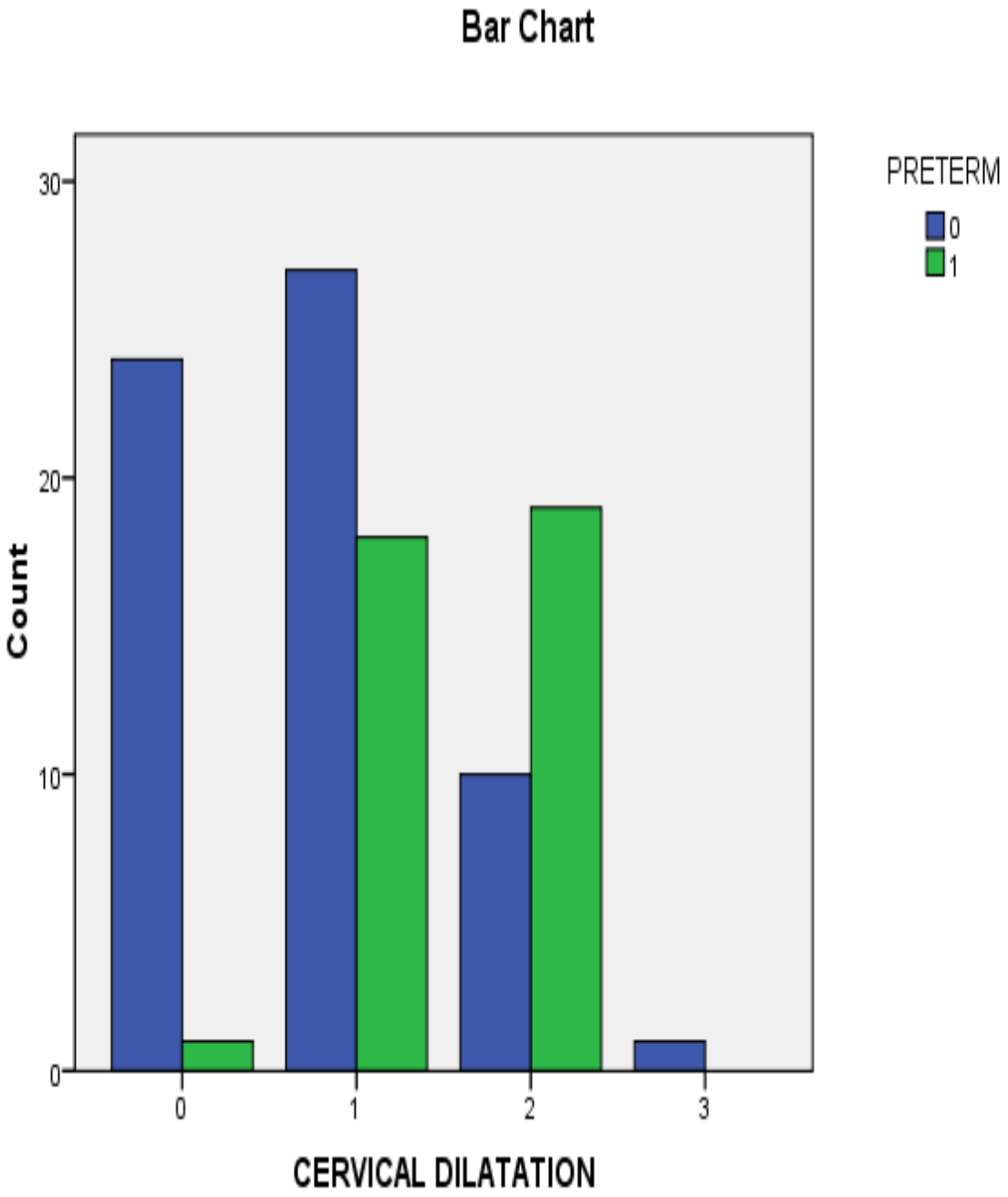
Chi-Square Tests

TABLE III b

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	22.276[a]	3	.000
Likelihood Ratio	26.482	3	.000
Linear-by-Linear Association	19.012	1	.000
McNemar-Bowker Test	.	.	.[b]
N of Valid Cases	100		

INTERPRETATION;

According to cervical dilatation, 25 patients had no dilatation. In 25,2.6% delivered as preterm. 45patients had 1cm dilatation. out ofthis, 47.4% had preterm delivery.29 patients had 2cm dilatation. Out of this 50% delivered as preterm. So most of the preterm occur in 1 to 2 cmdilatation. In this study there was a statistical significance between cervical dilatation and preterm.(p-0.000)


Bar Chart
PRETERM
0
1
Count
30
20
10
0
0
1
2
3
CERVICAL DILATATION

TEST RESULT * PRETERM

TABLE IV a

			PRETERM		
			0	1	Total
TEST RESULT	negative	Count	59	6	65
		% within TEST RESULT	90.8%	9.2%	100.0%
		% within PRETERM	95.2%	15.8%	65.0%
		% of Total	59.0%	6.0%	65.0%
	positive	Count	3	32	35
		% within TEST RESULT	8.6%	91.4%	100.0%
		% within PRETERM	4.8%	84.2%	35.0%
		% of Total	3.0%	32.0%	35.0%
	Total	Count	62	38	100
		% within TEST RESULT	62.0%	38.0%	100.0%
		% within PRETERM	100.0%	100.0%	100.0%
		% of Total	62.0%	38.0%	100.0%

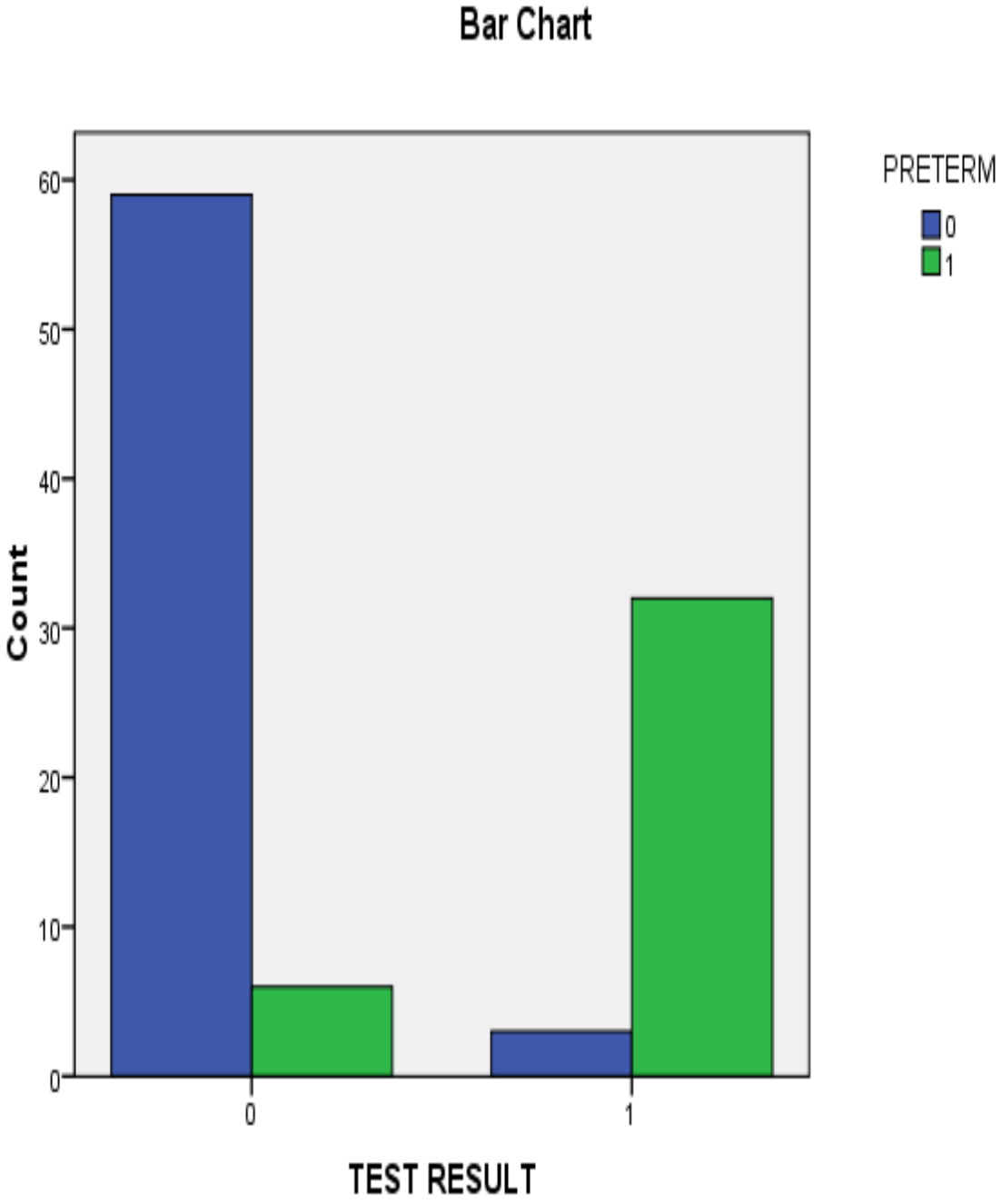
Chi-Square Test

TABLE IVb

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	65.242[a]	1	.000		
Continuity Correction[b]	61.800	1	.000		
Likelihood Ratio	72.317	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	64.589	1	.000		
McNemar Test				.508[c]	
N of Valid Cases	100				

INTERPRETATION;

In this study, among the 100 patient, 65 were test negative. Out of this only 15.8% delivered as preterm. Another 35 patient were test positive . Out of this 35 positive patient 84.2% delivered as preterm. This study shows , There was a statistical significance between the test and preterm.(P-0.000)


Bar Chart
PRETERM
0
1
Count
60
50
40
30
20
10
0
0
1
TEST RESULT

NICU ADMISSION * PRETERM

TABLE V a

			PRETERM		
			0	1	Total
NICU ADMISSION	no	Count	62	18	80
		% within NICU ADMISSION	77.5%	22.5%	100.0%
		% within PRETERM	100.0%	47.4%	80.0%
		% of Total	62.0%	18.0%	80.0%
	yes	Count	0	20	20
		% within NICU ADMISSION	.0%	100.0%	100.0%
		% within PRETERM	.0%	52.6%	20.0%
		% of Total	.0%	20.0%	20.0%
	Total	Count	62	38	100
		% within NICU ADMISSION	62.0%	38.0%	100.0%
		% within PRETERM	100.0%	100.0%	100.0%
		% of Total	62.0%	38.0%	100.0%

