SALIVARY PROGESTERONE AS A BIOCHEMICAL MARKER TO PREDICT PRETERM BIRTH IN ASYMPTOMATIC HIGH RISK WOMEN

Dissertation submitted to

The Tamil Nadu Dr.M.G.R Medical University

In partial fulfillment for the award of the Degree of

M.S. (OBSTETRICS AND GYNECOLOGY)

BRANCH II

THE TAMIL NADU Dr.M.G.R MEDICAL UNIVERSITY

INSTITUTE OF OBSTETRICS AND GYNAECOLOGY,

GOVT WOMEN AND CHILDREN HOSPITAL,

MADRAS MEDICAL COLLEGE AND RESEARCH INSTITUTE.

APRIL - 2017

BONAFIDE CERTIFICATE

This is to certify that this dissertation entitled **"SALIVARY PROGESTERONE AS A BIOCHEMICAL MARKER TO PREDICT PRETERM BIRTH IN ASYMPTOMATIC HIGH RISK WOMEN''** is the bonafide work done by **Dr.MAHALAKSHMI.M.**, post graduate in obstetrics and gynaecology under my overall supervision and guidance in the institute of Obstetrics and Gynaecology, GOVT Women and Children Hospital, Madras medical college Chennai, in partial fulfillment of the requirements of The Tamil Nadu Dr.M.G.R University for the award of M.S DEGREE in Obstetrics and Gynaecology

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DECLARATION

I, Dr. M. Mahalakshmi, solemnly declare that the dissertation titled, **"SALIVARY PROGESTERONE AS A BIOCHEMICAL MARKER TO PREDICT PRETERM BIRTH IN ASYMPTOMATIC HIGH RISK WOMEN''** has been done by me. I also declare that this bonafide work or part of this work was not submitted by me for any award, degree, diploma to any other university either in India or abroad.

This is submitted to The Tamil Nadu Dr.MGR medical University, Chennai in partial fulfillment of the rules and regulations for the award of M.S Degree (Obstetrics and Gynaecology) held in April 2017.

Place:

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CONTENTS

Introduction

1. INTRODUCTION

Preterm birth is defined as birth between the age of viability and 37 completed weeks of gestation. It includes deliveries between 24 to 36 weeks and 6 days gestation and also includes all births with birth weight above 500gms. The incidence varies from 5% to 8% among most developed and developing countries. Infants between 34 and 36 weeks account for approximately 75 percent of all preterm births.

Preterm birth cause an increased perinatal mortality, long term morbidity and affects health economics. India has the highest number of preterm births and deaths in the world.

The four main reasons for preterm birth are:

1. Induction of labor for fetal or maternal causes or the infant is delivered by caesarean delivery before onset of labor – 30 to 35%
2. Idiopathic preterm labour with intact membranes – 40 to 45%
3. Idiopathic preterm premature rupture of membranes – 30 to 35%
4. Higher order pregnancy. (ovulation induction)

Aims and Objectives

2. AIM OF THE STUDY

To evaluate salivary progesterone as a predictor of preterm birth and compare it with transvaginal cervical length in asymptomatic high risk women.

Overview

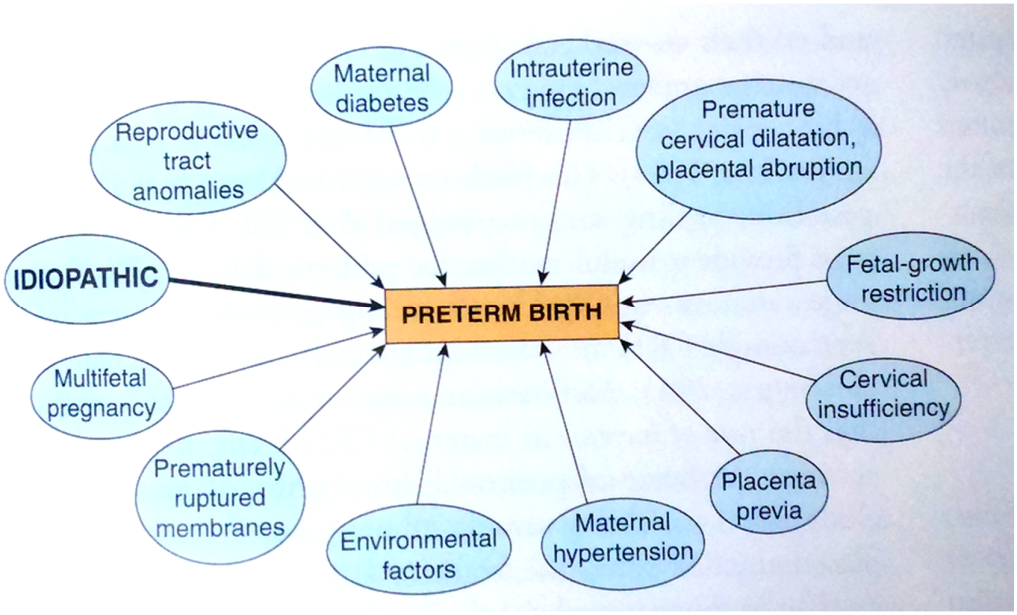
3. OVERVIEW

DEFINITION

Preterm labour is defined as the onset of regular, painful, frequent, uterine contractions causing progressive effacement and dilation of cervix from the period of viability and earlier than gestational age of 37 completed weeks.

RISKS FOR PRETERM BIRTH

Idiopathic preterm birth is the most common cause of preterm birth . Other factors are PPROM, genetic, infection, nutrition, behaviour and the environment.



ANTECEDANTS AND CONTRIBUTING FACTORS FOR PRETERM BIRTH

1. Threatened abortion

Vaginal bleeding in early pregnancy (6 to 13 weeks) were associated with subsequent preterm labor. (Weiss and associates, 2004).

2. Social factors

Lower socioeconomic status, Smoking, less weight gain in pregnancy, advancing maternal age, short stature, certain drugs and deficiency of vitamin C increases the risk of preterm labor.

3. Racial - Ethnic factors

African –American and Afro-caribbean are at higher risk of preterm deliveries (Goldenberg and colleagues, 2008b).

4. Work during pregnancy

Occupational factors like prolonged standing or walking, strenuous work and long weekly hours increases the rsk of preterm labor. (Casnueva, 2005 and all their colleagues).

5. Genetic Factors

Chorioamnionitis is potentiated by immunoregulatory genes in cases of preterm delivery due to infection (varner and Esplin, 2005).

6. Periodontal disease

Periodontal disease increases the risk of preterm birth- odds ratio 2.83 (Goepfert and co-workers, 2004)

7. Birth defects

Congenital anomalies were associated with preterm birth and low birth weight. (First trimester evaluation of risk (FASTER) trial, Delan and colleagues, 2007).

8. Interval between pregnancies

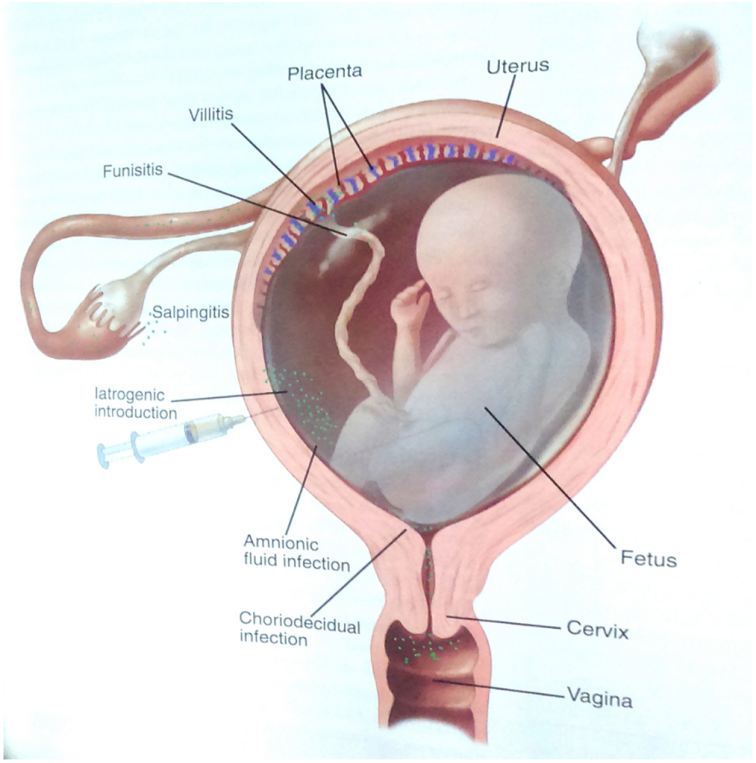
Interpregnancy interval lesser than 18 months and more than 59 months has increased risk of preterm birth (Conde-Agudelo , co-workers, 2006)

9. Prior preterm birth

Recurrent spontaneous preterm births according to prior outcome	
Birth outcome	Second birth ≤34 weeks in percent
First birth ≥35 weeks	5
First birth ≤34 weeks	16
First and second birth ≤34 weeks	41
Data from 15,683 women delivering their first and subsequent pregnancies at Parkland Hospital. Adapted from Bloom and associates (2001) with permission	

10. Infection

25-40% of preterm birth is contributed by intrauterine infection.



The two microorganisms implicated , ureaplasma urealyticum and mycoplasma hominis, induce release of inflammatory cytokines like interleukins and tumour necrosis factor (TNF). This in turn, stimulate the production of prostaglandin which stimulates uterine contraction and/or matrix degrading enzymes which results in preterm prelabor rupture of membranes.

11. Bacterial Vaginosis

It leads to preterm labor, preterm prelabour rupture of membranes, chorio amnionitis and amniotic fluid infection (Hiller,1995; larki,1992; Leitich,2003 a,b, and all their colleagues). Chronic stress, ethnic differences and frequent douching cause bacterial vaginosis (Culhane and co-workers, 2002, Ness and associates, 2002)

12. Medical Disorders

Anaemia, liver disease, asthma, hypertensive disorder, renal disease, tuberculosis, cardiac disease, diabetes, hyperthyroidism, malaria, hyperpyrexia also cause preterm birth.

13. Iatrogenic

Elective premature induction due to fetal or maternal indication. Induction with wrong estimation of gestational age also contribute to preterm birth.

14. Miscellaneous

Abdominal surgeries during pregnancy, severe trauma and drugs like quinine increases the risk of preterm birth.

PREDICTORS OF PRETERM BIRTH:

A. WARNING SIGNALS:

- Menstrual like cramps
- Dull low backache
- Abdominal cramps
- Sense of pelvic pressure or heaviness in the vagina,
- Glairy mucoid vaginal discharge

B. TRANSVAGINAL SONOGRAPHY

The application of transvaginal sonography for cervical length has emerged as a recommendation by the American college of Radiology.The cervical length <2.5cm, funneling or widening of cervical canal, (Y, V, U shape), bulging of membranes in cervical canal and thinning of lower uterine segment can be identified..

C. BIOCHEMICAL MARKERS:

1. Fetal fibronectin:

It is a glycoprotein produced by hepatocytes, fibroblast, endothelial cells, and fetal amnion. It is present in amniotic fluid and the extra villous tropho decidual interface. The substance is present in cervicovaginal fluid before 20 weeks of gestation, and reappear only after spontaneous rupture of membranes at term. Fetal fibronectin level of >50 ng/ml estimated by

ELISA is considered as a positive predictor of preterm labour. This test has high sensitivity and high negative predictive value .

2. Salivary estriol: values more than 2.3ng/ml predicts preterm labour.
3. Serum collagenases.
4. Tissue inhibitor of metalloproteinase (TIMP)
5. Ferritin/ Iron ratio
6. Relaxin.
7. Serum triglycerides.
8. Corticotrophin releasing hormone (CRH).
9. Mediators of inflammation and infection.
    a. C-Reactive Protein.
    b. Leucocyte esterase.
    c. Cytokine.
    d. Amniotic fluid glucose concentration.
    e. Zinc.
    f. Lipocortin-I.
    g. Positive cultures.
10. Salivary progesterone.

D. HOME UTERINE ACTIVITY MONITORING:

Contractions are recorded by telemetry twice a day. It is costly and not an easily available equipment. However it is not useful in reducing the incidence of preterm labour.

E. FOETAL BREATHING MOVEMENT:

Patients are likely to go in preterm labour within 48 hours, if absent fetal breathing movements are detected in real time ultrasonogram.

F. RISK SCORING SYSTEM:

Papiemick (1974) used an elaborate scoring system for detection of patient more prone for spontaneous preterm labour which was later, modified by Creasy et al. Those with 10 or more scores were more prone for preterm labour.