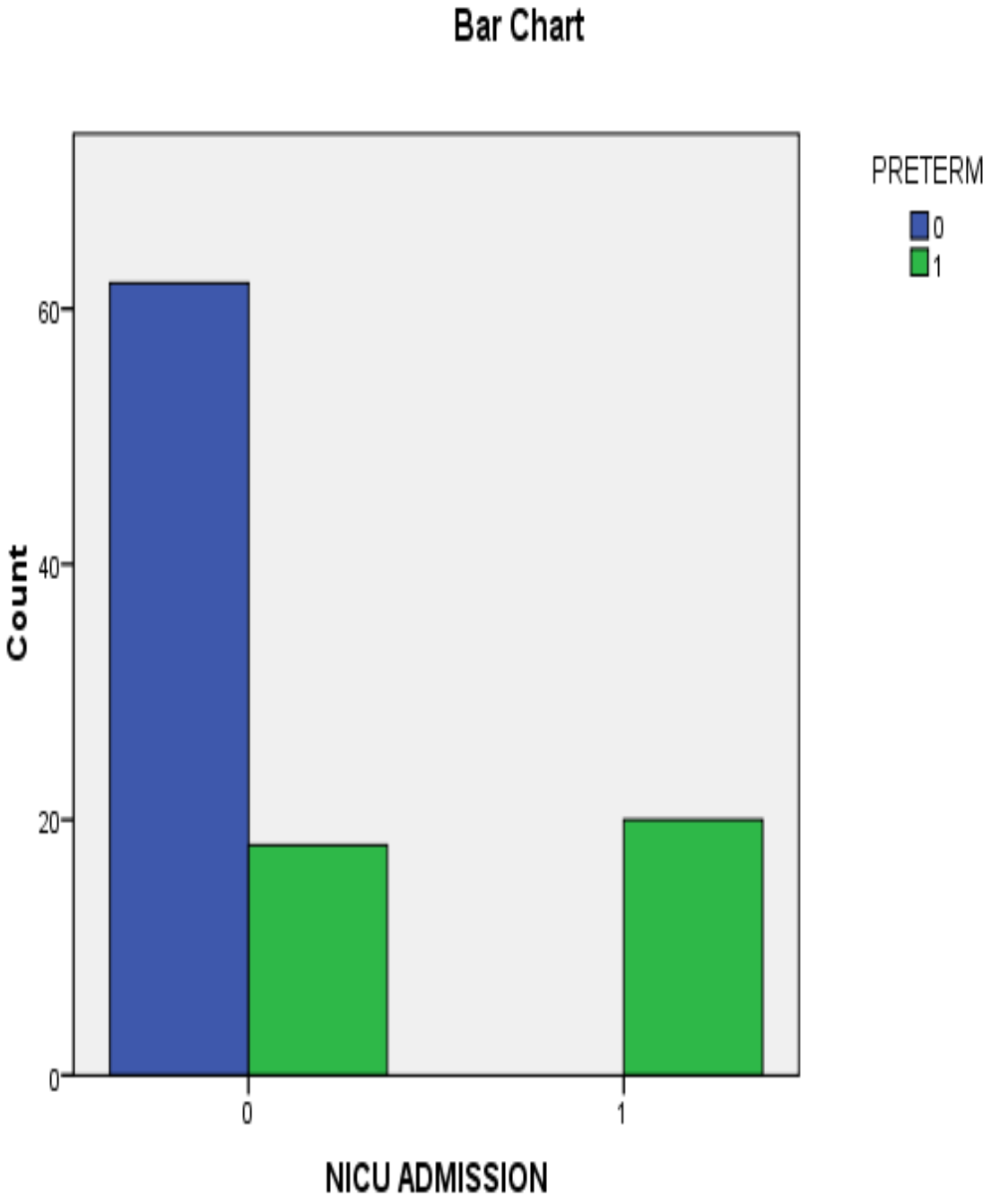
Chi-Square Tests

TABLE V b

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	40.789[a]	1	.000		
Continuity Correction[b]	37.566	1	.000		
Likelihood Ratio	47.507	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	40.382	1	.000		
McNemar Test				.000[c]	
N of Valid Cases	100				

INTERPRETATION;

In this study 20 babies were admitted in NICU, and all of them were delivered as preterm. 80 babies were not admitted in NICU. Out of this 80only 22.5% delivered as preterm. So there was a statistical significance between NICU admissionand preterm(P-0.000)


Bar Chart
PRETERM
0
1
Count
60
40
20
0
0
1
NICU ADMISSION

AGE GROUP * TEST RESULT

TABLE VI a

			TEST RESULT		
			0	1	Total
AGE GROUP	LESS THAN 20 YEARS	Count	9	9	18
		% within AGE GROUP	50.0%	50.0%	100.0%
		% within TEST RESULT	13.8%	25.7%	18.0%
		% of Total	9.0%	9.0%	18.0%
	20 TO 30 YEARS	Count	49	24	73
		% within AGE GROUP	67.1%	32.9%	100.0%
		% within TEST RESULT	75.4%	68.6%	73.0%
		% of Total	49.0%	24.0%	73.0%
	MORE THAN 30 YEARS	Count	7	2	9
		% within AGE GROUP	77.8%	22.2%	100.0%
		% within TEST RESULT	10.8%	5.7%	9.0%
		% of Total	7.0%	2.0%	9.0%
	Total	Count	65	35	100
		% within AGE GROUP	65.0%	35.0%	100.0%
		% within TEST RESULT	100.0%	100.0%	100.0%
		% of Total	65.0%	35.0%	100.0%

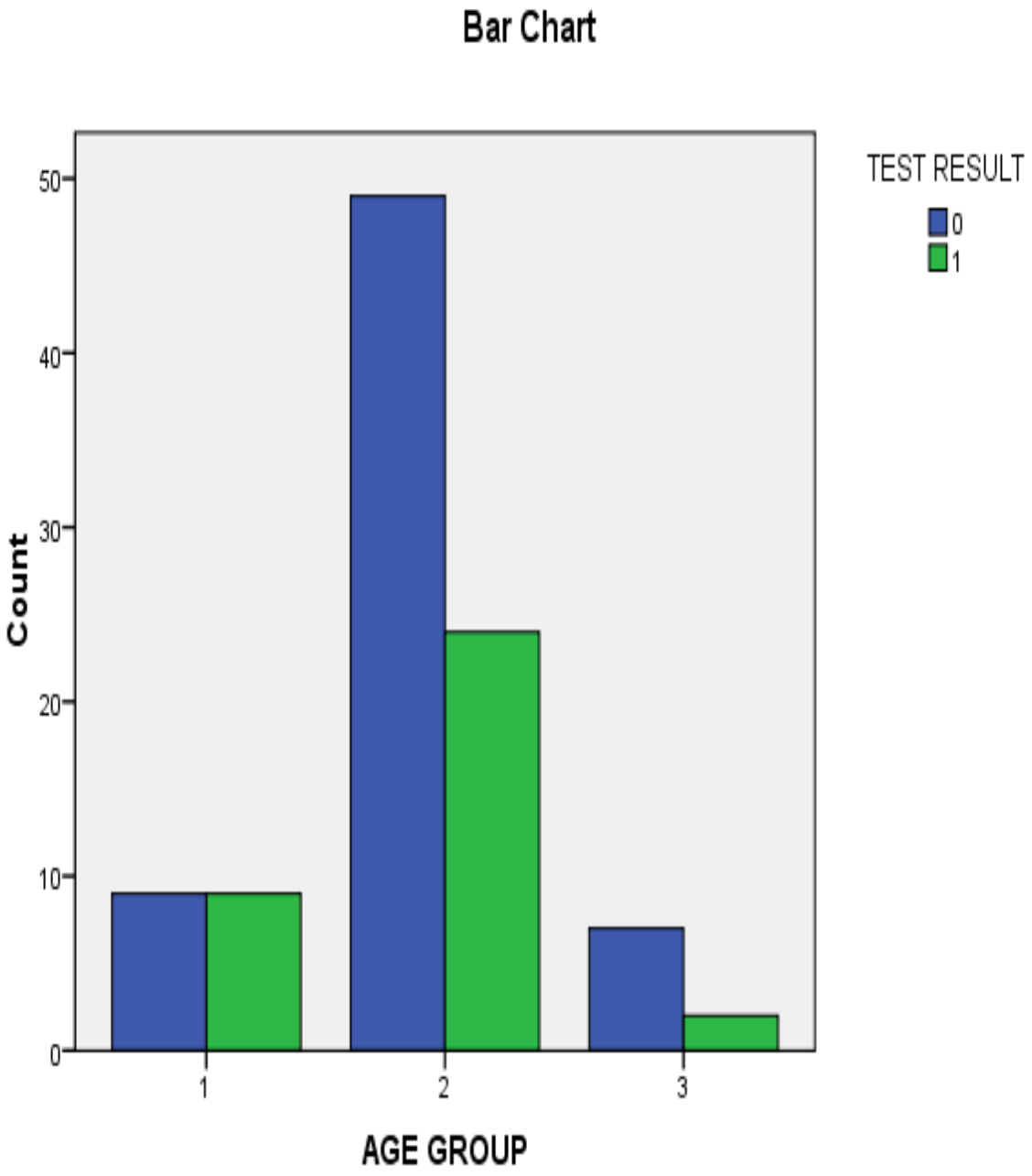
Chi-square test

TABLE VI b

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.571[a]	2	.277
Likelihood Ratio	2.539	2	.281
Linear-by-Linear Association	2.463	1	.117
McNemar-Bowker Test	.	.	.[b]
N of Valid Cases	100		

INTERPRETATION;

In this study 73% patient constitute 20 to 30 yrs of age group. Out of 73%, 24% had test positive. In less than 20 yrs of age group out of 18%, 9% had test positive. according to this study there was no statistical association between age group and test result.(P-0.277)



The bar diagram shows the association between the age group and test result.