ACOG CRITERIA:

ACOG (1997) criteria to diagnose preterm labour:

Contractions of 4 in 20 minutes with progressive change in the cervix,

Cervical dilation more than or equal to 1cm,

Cervical effacement more than or equal to 80%

PREVENTION OF PRETERM BIRTH:

1. Improving the socioeconomic condition.
2. Patient education and prepregnancy counseling regarding warning signals.
3. Identifying and correcting risk factor whenever possible-1.Proper nutrition, 2. Avoid smoking, alcohol, 3. Adequate rest-avoidance of physical and mental stress, 4. Control of medical diseases, 5. Cervical encirclage in proved case of cervical incompetence.
4. Any operation in pregnant woman to be planned during second trimester.
5. Proper assessment before induction of labour to avoid iatrogenic prematurity.
6. Treat vaginal and cervical infections and asymptomatic bacteriuria in pregnancy .
7. Coitus, late in pregnancy should be avoided.
8. Prophylactic tocolysis is not indicated.
9. Cervical Encerclage - A short cervix diagnosed by ultrasound in asymptomatic women might be an indication for cerclage. .
10. Progesterone- Weekly intramuscular injection of 250mg of 17-OH progesterone caproate from 20 to 36 weeks, to high risk women lowered the rates of preterm birth and perinatal mortality when compared to placebo.

DIAGNOSIS OF PRETERM LABOUR

1. Symptoms of preterm labour.
2. Clinical examination.
3. Ultrasonogram.
4. Cardiotocograph

MANAGEMENT OF PRETERM LABOUR

1. Bed rest , hydration

2. Antenatal steroid

12mg of betamethasone- 2 doses of intramuscular injections 24 hours apart or 6mg of dexamethasone - 4 doses of intramuscular injections 12 hours apart can be given between 24 and 34 weeks of gestation to all women who are prone for preterm delivery within 7 days.

3. Tocolysis

Tocolytics are the drugs which inhibit uterine activity. They are

a. BETA SYMPATHOMIMETICS

The inhibition of uterine contractions by this drug is short lived.

I generation: Isoxsuprine, orciprenaline, Isoprenaline

II generation: Ritodrine, Terbutaline, Fenoterol

b. MAGNESIUM SULPHATE

$MgSO_4$ acts by uncoupling the depolarization contraction coupling (Elliott, 1983)

Therapeutic level is 4-8mmol per liters.

c. PROSTAGLANDIN SYNTHETASE INHIBITORS

Drugs like aspirin, indomethacin are used to prevent preterm labour in patients with cardiac disease and hyperthyroidism. They are not routinely used because of fear of PDA closure and pulmonary hypertension in fetus.

d. CALCIUM CHANNEL BLOCKERS

Nifedipine act by inhibiting the influx of extracellular calcium and release of intracellular calcium from the sarcoplasmic reticulum during inward calcium current of action potential, reducing the tone of smooth muscles.

e. OXYTOCIN ANTAGONIST (ATOSIBAN)

This oxytocin analogue competitively blocks the oxytocin receptors and inhibits preterm labour. RCOG guidelines says that if tocolytics is administered, the first choice should be oxytocin antagonists followed by Nifedipine.

IMMEDIATE CONSEQUENCES OF PRETERM LABOUR

Perinatal mortality:

Preterm labor accounts for 85% of deaths in structurally normal infants.

The survival rates for preterm babies in India are as follows:

26-30 Weeks	-	67%
30-34 Weeks	-	75%
34-38 Weeks	-	94.3%

Neonatal morbidity:

The incidence of morbidities in Indian studies are

1. Respiratory Distress Syndrome 80%
2. Patent Ductus Arteriosus 50%
3. Intraventricular haemorrhage 31.5%
4. Retinopathy of Prematurity 25.2%

Hypothermia and hypoglycemia are common problems in preterm babies. Other major problems related to preterm delivery include intraventricular hemorrhage, periventricular leucomalacia and retinopathy of prematurity.

LONG TERM CONSEQUENCES OF PRETERM LABOR

Cerebral palsy, intellectual impairments and behavioral problems are more frequent in preterm babies.

Refractive errors and strabismus are also common. Deafness occur in 1.5-9% .

There is poor feto-maternal bonding due to the psychological and physical stress it puts. Newborn with membrane disease or who required assisted ventilation may develop chronic pulmonary disease. Infants delivered preterm are more prone for hospitalization in the earlier ages of life. Preterm male infants frequently have inguinal hernia .

Dogye and colleagues (1994) reported that only 20% of preterm infants were actually free of impairment at 5 years of age

ECONOMIC CONSIDERATIONS

The cost of acute hospital care for preterm infants is very high. Antenatal care for these mothers may prove costly as many of them have obstetrical complications. The long hospital stay adds to the economic burden.. After discharge from the hospital, the health care and social service system continue to incur substantial costs for the special needs and special education for these children, more so with long term morbidity. Added to this, the loss of productivity on the part of the parents also increases the economic burden.

Review of Literature

4. REVIEW OF LITERATURE

Prematurity is the most common cause of neonatal and infant mortality and morbidity. The preterm newborns pose a major financial burden. . It is for these reasons, strategies for prediction and prevention of preterm labor is necessary. Several biological, clinical and sonographic markers have been suggested as tools for predicting preterm labor. The tested biological markers included cervico-vaginal fetal fibronectin level, human chorionic gonadotropin (hCG) level and serum corticotropin releasing hormone (CRH). Most of these tested markers lack either acceptable validity or feasibility and availability. So a quicker, cheaper, simpler test with greater accuracy for predicting preterm labor is needed, so that one can avoid unnecessary tocolysis and take appropriate intervention or refer earlier to a tertiary care centre.

Goldenberg and colleagues (2008b) related pathogenesis of preterm labour to

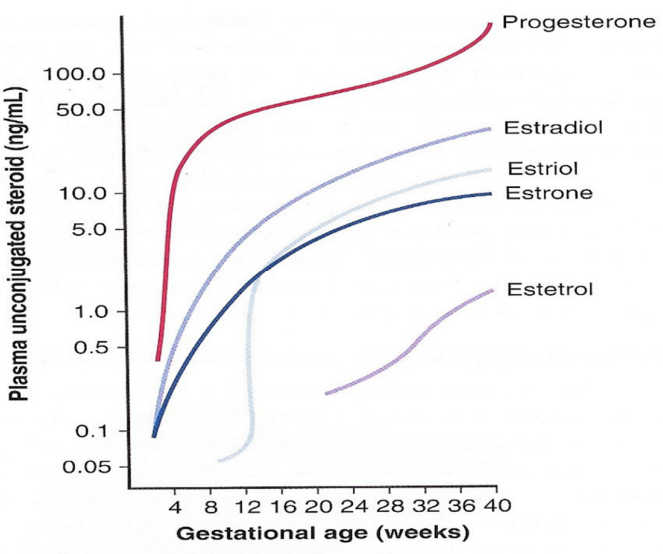
1. Withdrawal of Progesterone
2. Initiation of Oxytocin
3. Activation of decidua.

Role of Progesterone in parturition

The studies conducted in sheep supports progesterone withdrawal theory.

After 6-7 week gestation, the ovary produces very little progesterone (Diczfalwey and Troen, 1961).

After 8 weeks, the placenta secretes progesterone , and there is a progressive increase in serum progesterone levels. About 250mg of progesterone is produced daily in late pregnancy .



The Placental trophoblast produces a large amount of progesterone utilizing maternal plasma cholesterol (Hellig and associates,1970), preferentially LDL cholesterol (simpson and Burkhart, 1980)

During pregnancy, the concentration of 5α-dihydro progesterone in the plasma increases disproportionately. It is synthesized by syncytiotrophoblast from precursors got from fetus. (Dombroski and coworker, 1997). This increase in the progesterone metabolite and progesterone causes resistance to pressor agents in pregnancy.

The fall in progesterone level directly precedes the progression of uterine quiescence and cervical competence into uterine activation and cervical ripening of parturition in many species. Supplementing progesterone delays parturition by decreasing the uterine activity and continued maintenance of competency of cervix. (Challis and Lye, 1994). Thus the progesterone deficient myometrium is quiescent.

Teleological evidence reveals that an increased ratio of progesterone to estrogen is necessary for sustaining the pregnancy and that a fall in the progesterone to estrogen ratio results in parturition.

The estrogen acts to promote progesterone responsiveness, and thus, promote uterine quiescence. The estrogen receptor acting via the estrogen-response element of the progesterone-receptor gene, induces progesterone-receptor synthesis.

Progesterone increases uterine quiescence by decreasing the expression of contraction-associated proteins (CAPS) and inhibiting the expression of connexin43.

Functional progesterone withdrawal or antagonism occurs through possible ways:

1. Alteration in the expression of the progesterone receptor (PR) protein isoforms, PR-A, PR-B and PR-C in the nucleus.
2. Alteration in the expression of membrane-bound progesterone receptors.
3. Post translation modification of the receptor, specific to progesterone.
4. Changes in progesterone receptor activity through variations in the expression of co-activators or co-repressors that directly influence receptor function.
5. Inactivation of progesterone by locally produced steroid-metabolizing enzymes .

PR-B moderates progesterone actions, whereas PR-A and PR-C diminutes progesterone responsiveness. Studies show that there is a transferral in the relative ratio of PR-A to PR-B , late in gestation. The ratio of PR-A and PR-B is altered in decidua and chorion. The receptor isoform in the stroma of cervix also showed variations. PR-C to PR-B ratio is increased in fundus.

Studies reveal that 5-α reductase type 1 enzymes when expressed, break down progesterone to by products resulting in failure of cervix to ripen. There is an increase in estrogen and decrease in progesterone level, in deficiency of the enzyme , 20-α-hydroxy steroid dehydrogenase. (Prekorz and associates, 2005). Decrease in 17β-hydroxy steroid dehydrogenase type 2 in the human cervix at term results in a net increase in estrogen and decrease in progesterone. And finally, glucocorticoids also has anti-progestin activity (Karalis and co-workers, 1996).

With the onset of labor, the fetal-adrenal axis gets sensitized to adrenocorticotrophic hormones, and cortisol secretion is stimulated. Placental 17-α hydroxylase activity is potentiated by cortisol. This, in turn reduces progesterone production and increase estrogen production. This altered estrogen/progesterone ratio results in increased prostaglandin formation, thus inducing labor.

Concentrations of steroids in saliva correlates well with their serum concentrations and reflect the free, unconjugated, and, thus, the biologically active portion of the plasma hormone profile.

Advantages of saliva

- Ultrafiltrate of plasma
- Collection is easy
- Storage is easy

Limitation

1. Patient activity/posture, food consumption
2. Oral lesions, abrasions, gingivitis

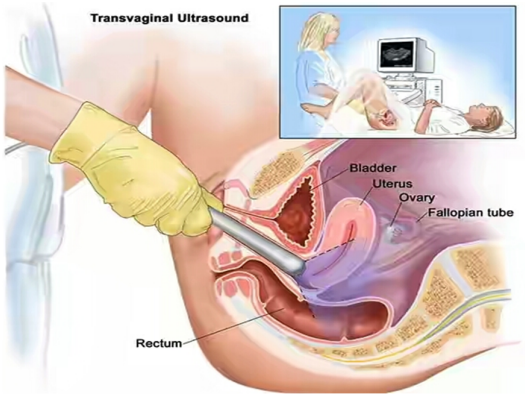
ROLE OF ULTRASONOGRAPHY

The word “cervix” refers to “neck of the womb”. It is the distal narrow and cylindrical part of the uterus, which enters the vagina at right angles to it. The ectocervix, the portion projecting into the vagina, also known as “portiovaginalis”, is convex and elliptical. It measures 3cm long and 2.5cm wide and opens out through the external os.

The endocervical canal extends between the internal os and the uterine cavity. The internal os is the upper limit of the endocervical canal and opens into the uterine cavity.

TRANSVAGINAL SONOGRAPHY

Transvaginal sonogram can be performed similar to gynaecologic examination. It is simple, cost-effective, reproducible and reliable method to assess and predict the risk of preterm delivery.



An electronic array transvaginal transducer

Limitations:

- Incomplete or failure to empty the maternal bladder is associated with false measurement.
- Increased pressure on the vaginal probe.
- Any polyp, fibroid, cervical growth, that obscure proper imaging.
- A poorly developed lower uterine segment.

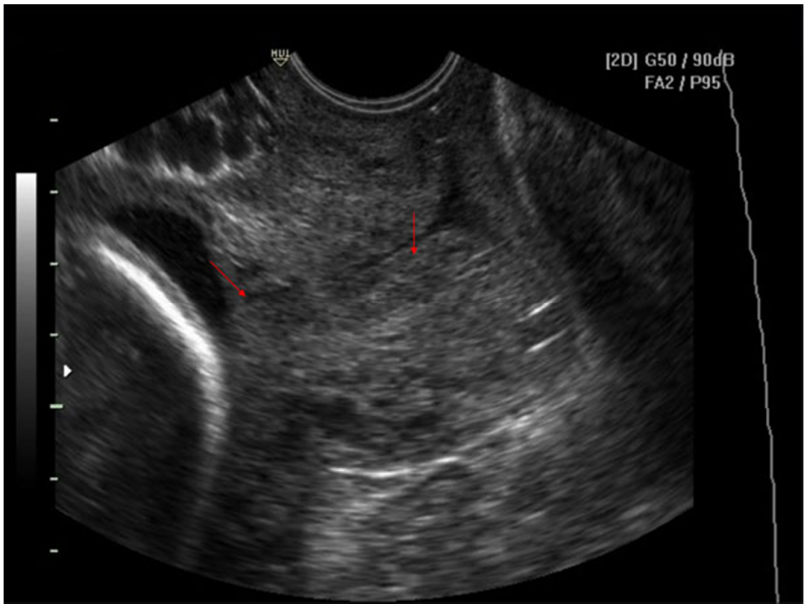
To minimise the intra-observer variability, the below methods are suggested.

The flat dimple or an isosceles triangle seen is the internal os..

The cervix should be visualized as a whole.

The external os gives symmetric appearance.

The distance from the surface of the posterior lip to the cervical canal is equal to the distance from the surface of the anterior lip to the cervical canal.



Trans-vaginal measurement of cervix length.

These conditions when met, ensures visualization of the entire cervix and placement of only minimal pressure on the cervix by the transducer (which may falsely decrease the cervical length and create false funneling. Using these guidelines, the intra-observer variability decreases from 3.04 to 1.24mm.

In primigravida population, the smaller the cervix, they were more prone for preterm labour. However, in the multiparous women, the internal os dilation was a more useful predictor.

Materials and Methods

5. MATERIALS AND METHODS

This prospective study was done in IOG, Egmore, Chennai from January 2015 to March 2016. Informed written consent was obtained from all participants in the study.

Subject selection: They were selected from the AN clinic, IOG

Inclusion Criteria:

1. Asymptomatic women with singleton pregnancy with history of previous preterm birth.
2. Previous preterm prelabor rupture of membranes.
3. Late spontaneous miscarriage (20 to 28 weeks).

Exclusion Criteria:

1. Multiple gestation.
2. Congenital anomalies of uterus/fetus.
3. Antepartum haemorrhage.
4. Obstetric complications requiring iatrogenic preterm birth.
5. Non -reassuring fetal heart rate pattern.
6. Fetal growth restriction.

7. Medical disorders like hypertensive disorders of pregnancy, hyperglycemia in pregnancy, renal disorders, cardiac disease, chronic liver disease, vaginal infections, cervical cerclage.
8. Medications affecting hormonal concentration-antipsychotics, corticosteroids or progesterone therapy.
9. Tocolysis.
10. Any addiction-smoking, alcohol.
11. Bleeding from the gums.

Screening Procedures/Visits

All AN women recruited were subjected to salivary progesterone estimation at 24 to 28 weeks. At the same time, they were subjected to transvaginal cervical length measurement.

I) Estimation of Salivary progesterone:

Following consent, after overnight fasting, mouth rinsed with water 10 minutes before collecting saliva . A sterile, wide mouthed glass or plastic container was used for collecting samples. 3 unstimulated samples were collected within 2 hours and pooled together. The sample was stored at or below -20^0 c within 30 minutes until the test.

SAMPLE PROCESSING

Colorless salivary samples without any contaminants like food or blood were collected.

Sample Collection

The container should be made of ultrapure polypropylene. Sample were collected either in the fasting state or after avoiding milk products and food of animal origin. Or else saliva were collected while anticipating a meal. Each sample should be a minimum of 0.5ml.

Sample Storage and Preparation

Saliva samples can be stored for 7 days at ambient temperature. Samples can be stored at at 4^0 c for a period of up to one month. Samples were stored at a temperature of -20^0c. Before proceeding with the test, sample were thawed and centrifuged at least once in order to separate the mucin by centrifugation for atleast 5 – 10 minutes . The clear supernatant layer was be used for assay.

Dilution of Specimen

The highest calibrator was (5000 pg/ml).Samples suspected to have greater progesterone concentrations than the highest calibrator was diluted with the zero calibrator.

METHOD OF ASSAY

General instructions

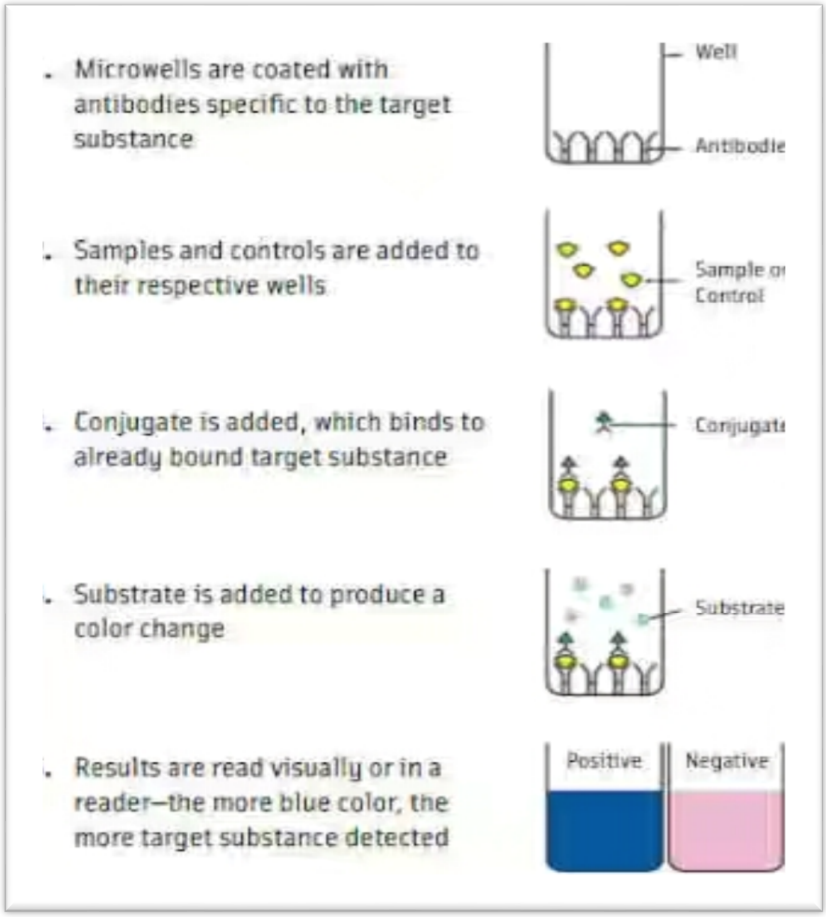
- All samples and test kits were brought to room temperature and mixed in such a way to avoid foaming.
- The entire procedure was carried out uninterruptedly.
- Separate disposable pipette tips were used for each reagents and samples.
- Since absorbance depends on the incubation time and temperature, all containers were kept open and pipette kept ready before starting the procedure.

Steps

1. A sufficient microplate wells to accommodate calibrators, controls and patient samples were prepared.
2. The wells were filled appropriately with control , sample and 100 microlitres of each calibrator..
3. 50 microlitres of enzyme conjugate were pipetted into the wells.
4. The microplate well was placed on a mixer and incubated at room temperature for 60 minutes.
5. The content in the wells were discarded and the wells rinsed with diluted wash solution atleast 4 times. The wash solution was removed with absorbent paper completely.

6. 200 microlitres of substrate solution was added to each of the well.
7. Incubated in the dark for 30 minutes without shaking.
8. Later, stop solution was added to each well in a quantity of 50 microlitres.
9. The absorbance was read within 15 minutes at 450 nm
10. Results got in absorbance units were used to draw a standard curve and the concentration of progesterone in each sample got from the calibrator curve.

STEPS OF ELISA TEST



II. Determination of cervical length:

Measurement was done with the patient in dorsal position and with empty bladder by introducing the probe into the anterior fornix. 3 measurements were taken and the shortest measurement was recorded.

I) Follow up:

Salivary progesterone estimation was done again between 29 – 32 weeks.. Cervical length measurement was also done at the same time. They were followed up regularly. Post delivery, records were verified for mode of delivery, gestational age at delivery, neonatal outcome and admission to NICU. Mother and newborn were followed up till discharge.

Analysis of Results

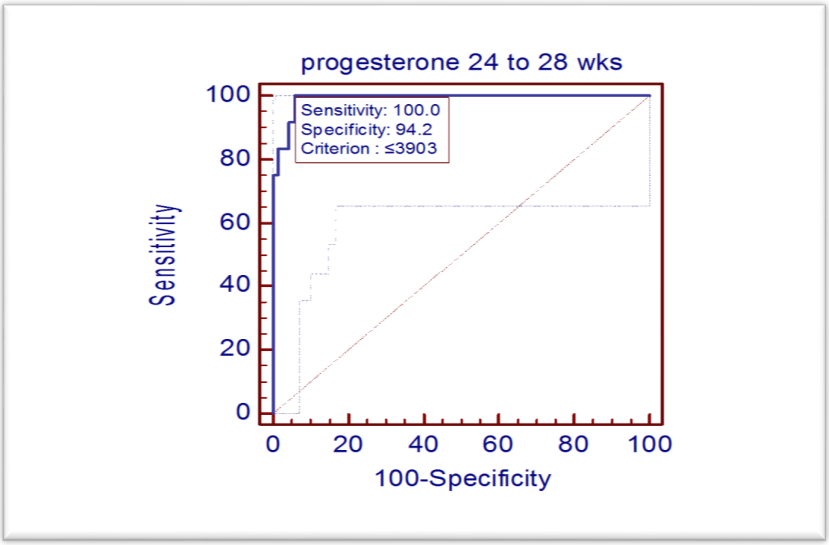
6. ANALYSIS OF RESULTS

No of patients enrolled in the study	-	90
No of patients who completed the study	-	81
No of patients who were excluded	-	9
Final list of patients	-	81
Total number of patients delivered preterm	-	12
Incidence of preterm birth in this study	-	14.81%
No of preterm babies who required NICU admission	-	12

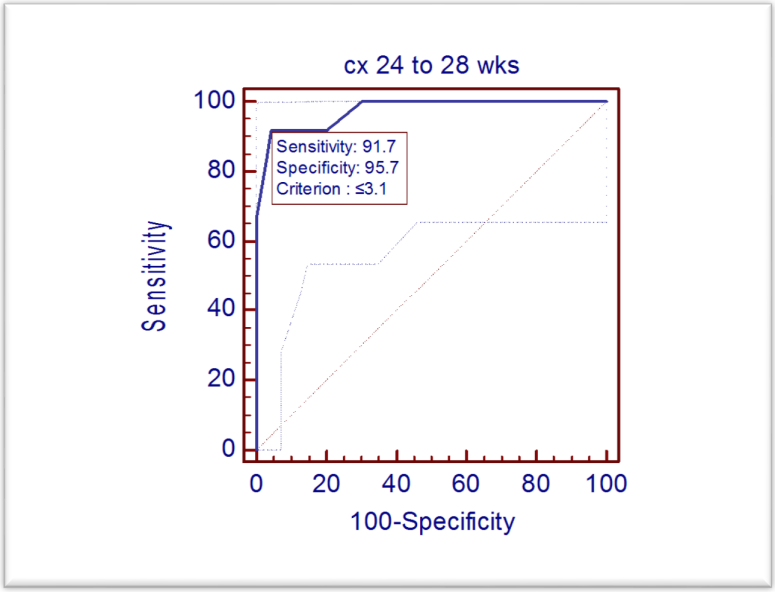
The datas were evaluated using Receiver operator characteristic curve, chi-square test, t-test and linear regression curve.

RECEIVER OPERATOR CHARACTERISTIC CURVE

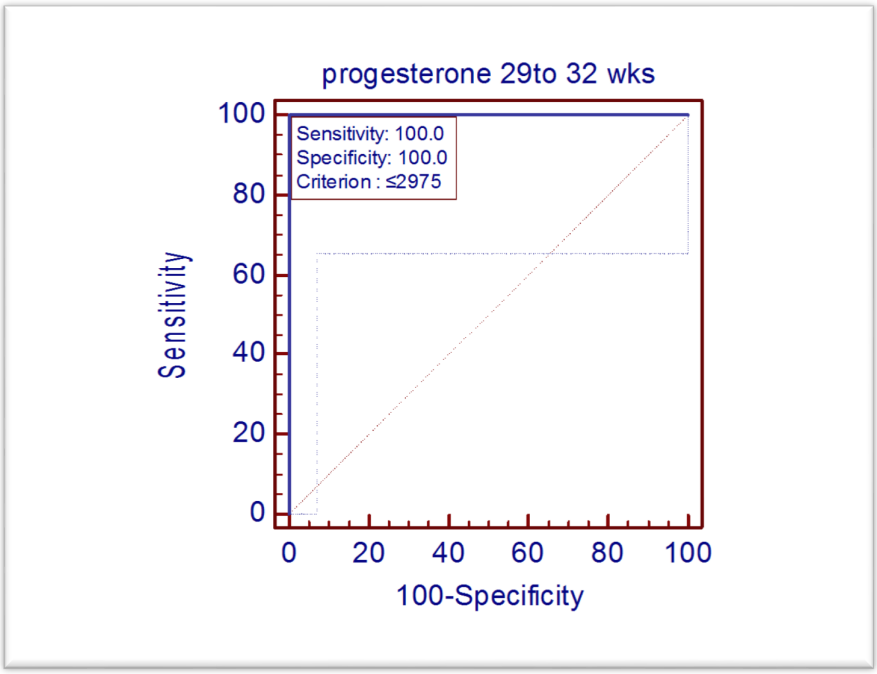
SALIVARY PROGESTERONE VS OUTCOME - 24 TO 28 WKS