OBSTETRIC SCORE * TEST RESULT

TABLE VII a

			TEST RESULT		
			0	1	Total
OBSTETRIC SCORE	primi	Count	37	20	57
		% within OBSTETRIC SCORE	64.9%	35.1%	100.0%
		% within TEST RESULT	56.9%	57.1%	57.0%
		% of Total	37.0%	20.0%	57.0%
	multi	Count	28	15	43
		% within OBSTETRIC SCORE	65.1%	34.9%	100.0%
		% within TEST RESULT	43.1%	42.9%	43.0%
		% of Total	28.0%	15.0%	43.0%
	Total	Count	65	35	100
		% within OBSTETRIC SCORE	65.0%	35.0%	100.0%
		% within TEST RESULT	100.0%	100.0%	100.0%
		% of Total	65.0%	35.0%	100.0%

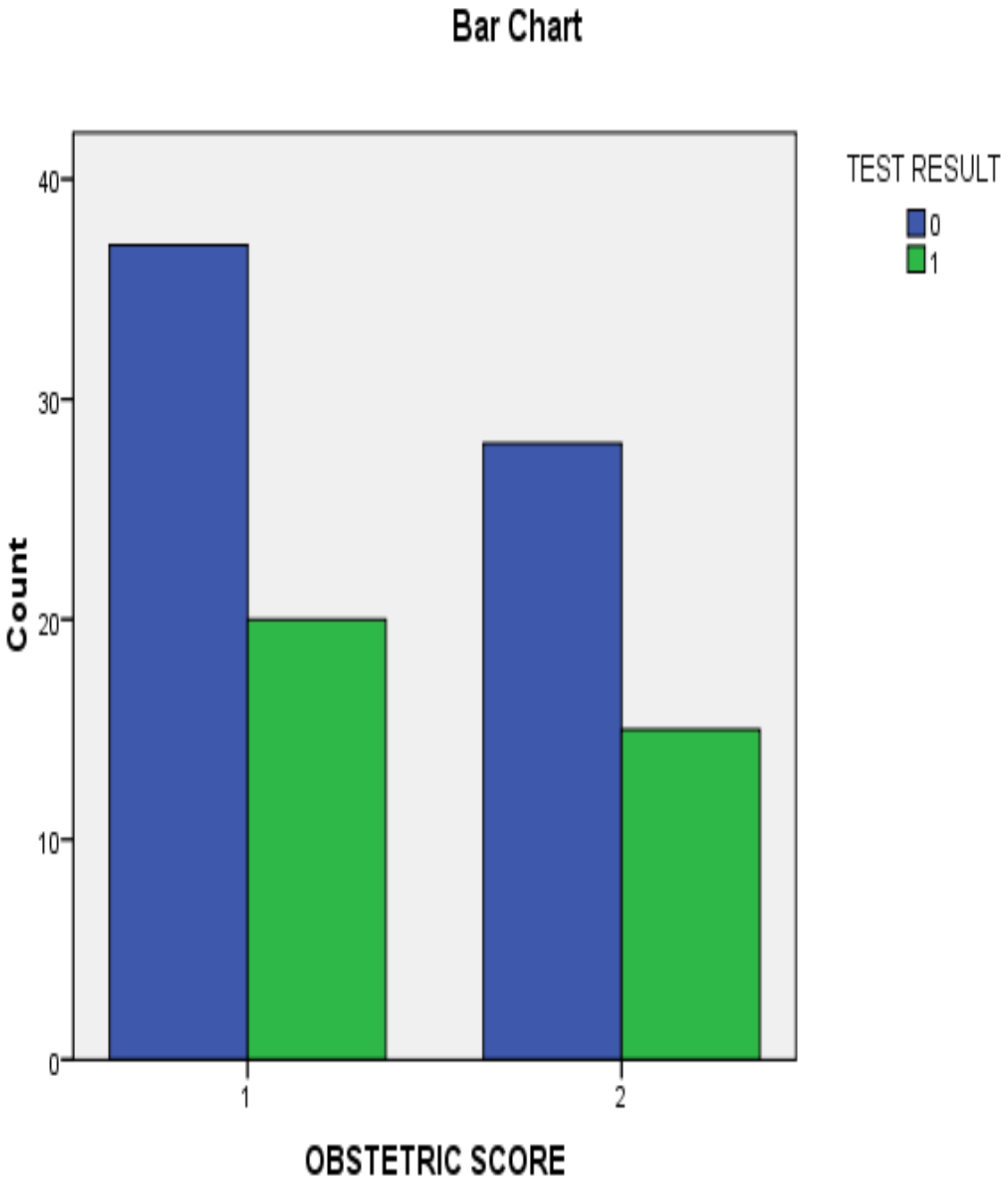
Chi-Square Tests

TABLE VII b

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.000[a]	1	.983		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.000	1	.983		
Fisher's Exact Test				1.000	.577
Linear-by-Linear Association	.000	1	.983		
McNemar Test				.[c]	
N of Valid Cases	100				

INTERPRETATION;

In this study out of 100 patient , 35 patient were test positive. In This 35, 57.1% were primi, and 42.9% were multi .The p value was 0.577.so there was no statistical association between obstetrics score and test result.


Bar Chart
TEST RESULT
0
1
Count
40
30
20
10
0
1
2
OBSTETRIC SCORE

CERVICAL DILATATION * TEST RESULT

TABLE VIII a

			TEST RESULT		
			0	1	Total
CERVICAL DILATATION	NIL	Count	25	0	25
		% within CERVICAL DILATATION	100.0%	.0%	100.0%
		% within TEST RESULT	38.5%	.0%	25.0%
		% of Total	25.0%	.0%	25.0%
	1CM	Count	26	19	45
		% within CERVICAL DILATATION	57.8%	42.2%	100.0%
		% within TEST RESULT	40.0%	54.3%	45.0%
		% of Total	26.0%	19.0%	45.0%
	2CM	Count	13	16	29
		% within CERVICAL DILATATION	44.8%	55.2%	100.0%
		% within TEST RESULT	20.0%	45.7%	29.0%
		% of Total	13.0%	16.0%	29.0%
	3CM	Count	1	0	1
		% within CERVICAL DILATATION	100.0%	.0%	100.0%
		% within TEST RESULT	1.5%	.0%	1.0%
		% of Total	1.0%	.0%	1.0%
	Total	Count	65	35	100
		% within CERVICAL DILATATION	65.0%	35.0%	100.0%
		% within TEST RESULT	100.0%	100.0%	100.0%
		% of Total	65.0%	35.0%	100.0%

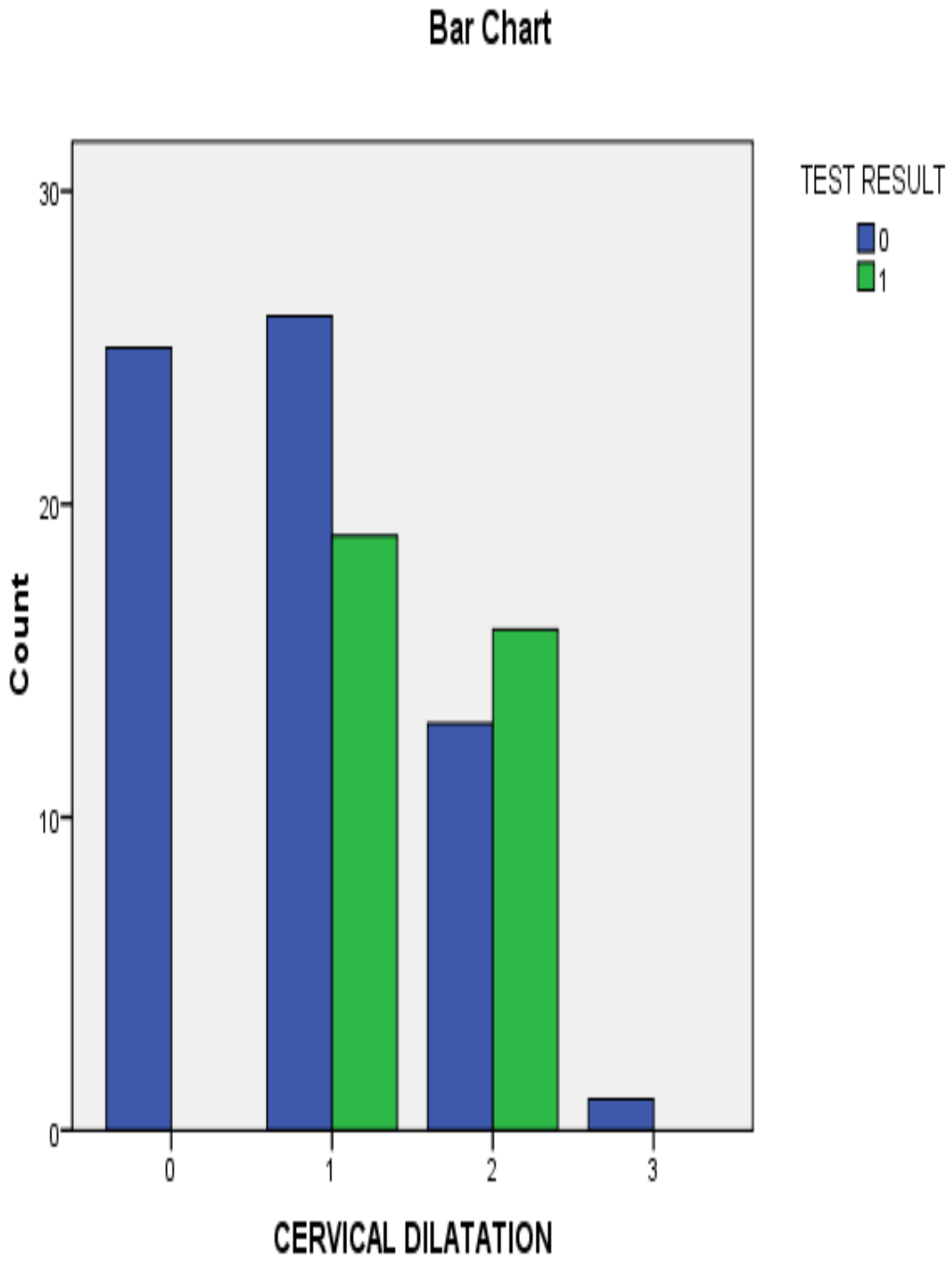
Chi-Square Tests

TABLE VIII b

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	20.219[a]	3	.000
Likelihood Ratio	28.308	3	.000
Linear-by-Linear Association	15.409	1	.000
McNemar-Bowker Test	.	.	.[b]
N of Valid Cases	100		

INTERPRETATION;

Out of 35 positive patient ,54.3% had 1Cmcervical dilatation,45.7% had 2 cm cervical dilatation. 99% test positive patient had 1-2cm cervical dilatation .P value was 0.000. There was a significantstatistical association between test result and cervical dilatation in this study.


Bar Chart
TEST RESULT
0
1
Count
30
20
10
0
0
1
2
3
CERVICAL DILATATION

NICU ADMISSION * TEST RESULT

TABLE IX a

			TEST RESULT		
			0	1	Total
NICU ADMISSION	NO	Count	63	17	80
		% within NICU ADMISSION	78.8%	21.3%	100.0%
		% within TEST RESULT	96.9%	48.6%	80.0%
		% of Total	63.0%	17.0%	80.0%
	YES	Count	2	18	20
		% within NICU ADMISSION	10.0%	90.0%	100.0%
		% within TEST RESULT	3.1%	51.4%	20.0%
		% of Total	2.0%	18.0%	20.0%
	Total	Count	65	35	100
		% within NICU ADMISSION	65.0%	35.0%	100.0%
		% within TEST RESULT	100.0%	100.0%	100.0%
		% of Total	65.0%	35.0%	100.0%

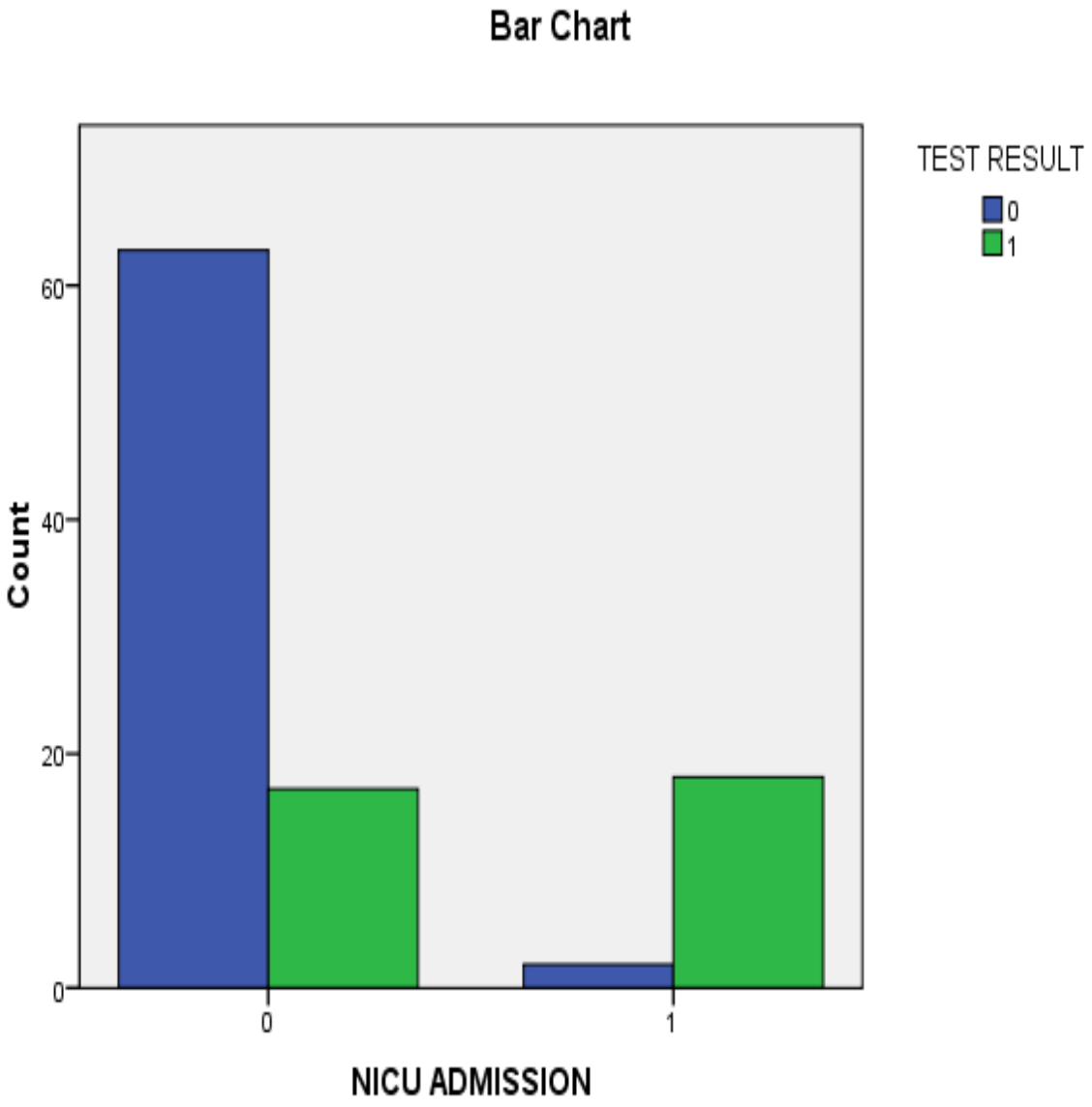
Chi-Square Tests

TABLE IX b

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	33.242[a]	1	.000		
Continuity Correction[b]	30.288	1	.000		
Likelihood Ratio	33.726	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	32.909	1	.000		
McNemar Test				.001[c]	
N of Valid Cases	100				

INTERPRETATION;

Out of 65 negative test patient only 10% of babies were admitted in NICU. But in 35 positive test patients 90% babies were admitted in NICU.P value was 0.000. So there was a statistical significant between NICU admission and test result in this study.


Bar Chart
TEST RESULT
0
1
Count
60
40
20
0
0
1
NICU ADMISSION

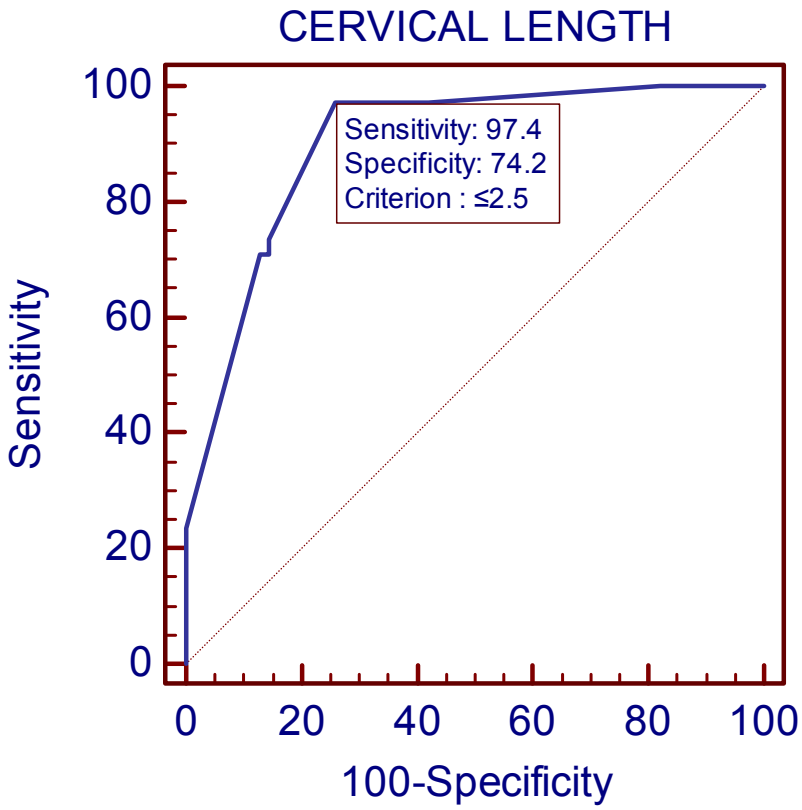
Group Statistics

TABLE X

	TEST RESULT	N	Mean	Std. Deviation	Std. Error Mean
WEGHIT OF BABY	1	35	1.923	.5621	.0950
	0	65	2.822	.3955	.0491
APGAR 1 MIN	1	35	5.49	1.853	.313
	0	65	6.95	.959	.119
APGAR 5 MIN	1	35	7.03	1.524	.258
	0	65	8.18	.682	.085

INTERPRETATION

The mean birth weight of the baby in test positive patient was 1.9 kg. The mean birth weight of the baby in test negative patient was 2,8 kg The one minute and 5 minute apgar in test positive patient were 5 & 6 The one minute and 5 minute apgar in test negative patient were 7 & 8



ROC curve

Variable	CERVICAL_LENGTH CERVICAL LENGTH
Classification variable	PRETERM PRETERM

Sample size		100
Positive group :	PRETERM = 1	38
Negative group	PRETERM = 0	62

Area under the ROC curve (AUC)