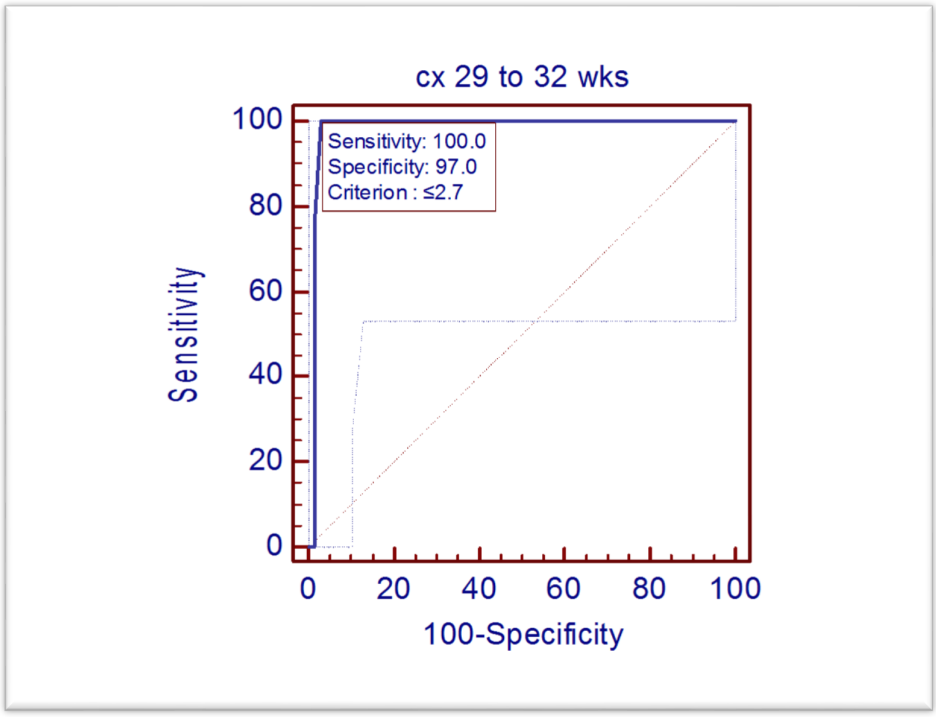
CERVIX LENGTH VS OUTCOME – 24 TO 28 WKS



SALIVARY PROGESTERONE VS OUTCOME - 29 TO 32 WKS



CERVIX LENGTH VS OUTCOME – 29 TO 32 WKS

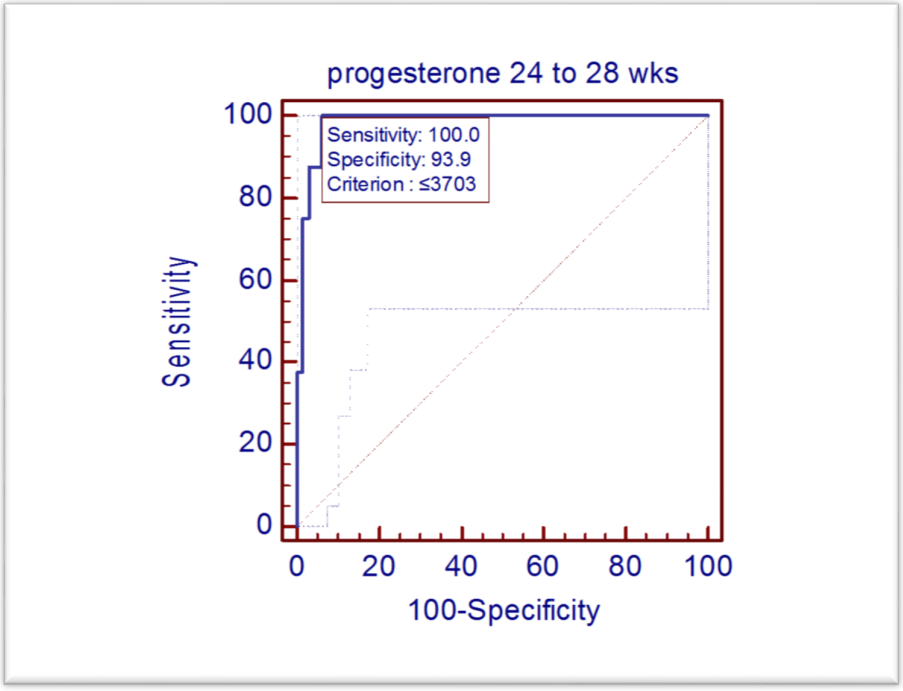


CONCLUSION

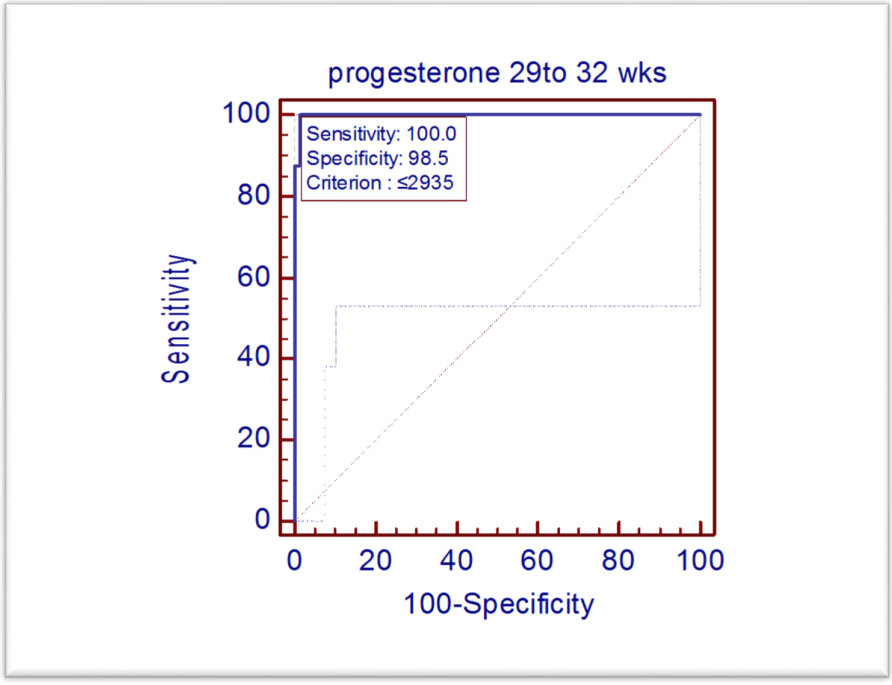
	Sensitivity	**Specificity**	**AUC**	**Criterion**
Progesterone 24-28 Weeks	100	94.2	0.990338	≤3903
Progesterone 29-32 Weeks	100	100	1.0000	≤2975
Cervix 24-28 Weeks	91.7	95.7	0.973430	≤3.1
Cervix 29-32 Weeks	100	98.6	0.997585	≤2.9

There is a statistical significance existing between labour outcome and salivary progesterone and cervical length measured between 24 to 28 weeks and 29 to 32 weeks.

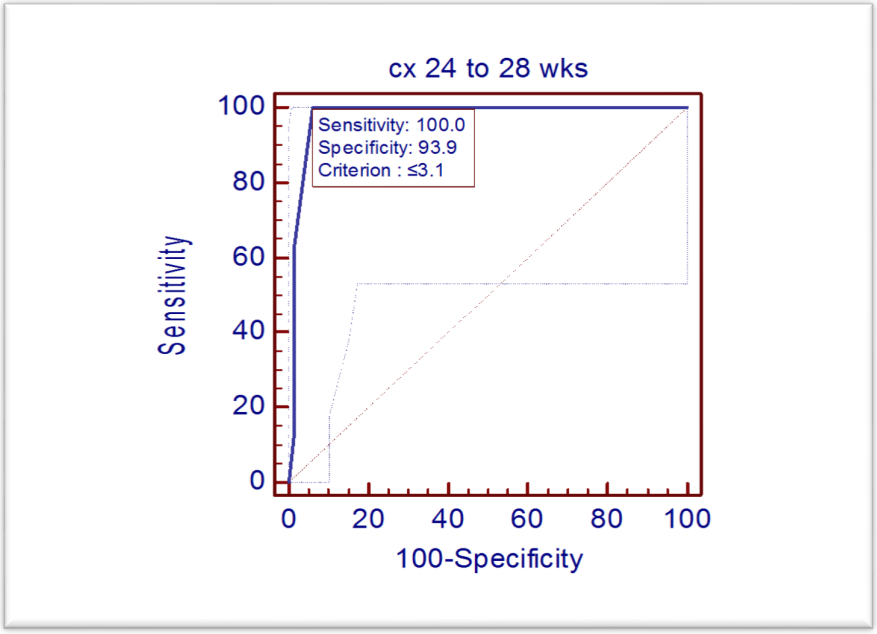
SALIVARY PROGESTERONE AND NEONATAL COMPLICATIONS - 24 TO 28 WEEKS



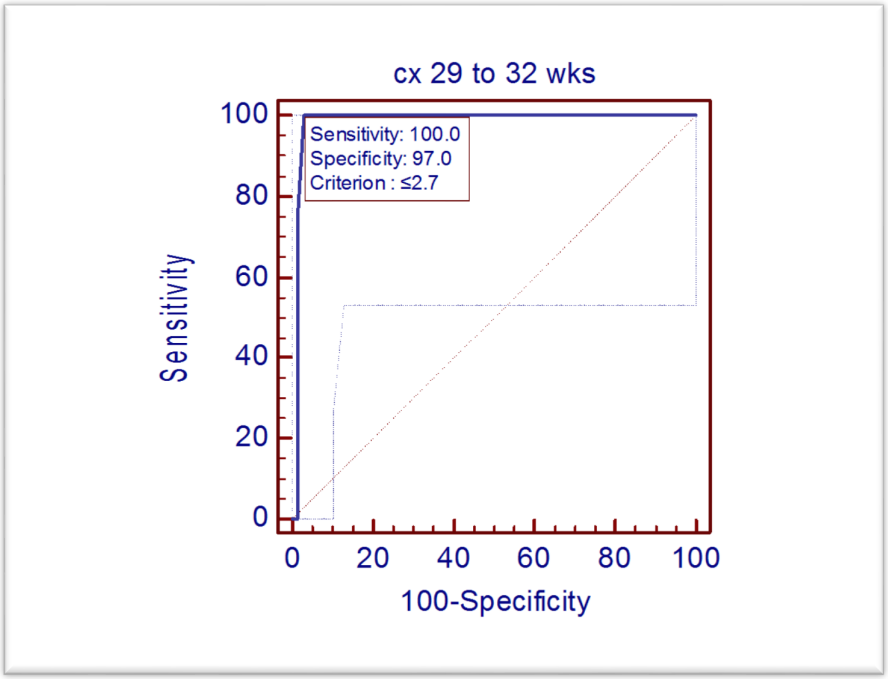
29 TO 32 WEEKS



CERVIX LENGTH VS NEONATAL COMPLICATIONS - 24 TO 28 WEEKS



29 TO 32 WEEKS



CONCLUSION

	Sensitivity	**Specificity**	**AUC**	**Criterion**
Progesterone 24-28 Weeks	100	93.9	0.982955	≤3703
Progesterone 29-32 Weeks	100	98.5	0.998106	≤2935
Cervix 24-28 Weeks	100	93.9	0.977273	≤3.1
Cervix 29-32 Weeks	100	97	0.982955	≤2.7

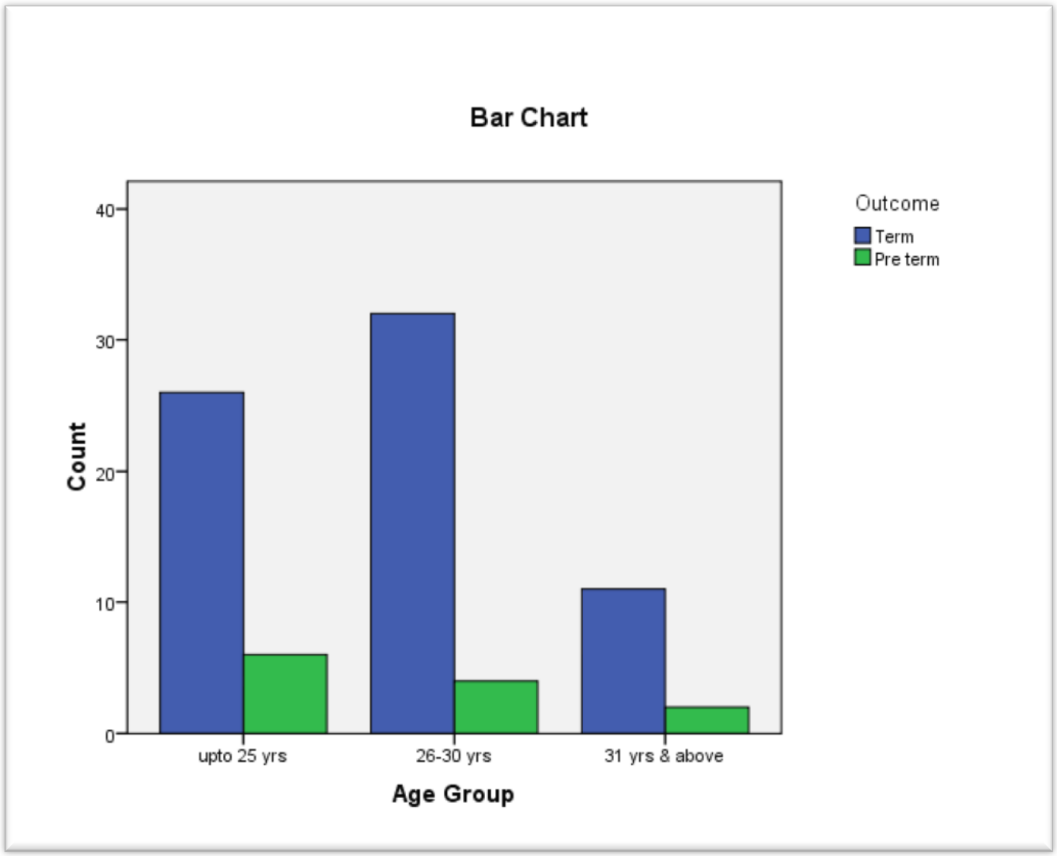
There is a statistical significance existing between salivary progesterone and cervical length measured between 24 to 28 weeks and 29 to 32 weeks with respect to neonatal complications.