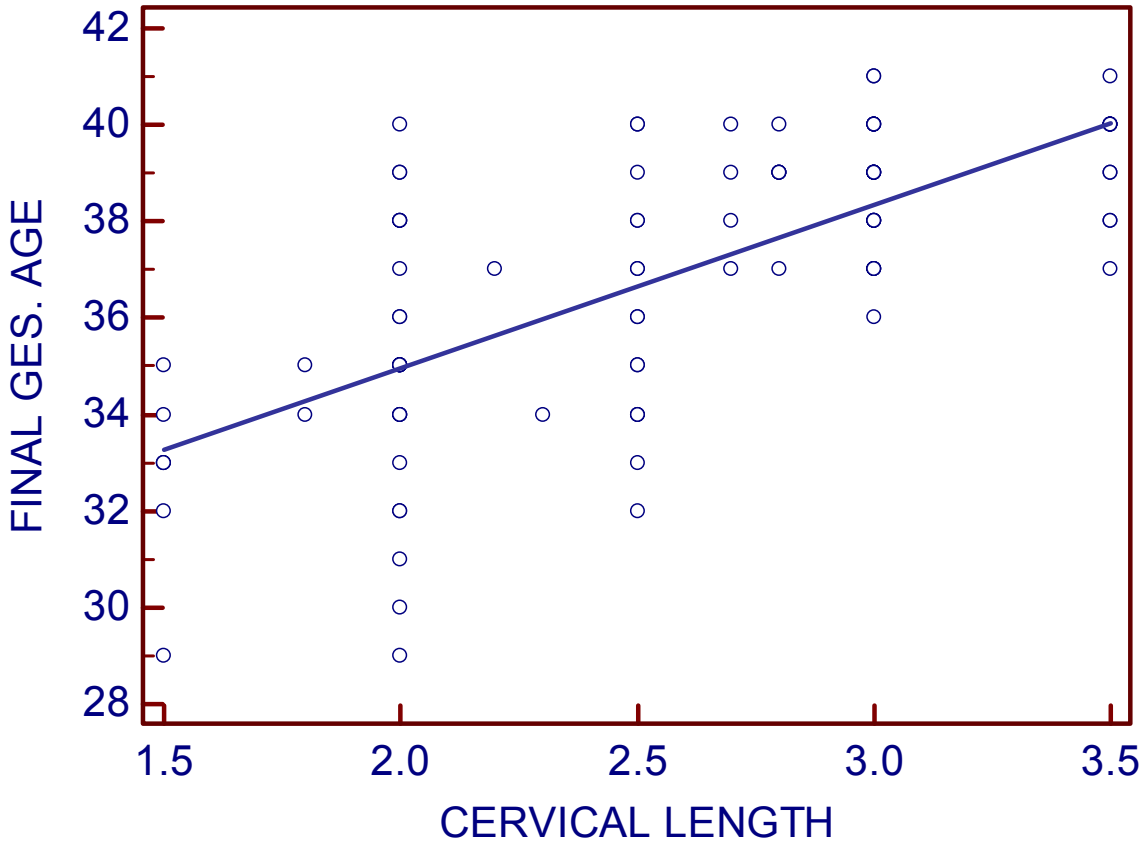
Area under the ROC curve (AUC)	0.901528
Standard Error[a]	0.0288
95% Confidence interval[b]	0.825637 to 0.952080
z statistic	13.924
Significance level P (Area=0.5)	<0.0001

Youden index

Youden index J	0.7156
Associated criterion	≤2.5

Criterion values and coordinates of the ROC curve[Hide]

Criterion	Sensitivity	95% CI	Specificity	95% CI	+LR	-LR	95% CI
<1.5	0.00	0.0 - 9.3	100.00	94.2 - 100.0		1.00	0.0 - 9.3
≤1.8	23.68	11.4 - 40.2	100.00	94.2 - 100.0		0.76	11.4 - 40.2
≤2	71.05	54.1 - 84.6	87.10	76.1 - 94.3	5.51	0.33	54.1 - 84.6
≤2.2	71.05	54.1 - 84.6	85.48	74.2 - 93.1	4.89	0.34	54.1 - 84.6
≤2.3	73.68	56.9 - 86.6	85.48	74.2 - 93.1	5.08	0.31	56.9 - 86.6
≤2.5	97.37	86.2 - 99.9	74.19	61.5 - 84.5	3.77	0.035	86.2 - 99.9
≤2.8	97.37	86.2 - 99.9	58.06	44.8 - 70.5	2.32	0.045	86.2 - 99.9
≤3	100.00	90.7 - 100.0	17.74	9.2 - 29.5	1.22	0.00	90.7 - 100.0
≤3.5	100.00	90.7 - 100.0	0.00	0.0 - 5.8	1.00		90.7 - 100.0



Regression

Dependent Y	FINAL_GES._AGE FINAL GES. AGE
Independent X	CERVICAL_LENGTH CERVICAL LENGTH

Sample size	100
Coefficient of determination R^2	0.4734
Residual standard deviation	2.0614

Regression Equation

y = 28.1881 + 3.3890 x

Parameter	Coefficient	Std. Error	95% CI	t	P
Intercept	28.1881	0.9426	26.3176 to 30.0586	29.9061	<0.0001
Slope	3.3890	0.3611	2.6724 to 4.1056	9.3852	<0.0001

Analysis of Variance

Source	DF	Sum of Squares	Mean Square
Regression	1	374.3067	374.3067
Residual	98	416.4533	4.2495

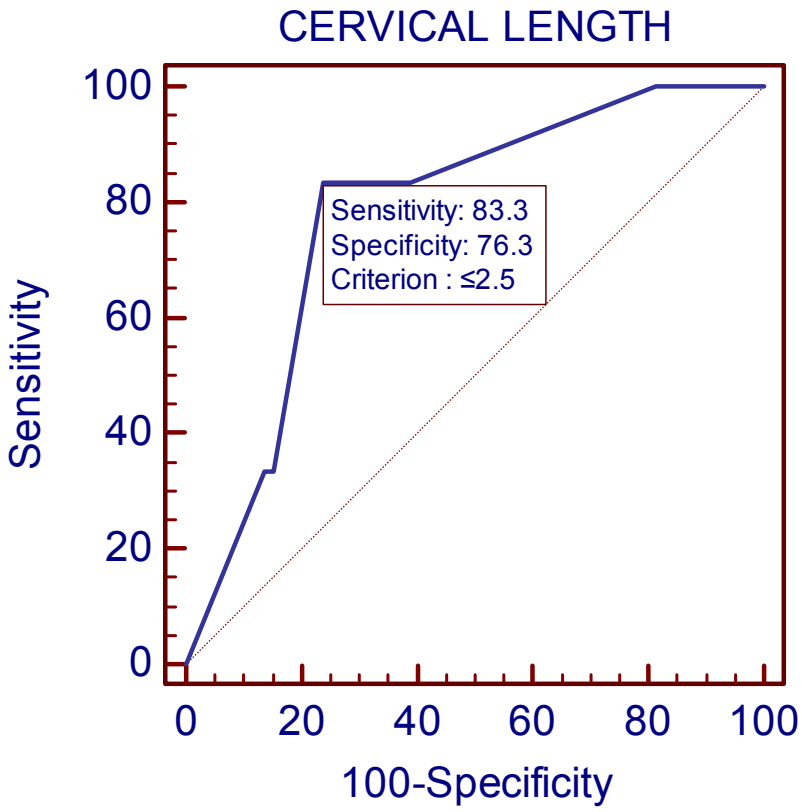
F-ratio	88.0820
Significance level	P<0.001

Correlation

Variable Y	FINAL_GES._AGE FINAL GES. AGE
Variable X	CERVICAL_LENGTH CERVICAL LENGTH

Sample size	100
Correlation coefficient r	0.6880
Significance level	P<0.0001
95% Confidence interval for r	0.5684 to 0.7791

Sample size	100
Correlation coefficient r	0.6880
Significance level	P<0.0001
95% Confidence interval for r	0.5684 to 0.7791



ROC curve

Variable	CERVICAL_LENGTH CERVICAL LENGTH
Classification variable	PRETERM PRETERM

Sample size		65
Positive group :	PRETERM = 1	6
Negative group :	PRETERM = 0	59

Disease prevalence (%)	unknown

Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.779661
Standard Error[a]	0.0881
95% Confidence interval[b]	0.659615 to 0.873026
z statistic	3.175
Significance level P (Area=0.5)	0.0015

Youden index

Youden index J	Youden index J
Associated criterion	Associated criterion

Criterion values and coordinates of the ROC curve[Hide]

Criterion	Sensitivity	95% CI	Specificity	95% CI	+LR	-LR
<2	0.00	0.0 - 9.3	100.00	94.2 - 100.0		1.00
≤2	23.68	11.4 - 40.2	100.00	94.2 - 100.0		0.76
≤2.2	71.05	54.1 - 84.6	87.10	76.1 - 94.3	5.51	0.33
≤2.5	71.05	54.1 - 84.6	85.48	74.2 - 93.1	4.89	0.34
≤2.8	73.68	56.9 - 86.6	85.48	74.2 - 93.1	5.08	0.31
≤3	97.37	86.2 - 99.9	74.19	61.5 - 84.5	3.77	0.035
≤3.5	97.37	86.2 - 99.9	58.06	44.8 - 70.5	2.32	0.045
<2	100.00	90.7 - 100.0	17.74	9.2 - 29.5	1.22	0.00
≤2	100.00	90.7 - 100.0	0.00	0.0 - 5.8	1.00	

Regression

Dependent Y	FINAL_GES._AGE FINAL GES. AGE
Independent X	CERVICAL_LENGTH CERVICAL LENGTH

Sample size	65
Coefficient of determination R^2	0.1092
Residual standard deviation	1.4950

Regression Equation

$y = 35.2994 + 1.1141 x$

Criterion	Sensitivity	Std. Error	95% CI	t	P
Intercept	35.2994	1.1477	33.0058 to 37.5929	30.7564	<0.0001
Slope	1.1141	0.4010	0.3128 to 1.9154	2.7783	0.0072

Analysis of Variance

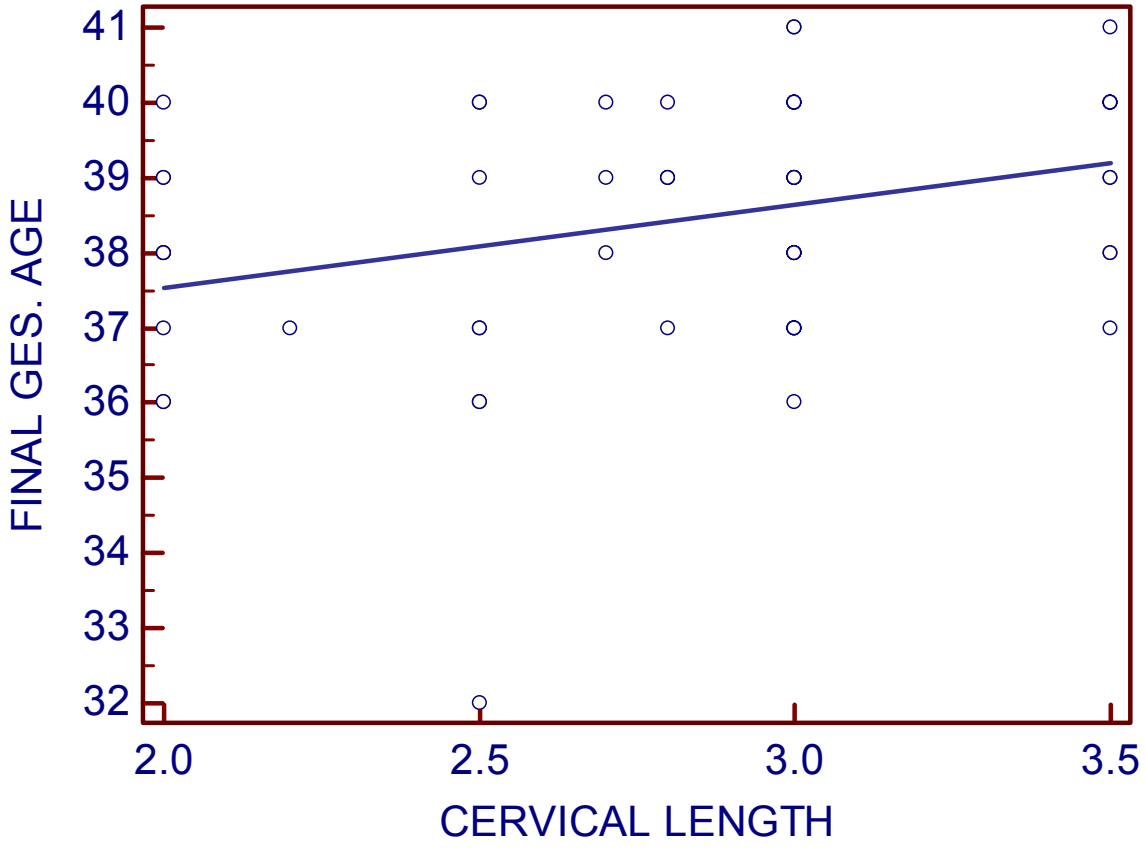
Source	DF	Sum of Squares	Mean Square
Regression	1	17.2525	17.2525
Residual	63	140.8090	2.2351