Age Group Vs Outcome

Crosstab					
			Outcome		
			Term	Pre-term	Total
Age Group	Up to 25 years	Count	26	6	32
		% within Age Group	81.3%	18.8%	100.0%
		% within Outcome	37.7%	50.0%	39.5%
		% of Total	32.1%	7.4%	39.5%
	26-30 years	Count	32	4	36
		% within Age Group	88.9%	11.1%	100.0%
		% within Outcome	46.4%	33.3%	44.4%
		% of Total	39.5%	4.9%	44.4%
	31 years & above	Count	11	2	13
		% within Age Group	84.6%	15.4%	100.0%
		% within Outcome	15.9%	16.7%	16.0%
		% of Total	13.6%	2.5%	16.0%
	Total	Count	69	12	81
		% within Age Group	85.2%	14.8%	100.0%
		% within Outcome	100.0%	100.0%	100.0%
		% of Total	85.2%	14.8%	100.0%

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	0.787[a]	2	0.675
Likelihood Ratio	0.793	2	0.673
Linear-by-Linear Association	0.271	1	0.603
N of Valid Cases	81		

AGE VS OUTCOME



χ^2= 0. 787 **P= 0.675**

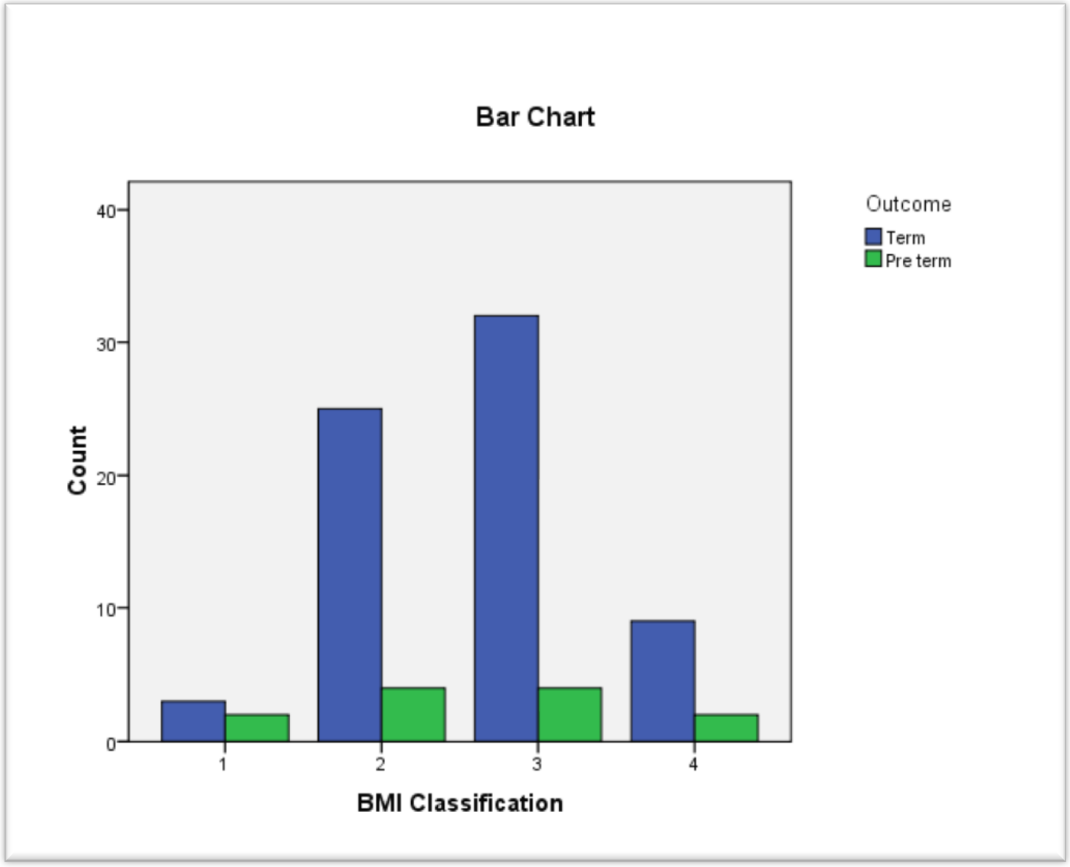
There is no statistical difference in labour outcome between different age groups.

BMI Classification Vs Outcome

Crosstab					
			Outcome		
			Term	Pre -term	Total
BMI Classification	1	Count	3	2	5
		% within BMI Classification	60.0%	40.0%	100.0%
		% within Outcome	4.3%	16.7%	6.2%
		% of Total	3.7%	2.5%	6.2%
	2	Count	25	4	29
		% within BMI Classification	86.2%	13.8%	100.0%
		% within Outcome	36.2%	33.3%	35.8%
		% of Total	30.9%	4.9%	35.8%
	3	Count	32	4	36
		% within BMI Classification	88.9%	11.1%	100.0%
		% within Outcome	46.4%	33.3%	44.4%
		% of Total	39.5%	4.9%	44.4%
	4	Count	9	2	11
		% within BMI Classification	81.8%	18.2%	100.0%
		% within Outcome	13.0%	16.7%	13.6%
		% of Total	11.1%	2.5%	13.6%
	Total	Count	69	12	81
		% within BMI Classification	85.2%	14.8%	100.0%
		% within Outcome	100.0%	100.0%	100.0%
		% of Total	85.2%	14.8%	100.0%

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	3.027[a]	3	0.387
Likelihood Ratio	2.410	3	0.492
Linear-by-Linear Association	0.533	1	0.465
N of Valid Cases	81		

BMI CLASSIFICATION VS OUTCOME



χ^2= 3.027 **P= 0.562**

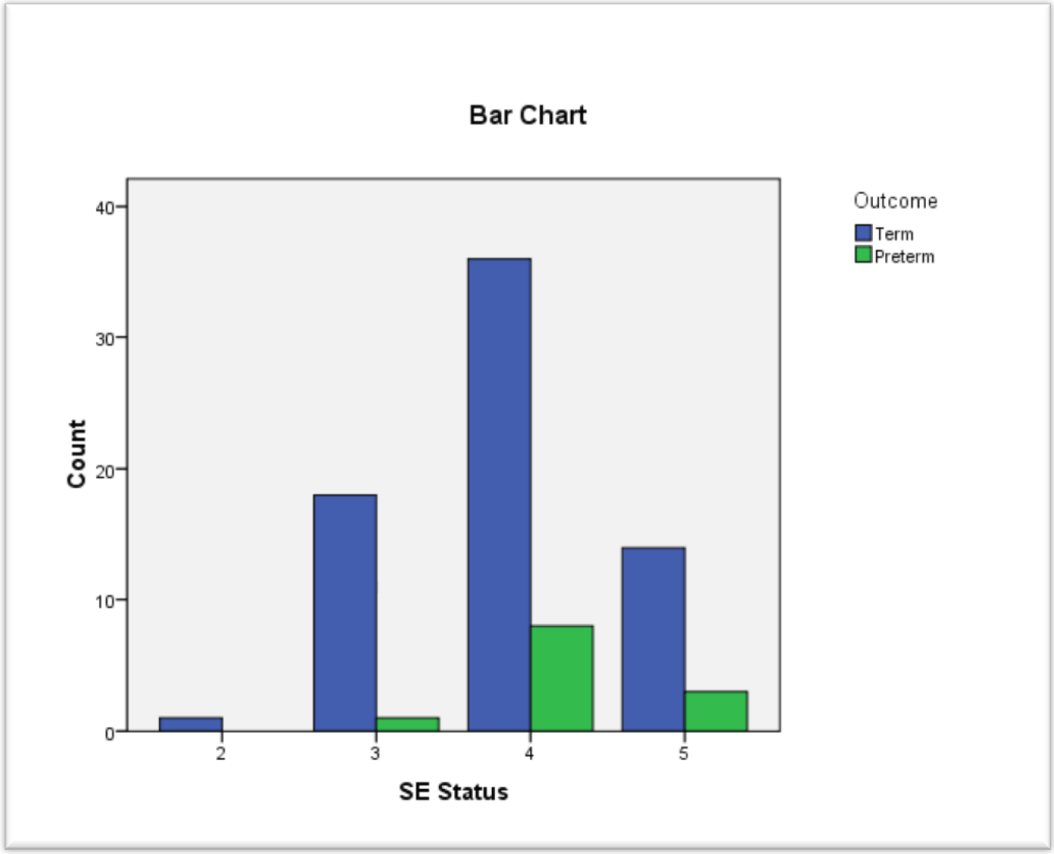
There is no statistical difference in labour outcome with respect to BMI.

SOCIO ECONOMIC STATUS VS OUTCOME

Crosstab					
			Outcome		
			Term	Pre-term	Total
SE Status	2	Count	1	0	1
		% within SE Status	100.0%	.0%	100.0%
		% within Outcome	1.4%	.0%	1.2%
		% of Total	1.2%	.0%	1.2%
	3	Count	18	1	19
		% within SE Status	94.7%	5.3%	100.0%
		% within Outcome	26.1%	8.3%	23.5%
		% of Total	22.2%	1.2%	23.5%
	4	Count	36	8	44
		% within SE Status	81.8%	18.2%	100.0%
		% within Outcome	52.2%	66.7%	54.3%
		% of Total	44.4%	9.9%	54.3%
	5	Count	14	3	17
		% within SE Status	82.4%	17.6%	100.0%
		% within Outcome	20.3%	25.0%	21.0%
		% of Total	17.3%	3.7%	21.0%
	Total	Count	69	12	81
		% within SE Status	85.2%	14.8%	100.0%
		% within Outcome	100.0%	100.0%	100.0%
		% of Total	85.2%	14.8%	100.0%

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.051[a]	3	0.562
Likelihood Ratio	2.553	3	0.466
Linear-by-Linear Association	1.322	1	0.250
N of Valid Cases	81		

SOCIO ECONOMIC STATUS VS OUTCOME



χ^2 =2.051 P=0.562

There is no significant difference between different socio economic status with respect to labour outcome.

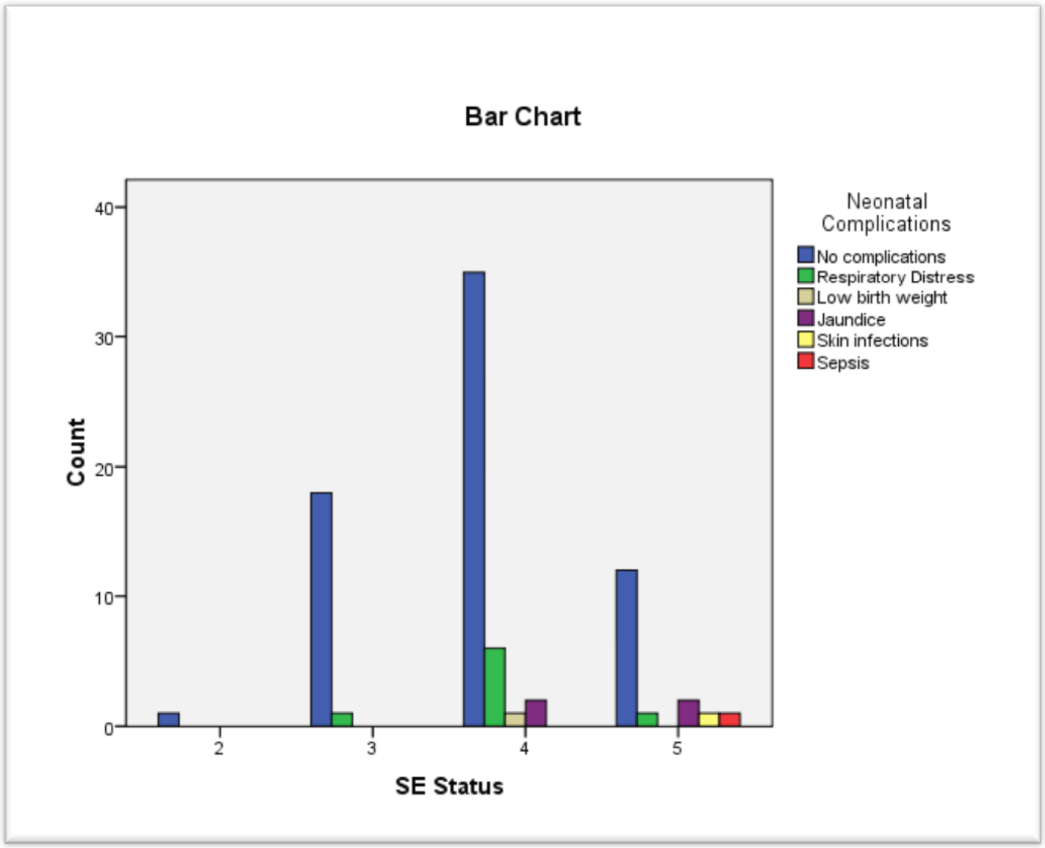
SOCIO ECONOMIC STATUS VS NEONATAL COMPLICATIONS

Crosstab					
			Neonatal Complications		
			No complications	Respiratory Distress	Low birth weight
SE Status	2	Count	1	0	0
		% within Neonatal Complications	1.5%	.0%	.0%
		% of Total	1.2%	.0%	.0%
	3	Count	18	1	0
		% within Neonatal Complications	27.3%	12.5%	.0%
		% of Total	22.2%	1.2%	.0%
	4	Count	35	6	1
		% within Neonatal Complications	53.0%	75.0%	100.0%
		% of Total	43.2%	7.4%	1.2%
	5	Count	12	1	0
		% within Neonatal Complications	18.2%	12.5%	.0%
		% of Total	14.8%	1.2%	.0%
Total		Count	66	8	1
		% within Neonatal Complications	100.0%	100.0%	100.0%
		% of Total	81.5%	9.9%	1.2%

Crosstab						
			Neonatal Complications			
			Jaundice	Skin infections	Sepsis	Total
SE Status	2	Count	0	0	0	1
		% within Neonatal Complications	.0%	.0%	.0%	1.2%
		% of Total	.0%	.0%	.0%	1.2%
	3	Count	0	0	0	19
		% within Neonatal Complications	.0%	.0%	.0%	23.5%
		% of Total	.0%	.0%	.0%	23.5%
	4	Count	2	0	0	44
		% within Neonatal Complications	50.0%	.0%	.0%	54.3%
		% of Total	2.5%	.0%	.0%	54.3%
	5	Count	2	1	1	17
		% within Neonatal Complications	50.0%	100.0%	100.0%	21.0%
		% of Total	2.5%	1.2%	1.2%	21.0%
	Total	Count	4	1	1	81
		% within Neonatal Complications	100.0%	100.0%	100.0%	100.0%
		% of Total	4.9%	1.2%	1.2%	100.0%

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	13.108[a]	15	0.594
Likelihood Ratio	12.890	15	0.611
Linear-by-Linear Association	7.121	1	0.008
N of Valid Cases	81		

SOCIOECONOMIC STATUS VS NEONATAL COMPLICATIONS



χ^2 =13.108 P=0.594

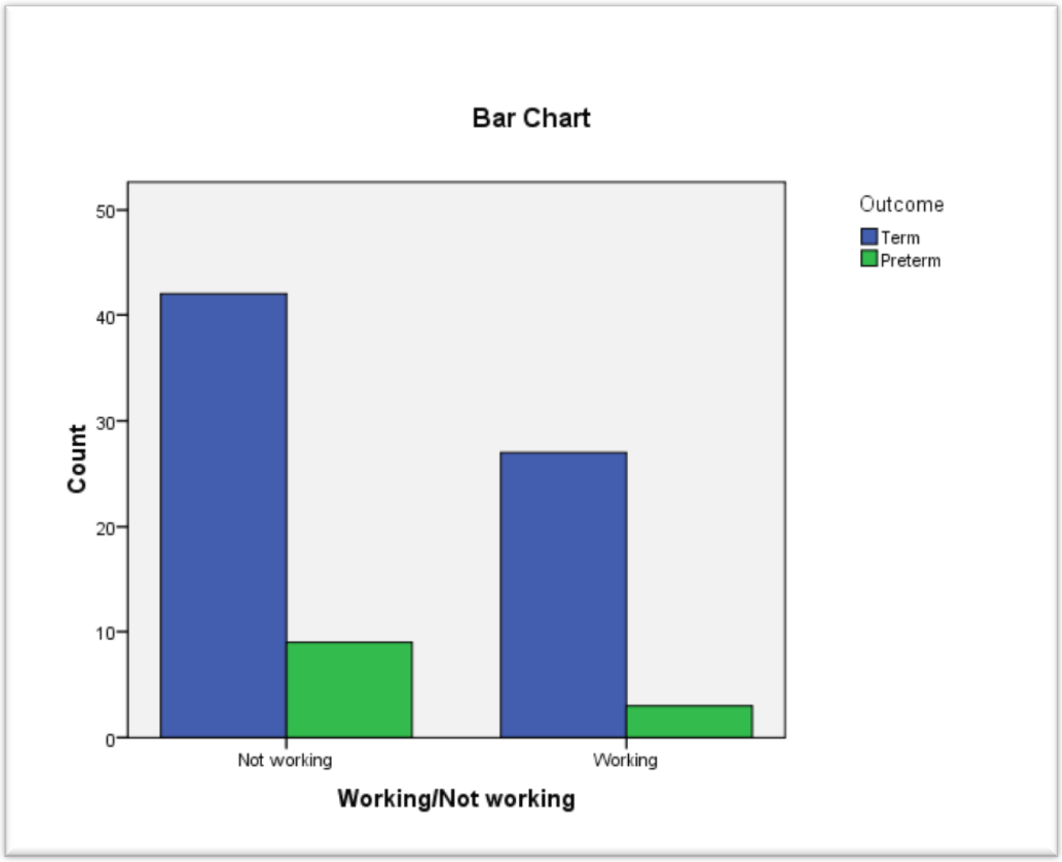
There is no significant difference between different socio economic status with respect to neonatal complications.

WORKING/NOTWORKING VS OUTCOME

Crosstab					
			Outcome		
			Term	Pre-term	Total
Working/ Not working	0	Count	42	9	51
		% within Working / Not working	82.4%	17.6%	100.0%
		% within Outcome	60.9%	75.0%	63.0%
		% of Total	51.9%	11.1%	63.0%
	1	Count	27	3	30
		% within Working / Not working	90.0%	10.0%	100.0%
		% within Outcome	39.1%	25.0%	37.0%
		% of Total	33.3%	3.7%	37.0%
	Total	Count	69	12	81
		% within Working / Not working	85.2%	14.8%	100.0%
		% within Outcome	100.0%	100.0%	100.0%
		% of Total	85.2%	14.8%	100.0%

Chi-Square Tests					
	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	0.875[a]	1	0.350		
Continuity Correction[b]	0.374	1	0.541		
Likelihood Ratio	0.919	1	0.338		
Fisher's Exact Test				0.520	0.276
Linear-by-Linear Association	0.864	1	0.352		
N of Valid Cases	81				

WORKING/NOTWORKING VS OUTCOME



χ^2 =0.875 P=0.350

There is no significant difference between different working status with respect to labour outcome.

WORKING/NOTWORKING VS NEONATAL COMPLICATIONS

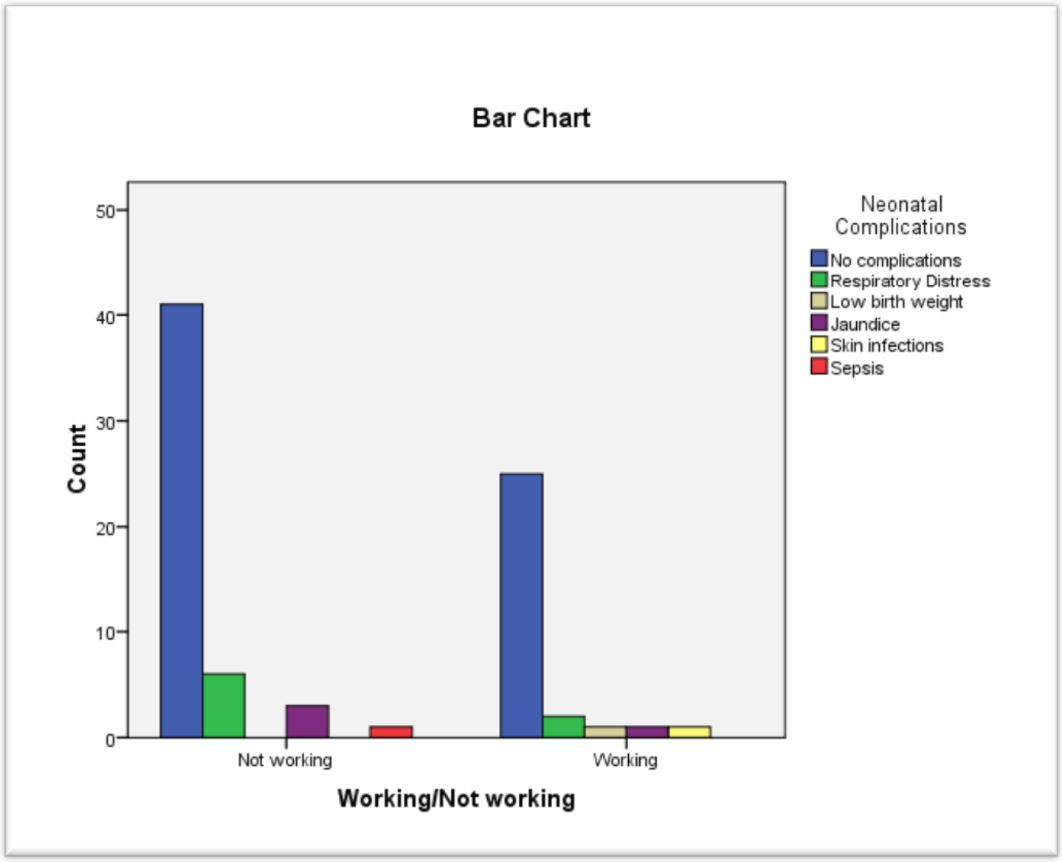
Crosstab				
			Neonatal Complications	
			No complications	Respiratory Distress
Working/ Not working	Not working	Count	41	6
		% within Neonatal Complications	62.1%	75.0%
		% of Total	50.6%	7.4%
	Working	Count	25	2
		% within Neonatal Complications	37.9%	25.0%
		% of Total	30.9%	2.5%
	Total	Count	66	8
		% within Neonatal Complications	100.0%	100.0%
		% of Total	81.5%	9.9%

Crosstab				
			Neonatal Complications	
			Low birth weight	Jaundice
Working/Not working	Not working	Count	0	3
		% within Neonatal Complications	.0%	75.0%
		% of Total	.0%	3.7%
	Working	Count	1	1
		% within Neonatal Complications	100.0%	25.0%
		% of Total	1.2%	1.2%
	Total	Count	1	4
		% within Neonatal Complications	100.0%	100.0%
		% of Total	1.2%	4.9%

Crosstab					
			Neonatal Complications		
			Skin infections	Sepsis	Total
Working/ Not working	Not working	Count	0	1	51
		% within Neonatal Complications	0.0%	100.0%	63.0%
		% of Total	0.0%	1.2%	63.0%
	Working	Count	1	0	30
		% within Neonatal Complications	100.0%	0.0%	37.0%
		% of Total	1.2%	0.0%	37.0%
	Total	Count	1	1	81
		% within Neonatal Complications	100.0%	100.0%	100.0%
		% of Total	1.2%	1.2%	100.0%

Chi-Square Tests			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	4.754[a]	5	.447
Likelihood Ratio	5.709	5	.336
Linear-by-Linear Association	.013	1	.910
N of Valid Cases	81		

WORKING/ NOT WORKING VS NEONATAL COMPLICATIONS



χ^2 =4.754 P=0.447

There is no significant difference between working status with respect to neonatal complications.