F-ratio	7.7190
Significance level	P=0.007

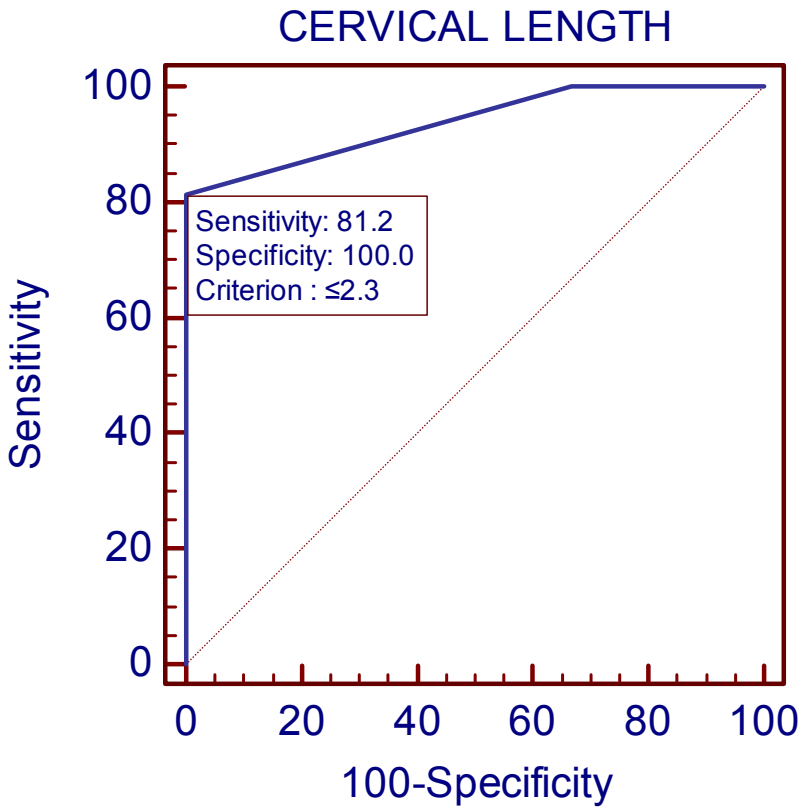
Correlation

Variable Y	FINAL_GES._AGE FINAL GES. AGE
Variable X	CERVICAL_LENGTH CERVICAL LENGTH

Sample size	65
Correlation coefficient r	0.3304
Significance level	P=0.0072
95% Confidence interval for r	0.09406 to 0.5315



This ROC curve shows, in test negative patient, the cervical length measurement was less than 2.5 cm the sensitivity and specificity to predict preterm were 83.3 and 76.3%The final mean gestational age was 38 weeks.(p=0.0072)



ROC curve

Variable	CERVICAL_LENGTH CERVICAL LENGTH
Classification variable	PRETERM PRETERM

Sample size		35
Positive group :	PRETERM = 1	32
Negative group :	PRETERM = 0	3

Disease prevalence (%)	unknown

Area under the ROC curve (AUC)

Area under the ROC curve (AUC)	0.937500
Standard Error[a]	0.0390
95% Confidence interval[b]	0.800906 to 0.991224
z statistic	11.212
Significance level P (Area=0.5)	<0.0001

Youden index

Youden index J	0.8125
Associated criterion	≤2.3

Criterion values and coordinates of the ROC curve[Hide]

Criterion	Sensitivity	95% CI	Specificity	95% CI	+LR	-LR
<1.5	0.00	0.0 - 10.9	100.00	29.2 - 100.0		1.00
≤2.3	81.25	63.6 - 92.8	100.00	29.2 - 100.0		0.19
≤2.5	100.00	89.1 - 100.0	33.33	0.8 - 90.6	1.50	0.00
≤2.7	100.00	89.1 - 100.0	0.00	0.0 - 70.8	1.00	

Regression

Dependent Y	FINAL_GES._AGE FINAL GES. AGE
Independent X	CERVICAL_LENGTH CERVICAL LENGTH

Sample size	35
Coefficient of determination R^2	0.1996
Residual standard deviation	1.8532

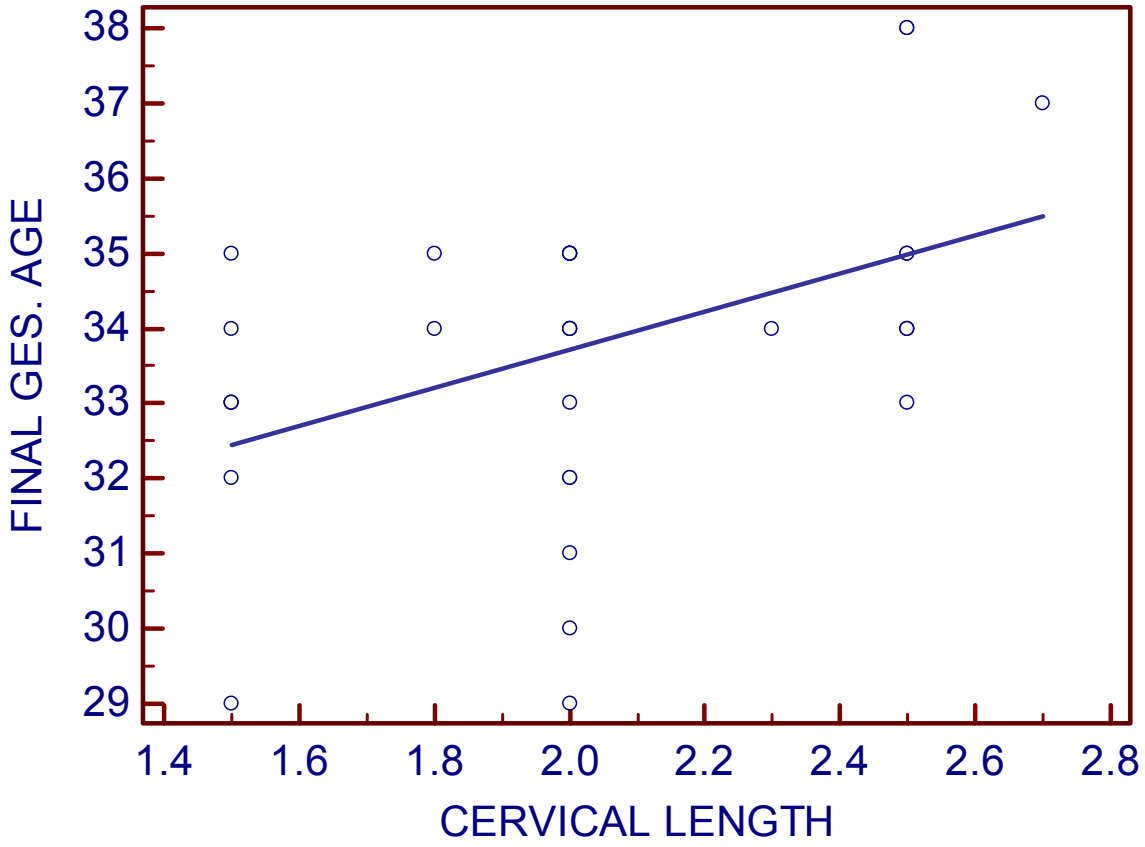
Regression Equation

y = 28.6372 + 2.5415 x

Parameter	Coefficient	Std. Error	95% CI	t	P	Parameter
Intercept	28.6372	1.8269	24.9204 to 32.3540	15.6757	<0.0001	Intercept
Slope	2.5415	0.8860	0.7389 to 4.3440	2.8685	0.0071	Slope

Analysis of Variance

Source	DF	Sum of Squares	Mean Square
Regression	1	28.2611	28.2611
Residual	33	Sum of Squares	3.4345



Correlation

Variable Y	FINAL_GES._AGE FINAL GES. AGE
Variable X	CERVICAL_LENGTH CERVICAL LENGTH

Sample size	35
Correlation coefficient r	0.4467
Significance level	P=0.0071
95% Confidence interval for r	0.1333 to 0.6789

TES TRESULT VS PRETERM

TEST RESULT	PRETERM	TERM	
POSITIVE	32	3	35
NEGATIVE	6	59	65
	38	62	

INTERPERTATION

Sensitivity : 84.21%

Specificity : 95.66%

Positive predictive value : 91.43%

Negative predictive value : 90.77%

Diagnostic accuracy of the test : 91%

CERVICAL LENGTH VS PRETERM

CERVICAL LENGTH	PRETERM	TERM	
< 2.5CM	37	16	53
>2.5CM	1	46	47
	38	62	

INTERPRETATION

Sensitivity	:	97.37%
Specificity	:	74.19%
Positive predictive value	:	69.81%
Negative predictive value	:	97.87%
Diagnostic accuracy of cervical length	:	83%

DISCUSSION

- In this study 100 women with preterm pains and less than 3cm cervical dilatation were selected
- General and obstetrics examination was done for all Cases including pelvic examination.
- Cervical swab for phIGFBP-1 was taken for all patient. The test was done by using bedside kit by immunoenzymetric assay. Thetest kit shows two dark line if phIGFBP-1 level more than10microgram. It was considered as positive.
- In 100 patient 38 patient delivered as preterm.35 cases were phIGFBP-1 test positive. Out of 35, 32 was delivered as preterm. 65 cases were test negative. Out of 65, 6 cases were delivered as preterm
- 73% of the patient were in the age group of 20-30 yrs,with average of 24 yrs.57.9%were primi, 42.1% were multi.
- NICU admission was more in preterm(100%) compared to term deliveries. The main cause of admission was low birth weight and respiratory distress syndrome.
- In 35 test positive patient, 96% patient had 1-2 cm cervicaldilatation(p-0.0001).There was a statistical significance between the test and preterm

delivery, cervical dilatation and NICU admission In this study The average weight of the baby in test positive patient was 1.9 kg

- The sensitivity and specificity of cervical length to predict preterm labor was 97.4% and 79.2%.The cervical length cut off was 2.5 cm. if cervical length was 2.5 cm ,the mean final gestational age was 35-36 weeks. If it was less than 2 cm, the mean final gestational age was 32-33 weeks. So cervical length measurement was a independent predictor of preterm delivery.
- If the test was negative and cervical length was2.5 cm, the sensitivity of the test to predict preterm delivery was 83.3%, specificity was 76.3%.

- If the test was positive and cervical length was less than 2.3 and the test was positive, the sensitivity was 81.2% and specificity was 100%. if patient had less than 2.3 cm cervical length and the test was positive, she more likely delivered as preterm

- In test positive patient(35), most of them delivered less than 35 weeks of gestation. Mean final gestational age in test positive was 33.3 weeks.so there was a strong association between gestational age at delivery and cervical lehgth in test positive patient.
- The ROC curve showed that 2.5 cm of cervical length was the best cutoff value for predicting preterm labor.

- The positive and negative predictive value of this test to predict preterm delivery were 91.43% and 90.77%
- The positive and negative predictive value of the cervical

Length (<2.5cm) to predict preterm delivery were 69.81% and 97.87%

- According to this study the diagnostic accuracy of cervical length was 83% . the diagnostic accuracy of phIGFBP-1 was 91%

CONCLUSION

- According to this study the phIGFBP-1 measurement in cervical secretion is a rapid and highly applicable test to predict preterm delivery in symptomatic women
- Cervical length measurement is also an independent predictor for preterm delivery. The best cutoff value of cervical length was 2.5 cm
- When the test was combined with cervical length Measurement (≤ 2.5CM)to predict preterm delivery, the sensitivity and specificity were increased.
- The diagnostic accuracy was more in the test group (91% than cervical length measurement (83%) to predict preterm delivery.
- So the phIGFBP-1 test can be used as bedside kit test to predict preterm delivery solely or in combination with cervical length measurement.
- So this test can be used to avoid unnecessary obstetrics intervention like tocolysis and hospitalization. In positive patient it will help to decide inutero transfer of the patient to tertiary care level.

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PROFORMA

1. **NAME** :
2. **AGE** :
3. **IP NO** :
4. **PARITY** :
5. **EDUCATION** :
6. **DATE OF ADMISSION** :
7. **GESTATIONAL AGE** :
8. **ANY HIGH RISK** :
9. **HISTORY** :

- painduration
- draining pv
- h/o urinary tract infection
- h/o vaginal bleeding
- previous cesarean

10.PER ABDOMINAL EXAMINATION:

11.PER VAGINAL EXAMINATION :

- Effacement
- Dilatation
- Membrane statu

12.IGFBP-1 :

- Positive/ negative

13. TYPE OF FOLLOW UP:

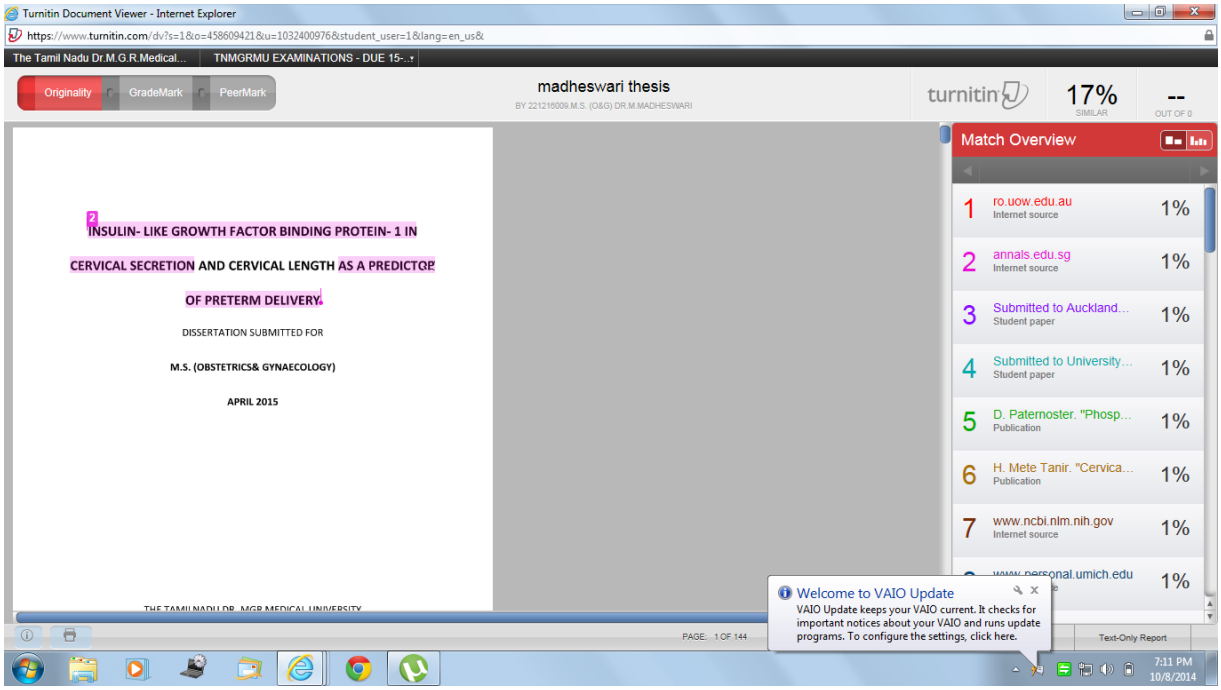
- Clinical
- Phone

14. TIME OF FOLLOW UP:

- First 7 days
- Up to 37weeks
- Tll delivery

15. DELIVARY:

- Within7 day
- Before 37 weeks
- After 37 weeks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INSULIN- LIKE GROWTH FACTOR BINDING PROTEIN- 1 IN
CERVICAL SECRETION AND CERVICAL LENGTH AS A PREDICTOR
OF PRETERM DELIVERY.
DISSERTATION SUBMITTED FOR
M.S. (OBSTETRICS& GYNAECOLOGY)
APRIL 2015
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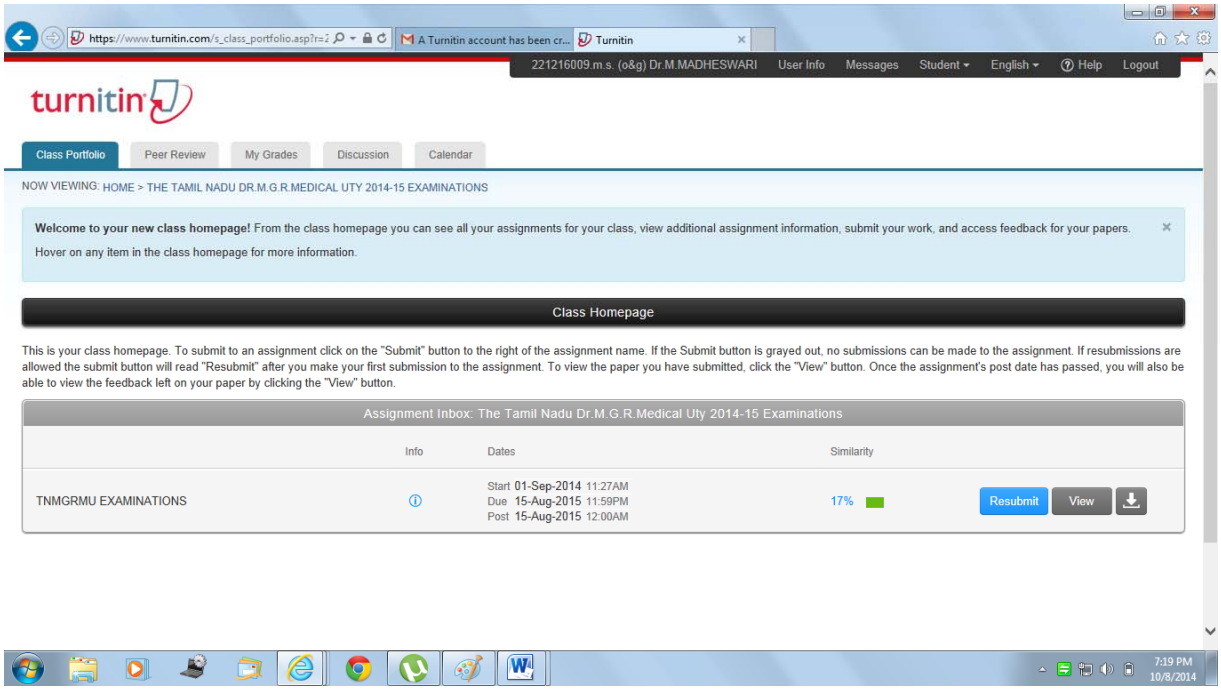
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S.NO	IP.NO	OBSTETRIC SCORE	GESTATIONAL AGE	CERVICAL DILATATION	CERVICAL LENGTH	TEST RESULT
1	3654	p	32	1	3	n
2	5342	m	34	2	1.5	p
3	5466	p	30	1	3	n
4	7543	m	33	2	2	n
5	8345	m	31	2	1.5	p
6	7655	p	35	0	3	n
7	7621	p	29	1	2.7	n
8	5439	p	33	1	2	p
9	6755	p	34	2.5	2.8	n
10	7433	m	32	0	2.8	n
11	8655	p	34	2	1.8	p
12	8932	p	35	0	3.5	n
13	8691	m	30	2	2	p
14	9231	m	32	2	2	n
15	9345	m	33	2	2	n
16	9511	p	34	2	3	n
17	9793	p	29	2	1.5	p
18	9834	p	32	0	2.5	n
19	9718	m	34	1	2.5	p
20	10231	p	33	0	2.8	n
21	10726	p	31	0	3	n
22	10854	m	31	2	2	p
23	10781	m	33	1	2.8	n
24	10891	p	34	1	3	n
25	11239	p	32	2	2	p
26	11485	p	30	0	2.7	N
27	11632	M	35	2	2.5	p
28	11740	m	32	2	2.2	n
29	11876	m	33	2	2.8	n
30	11809	p	34	0	3.5	n