INCLUSION CRITERIA VS OUTCOME

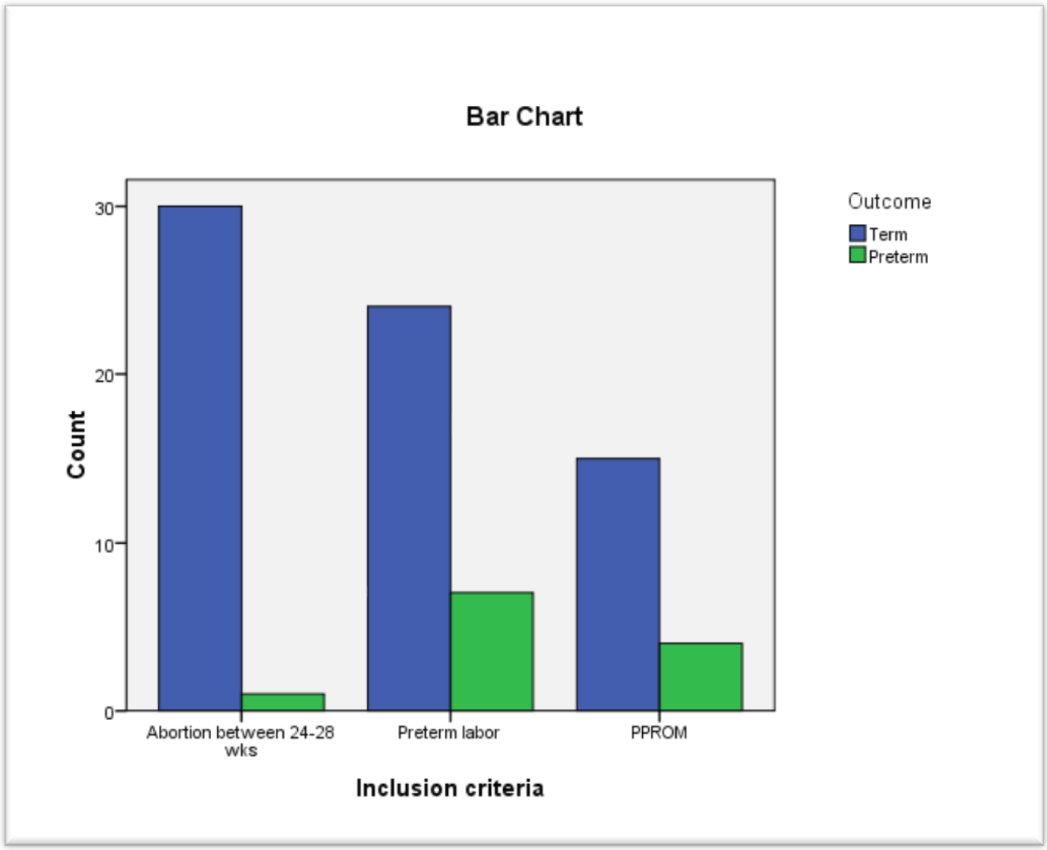
CROSS TAB

			Outcome		
			Term	**Preterm**	**Total**
Inclusion Criteria	Abortion between 24-28 Weeks	Count	30	1	31
		% within Outcome	43.5%	8.3%	38.3%
		% of Total	37.0%	1.2%	38.3%
	Preterm Labor	Count	24	7	31
		% within Outcome	34.8%	58.3%	38.3%
		% of Total	29.6%	8.6%	38.3%
	PPROM	Count	15	4	19
		% within Outcome	21.7%	33.3%	23.5%
		% of Total	18.5%	4.9%	23.5%
	Total	Count	69	12	81
		% within Outcome	100%	100%	100%
		% of Total	85.2%	14.8%	100%

Chi-Square Tests

	Value	Df	Asymp.Sig (2-Sided)
Pearson Chi-Square	5.366[a]	2	0.068
Likelihood Ratio	6.446	2	0.040
Linear-by-Linear Association	3.705	1	0.054
N of Valid Cases	81		

INCLUSION CRITERIA VS OUTCOME



χ^2 =5.366 P=0.068

There is no significant difference between the different inclusion criteria with respect to labour outcome.

INCLUSION CRITERIA VS NEONATAL COMPLICATIONS

Crosstab			
Inclusion criteria		**Neonatal Complications**	
		No complications	**Respiratory Distress**
Abortion between 24-28 Weeks	Count	28	0
	% within Neonatal Complications	42.4%	0.0%
	% of Total	34.6%	0.0%
Preterm labor	Count	26	4
	% within Neonatal Complications	39.4%	50.0%
	% of Total	32.1%	4.9%
PPROM	Count	12	4
	% within Neonatal Complications	18.2%	50.0%
	% of Total	14.8%	4.9%
Total	Count	66	8
	% within Neonatal Complications	100.0%	100.0%
	% of Total	81.5%	9.9%

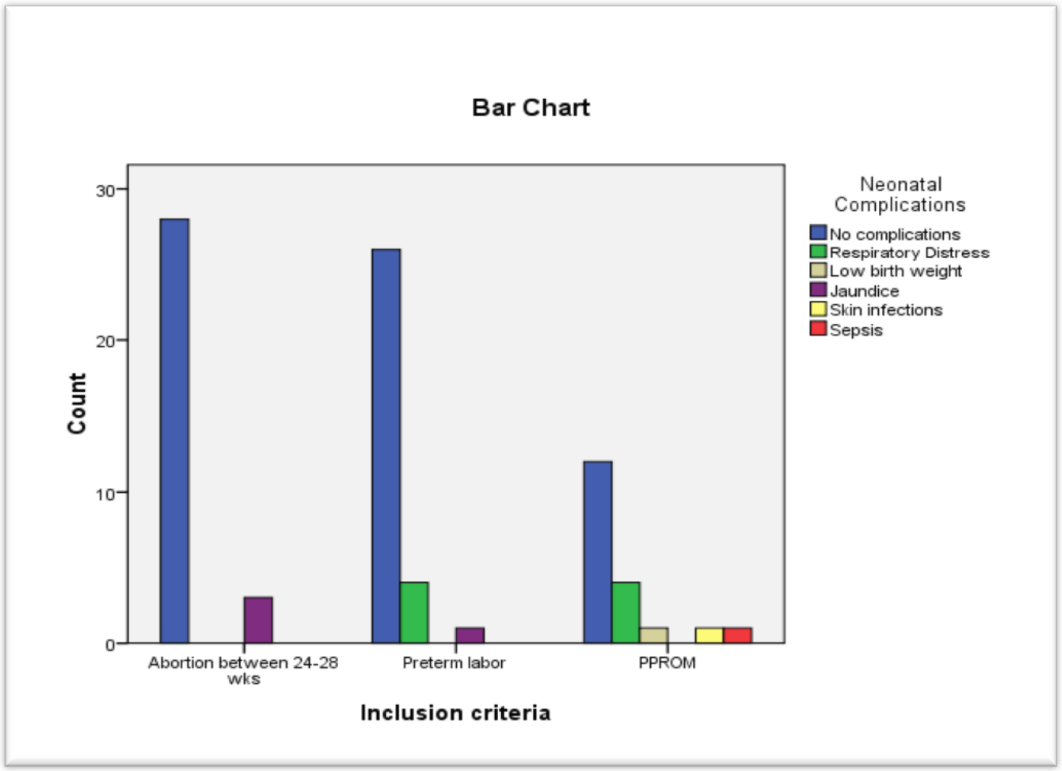
Crosstab			
Inclusion criteria		**Neonatal Complications**	
		Low birth weight	**Jaundice**
Abortion between 24-28 wks	Count	0	3
	% within Neonatal Complications	0.0%	75.0%
	% of Total	0.0%	3.7%
Preterm labor	Count	0	1
	% within Neonatal Complications	0.0%	25.0%
	% of Total	0.0%	1.2%
PPROM	Count	1	0
	% within Neonatal Complications	100.0%	.0%
	% of Total	1.2%	.0%
Total	Count	1	4
	% within Neonatal Complications	100.0%	100.0%
	% of Total	1.2%	4.9%

Crosstab			
Inclusion criteria		**Neonatal Complications**	
		Skin infections	**Sepsis**
Abortion between 24-28 Weeks	Count	0	0
	% within Neonatal Complications	0.0%	0.0%
	% of Total	0.0%	0.0%
Preterm labor	Count	0	0
	% within Neonatal Complications	0.0%	0.0%
	% of Total	0.0%	0.0%
PPROM	Count	1	1
	% within Neonatal Complications	100.0%	100.0%
	% of Total	1.2%	1.2%
Total	Count	1	1
	% within Neonatal Complications	100.0%	100.0%
	% of Total	1.2%	1.2%

Crosstab		
Inclusion criteria		**Total**
Abortion between 24-28 Weeks	Count	31
	% within Neonatal Complications	38.3%
	% of Total	38.3%
Preterm labor	Count	31
	% within Neonatal Complications	38.3%
	% of Total	38.3%
PPROM	Count	19
	% within Neonatal Complications	23.5%
	% of Total	23.5%
Total	Count	81
	% within Neonatal Complications	100.0%
	% of Total	100.0%

Chi-Square Tests			
	Value	**df**	**Asymp. Sig. (2-sided)**
Pearson Chi-Square	19.176[a]	10	.038
Likelihood Ratio	21.236	10	.020
Linear-by-Linear Association	2.413	1	.120
N of Valid Cases	81		

INCLUSION CRITERIA VS NEONATAL COMPLICATIONS



χ^2 =19.176 P=0.038

There exists a statistical significance between various inclusion criteria such as abortion, preterm and PPROM with respect to various neonatal complications.

PASSIVE SMOKING VS OUTCOME

(H/O Smoking among family members Vs Outcome)

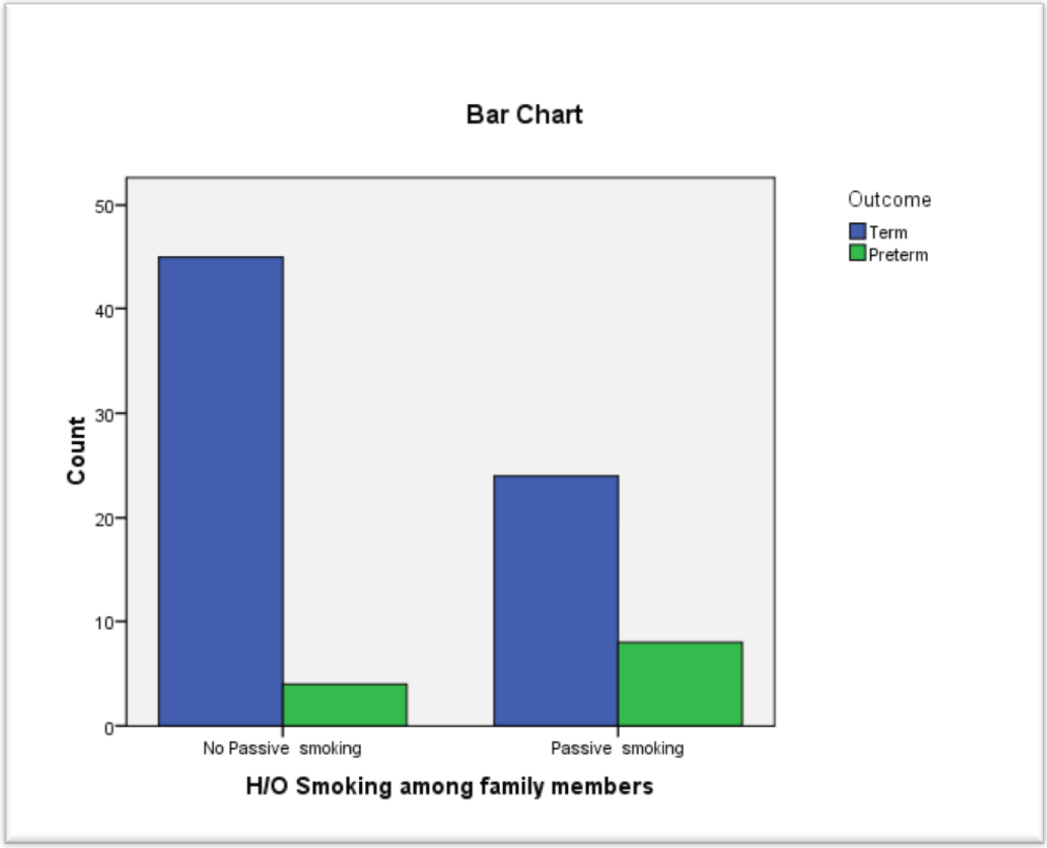
Cross Tab

			Outcome		
			Term	**Preterm**	**Total**
H/O Smoking among family members	No Passive Smoking	Count	45	4	49
		% within Outcome	65.2%	33.3%	60.5%
		% of Total	55.6%	4.9%	60.5%
	Passive Smoking	Count	24	8	32
		% within Outcome	34.8%	66.7%	39.5%
		% of Total	29.6%	9.9%	39.5%
	Total	Count	69	12	81
		% within Outcome	100%	100%	100%
		% of Total	85.2%	14.8%	100%

Chi-Square Tests

	Value	**Df**	**Asymp.Sig (2-Sided)**	**Exact Sig. (2-Sided)**	**Exact Sig. (1-Sided)**
Pearson Chi-Square	4.348[a]	1	0.037		
Continuity Correction[b]	3.116	1	0.078		
Likelihood Ratio	4.258	1	0.039		
Fisher's Exact Test				0.054	0.040
Linear-by-Linear Association	4.295	1	0.038		
N of Valid Cases	81				

PASSIVE SMOKING VS OUTCOME



χ^2 =4.348 P=0.037

Passive smoking increases the risk of preterm labor, which is statistically significant.