31	11978	p	31	0	3	n
32	11954	p	33	1	2.5	p
33	12013	m	34	2	1.8	p
34	12145	m	35	2	2	n
35	12278	p	32	0	3.5	n
36	12265	p	33	1	2.7	n
37	12311	p	33	1	2.5	p
38	12376	m	34	2	2.5	p
39	12433	m	36	2	2	n
40	12480	m	31	1	3	n
41	12541	p	34	1	2.5	p
42	12618	p	32	2	2	n
43	12679	m	35	2	2.5	n
44	12602	p	32	0	3.5	n
45	12700	p	33	1	2.3	p
46	12783	m	32	1	3	n
47	12831	m	30	1	3.5	n
48	12847	m	31	1	2.5	n
49	12915	p	33	1	1.5	p
50	12994	p	32	0	3	n
51	13015	p	34	0	3	n
52	13267	m	33	2	2.5	p
53	13302	m	30	1	3	n
54	13362	m	29	1	3.5	n
55	13409	p	32	1	2.7	p
56	13598	p	35	1	3	n
57	13631	m	35	1	2	p
58	13843	p	33	0	3.5	n
59	13901	p	33	1	3	n
60	14005	p	31	2	2	p
61	14461	m	34	2	2	n

62	14683	m	35	1	2	n
63	14830	p	33	1	2.5	p
64	15078	m	33	1	2.5	n
65	15294	p	32	0	3	n
66	15543	m	33	1	2	p
67	15571	m	35	1	3	n
68	15723	p	33	0	3	n
69	15800	p	34	1	2	p
70	15993	p	34	1	3	n
71	16203	p	28	1	2	p
72	16421	p	32	1	2	p
73	16459	p	35	1	2.5	n
74	16682	m	32	1	3	n
75	16707	m	33	1	2.5	n
76	16880	p	36	0	3	n
77	17046	p	35	2	2	p
78	17471	m	34	2	1.5	p
79	17639	m	34	2	2	n
80	17820	p	32	0	3	n
81	17935	p	34	0	3.5	n
82	18053	p	33	1	1.5	p
83	18360	m	34	2	2	p
84	18482	m	30	1	3	n
85	18567	m	29	1	2.5	n
86	18581	p	31	0	2.8	n
87	18674	p	33	0	3.5	n
88	18721	p	35	1	3	n
89	18870	p	33	1	2	p
90	19062	m	31	1	3.5	n
91	19276	p	34	1	2	p
92	19343	m	31	2	2	n

93	19654	m	32	2	1.5	p
94	20176	p	30	0	3	n
95	20452	p	33	0	3.5	n
96	21765	p	34	1	2	p
97	21862	m	33	0	3	n
98	21347	p	30	0	3	n
99	21654	m	33	1	2	p
100	21786	p	32	1	2.5	n

FINAL GES. AGE	SEVERE PRETERM	ASSO.MEDICAL CONDITION	WEGHIT OF BABY	NICU ADMISSION	APGAR	APGAR
39	0	0	2.8	n	7/10,8/10	7/10,8/11
35	0	1	2.1	n	6/10,8/10	6/10,8/11
38	0	0	2.7	n	7/10,8/10	7/10,8/11
40	0	0	3	n	8/10,9/10	8/10,9/11
32	1	0	1.2	y	5/10,6/10	5/10,6/11
39	0	1	3.2	n	7/10,8/10	7/10,8/11
38	0	2	2.6	n	7/10,9/10	7/10,9/11
34	0	0	2	n	6/10,7/10	6/10,7/11
39	0	0	3.1	n	7/10,8/10	7/10,8/11
37	0	0	2.5	n	6/10,8/10	6/10,8/11
34	0	0	2.3	y	3/10,6/10	3/10,6/11
38	0	0	2.5	n	6/10,8/10	6/10,8/11
30	1	1	1	y	3/10,5/10	3/10,5/11
37	0	0	2.4	n	6/10,8/10	6/10,8/11
39	0	0	2.7	n	7/10,8/10	7/10,8/11
36	0	0	2.4	y	4/10,6/10	4/10,6/11
29	1	0	0.8	y	2/10,4/10	2/10,4/11
36	0	0	2.8	n	6/10,7/10	6/10,7/11
38	0	0	2.9	n	8/10,9/10	8/10,9/11
40	0	0	2.9	n	7/10,8/10	7/10,8/11
41	0	1	2.9	n	8/10,9/10	8/10,9/11
32	1	2	0.9	y	2/10,4/10	2/10,4/11
39	0	0	3.2	n	7/10,8/10	7/10,8/11
38	0	0	3	n	8/10,9/10	8/10,9/11
32	0	1	1.4	y	4/10,6/10	4/10,6/11
39	0	0	2.8	N	7/10,8/10	7/10,8/11
35	0	0	2.2	n	6/10,8/10	6/10,8/11
37	0	2	2.5	n	7/10,8/10	7/10,8/11
39	0	0	2.9	n	7/10,8/10	7/10,8/11
40	0	0	3.3	n	8/10,9/10	8/10,9/11

37	0	0	2.6	n	8/10,9/10	8/10,9/11
33	0	0	1.9	y	5/10,6/10	5/10,6/11
35	0	2	2.2	n	7/10,9/10	7/10,9/11
38	0	0	2.9	n	8/10,9/10	8/10,9/11
39	0	0	2.8	n	6/10,8/10	6/10,8/11
40	0	1	3.2	n	7/10,8/10	7/10,8/11
38	0	0	2.7	n	7/10,8/10	7/10,8/11
34	0	2	2.1	y	5/10,6/10	5/10,6/11
39	0	0	2.9	n	7/10,8/10	7/10,8/11
37	0	2	2.5	n	8/10,9/10	8/10,9/11
35	0	0	2.3	n	6/10,7/10	6/10,7/11
36	0	1	2.2	n	7/10,8/10	7/10,8/11
37	0	0	2.8	n	7/10,8/10	7/10,8/11
40	0	0	3.4	n	7/101,8/10	7/101,8/11
34	0	0	2.1	y	3/10,6/10	3/10,6/11
39	0	1	2.9	n	7/10,8/10	7/10,8/11
40	0	2	3.2	n	8/10,9/10	8/10,9/11
39	0	0	2.5	n	8/10,9/10	8/10,9/11
33	0	0	1.7	y	5/10,6/10	5/10,6/11
40	0	0	3	n	7/10,8/10	7/10,8/11
38	0	1	3.1	n	7/10,9/10	7/10,9/11
34	0	0	1.8	y	5/10,7/10	5/10,7/11
40	0	0	3.4	n	7/10,8/10	7/10,8/11
37	0	0	2.5	n	7/10,8/10	7/10,8/11
37	0	2	2.6	n	8/10,9/10	8/10,9/11
39	0	0	3	n	7/10,8/10	7/10,8/11
35	0	2	2.3	n	6/10,8/10	6/10,8/11
40	0	0	3.5	n	7/10,9/10	7/10,9/11
39	0	0	2.8	n	7/10,8/10	7/10,8/11
31	1	0	1	y	3/10,5/10	3/10,5/11
36	0	0	2.2	n	7/10,8/10	7/10,8/11

38	0	2	2.9	n	7/10,8/10	7/10,8/11
34	0	0	2	n	7/10,8/10	7/10,8/11
37	0	0	2.4	n	8/10,9/10	8/10,9/11
39	0	0	2.8	n	8/10,9/10	8/10,9/11
34	0	2	2.1	n	6/10,8/10	6/10,8/11
38	0	0	2.4	n	7/10,8/10	7/10,8/11
40	0	0	3	n	7/10,8/10	7/10,8/11
35	0	0	2.3	n	8/10,9/10	8/10,9/11
37	0	0	2.9	n	8/10,9/10	8/10,9/11
29	1	0	0.6	y	2/10,4/10	2/10,4/11
33	1	2	1.8	y	4/10,6/10	4/10,6/11
36	0	0	2.3	n	6/10,7/10	6/10,7/11
38	0	0	2.5	n	7/10,8/10	7/10,8/11
40	0	0	2.9	n	8/10,9/10	8/10,9/11
41	0	1	3.8	n	8/10,9/10	8/10,9/11
35	0	0	2.6	n	7/10,9/10	7/10,9/11
34	0	2	2.3	n	7/10,8/10	7/10,8/11
38	0	0	2.9	n	7/10,8/10	7/10,8/11
40	0	0	2.5	n	6/10,8/10	6/10,8/11
39	0	1	2.9	n	7/10,8/10	7/10,8/11
33	0	0	1.8	y	6/10,7/10	6/10,7/11
35	0	0	2.2	n	7/10,8/10	7/10,8/11
37	0	2	2.7	n	7/10,8/10	7/10,8/11
32	1	0	1.4	y	3/10,6/10	3/10,6/11
39	0	0	3	n	6/10,7/10	6/10,7/11
41	0	0	3.9	n	7/10,8/10	7/10,8/11
40	0	0	3	n	7/10,8/10	7/10,8/11
34	0	0	2.2	n	8/10,9/10	8/10,9/11
38	0	2	2.7	n	6/10,8/10	6/10,8/11
35	0	0	2.2	n	7/10,8/10	7/10,8/11
38	0	0	2.8	n	7/10,8/10	7/10,8/11

33	0	0	1.4	y	4/10,6/10	4/10,6/11
38	0	0	3.4	n	7/10,8/10	7/10,8/11
40	0	0	2.9	n	8/10,9/10	8/10,9/11
35	0	2	2.1	n	7/10,8/10	7/10,8/11
39	0	0	2.2	n	4/10,7/10	4/10,7/11
37	0	0	2.7	n	7/10,9/10	7/10,9/11
34	0	0	2.2	n	7/10,8/10	7/10,8/11
40	0	0	2.9	n	8/10,9/10	8/10,9/11