NICU ADMISSION VS OUTCOME

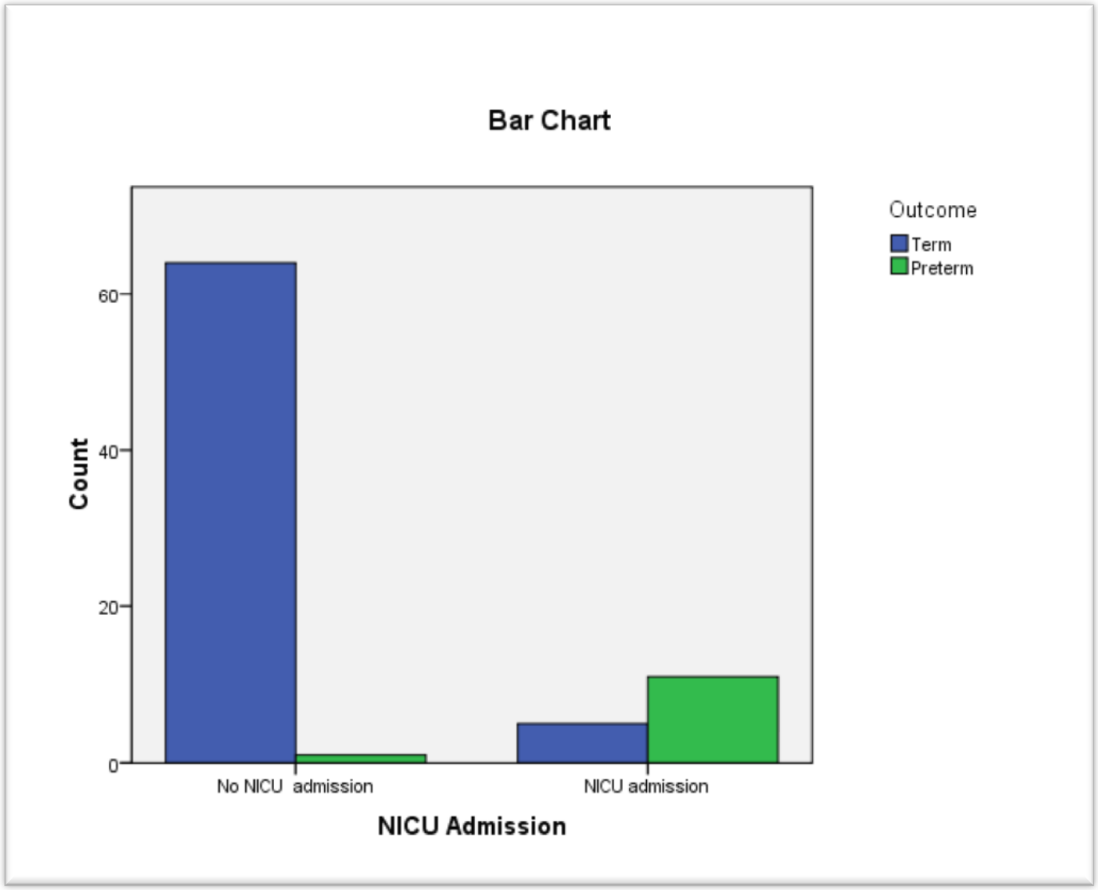
Cross Tab

			Outcome		
			Term	**Preterm**	**Total**
NICU Admission	No NICU Admission	Count	64	1	65
		% within Outcome	92.8%	8.3%	80.2%
		% of Total	79.0%	1.2%	80.2%
	NICU Admission	Count	5	11	16
		% within Outcome	7.2%	91.7%	19.8%
		% of Total	6.2%	13.6%	19.8%
	Total	Count	69	12	81
		% within Outcome	100%	100%	100%
		% of Total	85.2%	14.8%	100%

Chi-Square Tests

	Value	**Df**	**Asymp.Sig (2-Sided)**	**Exact Sig. (2-Sided)**	**Exact Sig. (1-Sided)**
Pearson Chi-Square	45.960[a]	1	0.000		
Continuity Correction[b]	40.788	1	0.000		
Likelihood Ratio	37.748	1	0.000		
Fisher's Exact Test				0.000	
Linear-by-Linear Association	45.392	1	0.000		
N of Valid Cases	81				

NICU ADMISSION VS OUTCOME



χ^2 =45.960 P=0.000

There exists a statistical significant increase in the risk of NICU admissions with respect to preterm labor.

NICU ADMISSION VS NEONATAL COMPLICATIONS

Crosstab				
			Neonatal Complications	
			No complications	Respiratory Distress
NICU Admission	No NICU admission	Count	65	0
		% within Neonatal Complications	98.5%	.0%
		% of Total	80.2%	.0%
	NICU admission	Count	1	8
		% within Neonatal Complications	1.5%	100.0%
		% of Total	1.2%	9.9%
	Total	Count	66	8
		% within Neonatal Complications	100.0%	100.0%
		% of Total	81.5%	9.9%

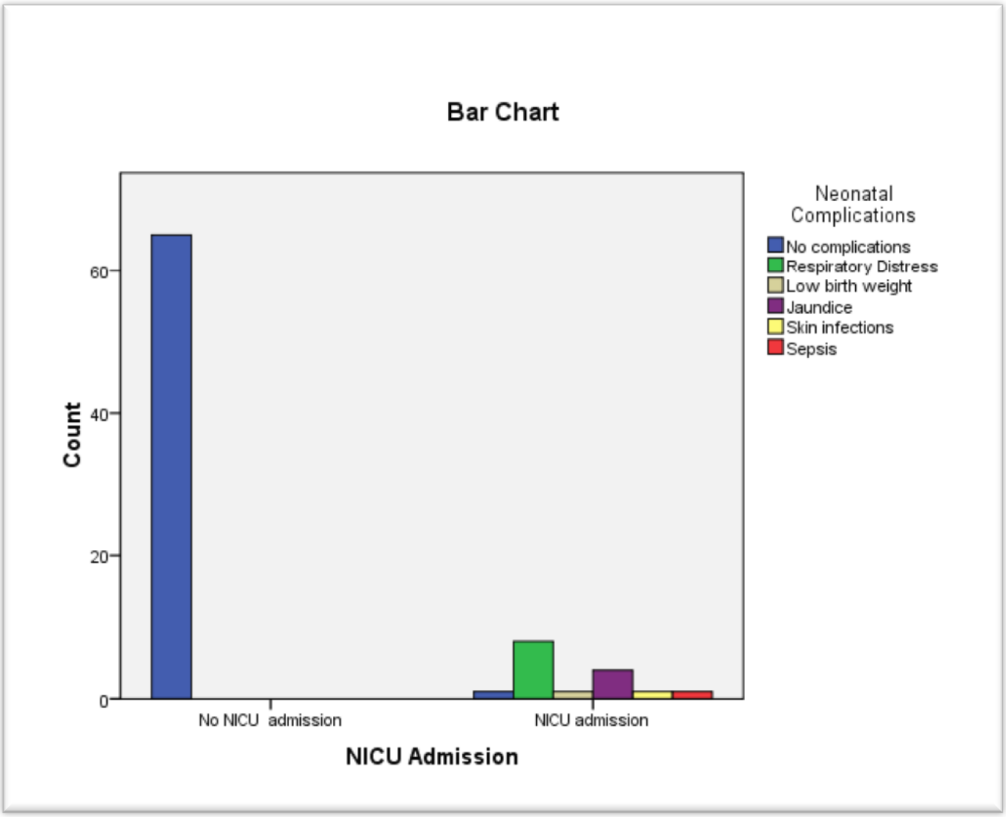
Crosstab				
			Neonatal Complications	
			Low birth weight	Jaundice
NICU Admission	No NICU admission	Count	0	0
		% within Neonatal Complications	0.0%	0.0%
		% of Total	0.0%	0.0%
	NICU admission	Count	1	4
		% within Neonatal Complications	100.0%	100.0%
		% of Total	1.2%	4.9%
	Total	Count	1	4
		% within Neonatal Complications	100.0%	100.0%
		% of Total	1.2%	4.9%

Crosstab				
			Neonatal Complications	
			Skin infections	Sepsis
NICU Admission	No NICU admission	Count	0	0
		% within Neonatal Complications	0.0%	0.0%
		% of Total	0.0%	0.0%
	NICU admission	Count	1	1
		% within Neonatal Complications	100.0%	100.0%
		% of Total	1.2%	1.2%
	Total	Count	1	1
		% within Neonatal Complications	100.0%	100.0%
		% of Total	1.2%	1.2%

Crosstab			
			Total
NICU Admission	No NICU admission	Count	65
		% within Neonatal Complications	80.2%
		% of Total	80.2%
	NICU admission	Count	16
		% within Neonatal Complications	19.8%
		% of Total	19.8%
	Total	Count	81
		% within Neonatal Complications	100.0%
		% of Total	100.0%

Chi-Square Tests			
	Value	**df**	**Asymp. Sig. (2-sided)**
Pearson Chi-Square	74.787[a]	5	.000
Likelihood Ratio	70.143	5	.000
Linear-by-Linear Association	49.988	1	.000
N of Valid Cases	81		

NICU ADMISSION VS NEONATAL COMPLICATIONS



χ^2 =74.787 P=0.000

There exists a statistically significant increase in neonatal complications in neonates admitted to NICU.

NEONATAL MORTALITY VS OUTCOME

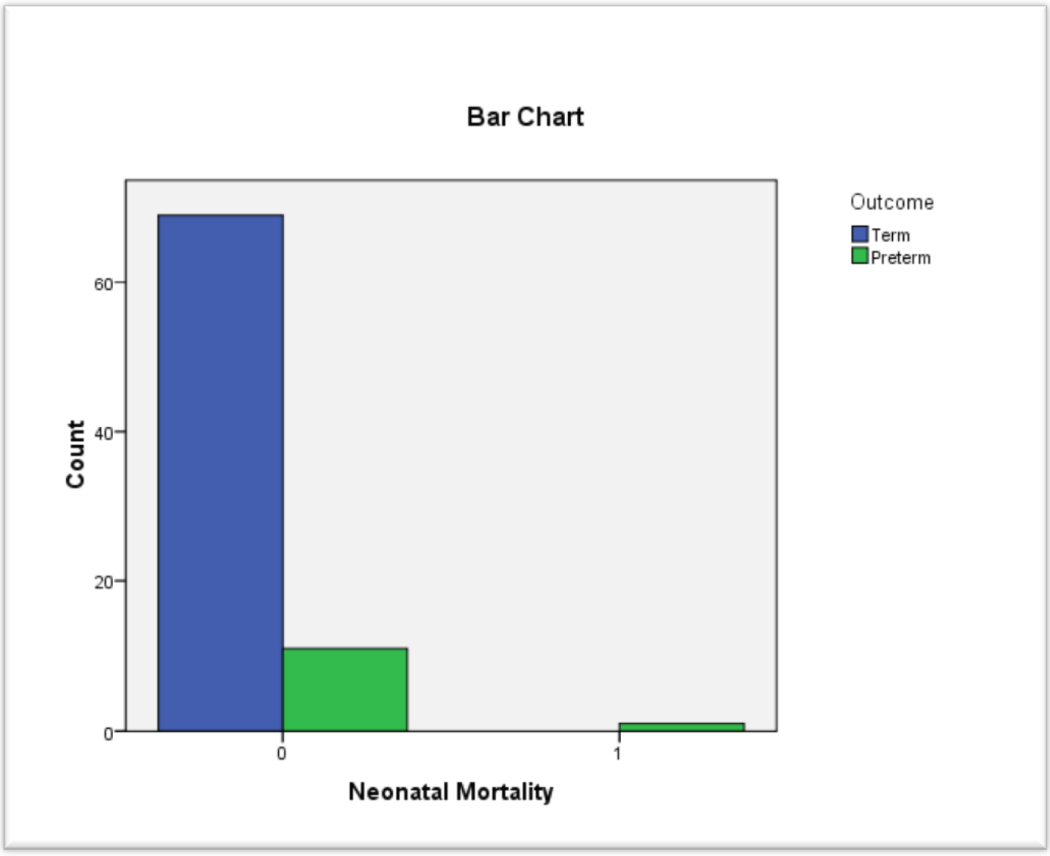
Cross Tab

			Outcome		
			Term	**Preterm**	**Total**
Neonatal Mortality	0	Count	69	11	80
		% within Outcome	100.0%	91.7%	98.8%
		% of Total	85.2%	13.6%	98.8%
	1	Count	0	1	1
		% within Outcome	0.0%	8.3%	1.2%
		% of Total	0.0%	1.2%	1.2%
	Total	Count	69	12	81
		% within Outcome	100%	100%	100%
		% of Total	85.2%	14.8%	100%

Chi-Square Tests

	Value	**Df**	**Asymp.Sig (2-Sided)**	**Exact Sig. (2-Sided)**	**Exact Sig. (1-Sided)**
Pearson Chi-Square	5.822[a]	1	0.016		
Continuity Correction[b]	0.993	1	0.319		
Likelihood Ratio	3.892	1	0.049		
Fisher's Exact Test				0.148	0.148
Linear-by-Linear Association	5.750	1	0.016		
N of Valid Cases	81				

NEONATAL MORTALITY VS OUTCOME



χ^2=5.822 P=0.016

Neonatal mortality is increased in the preterm group which is statistically significant.

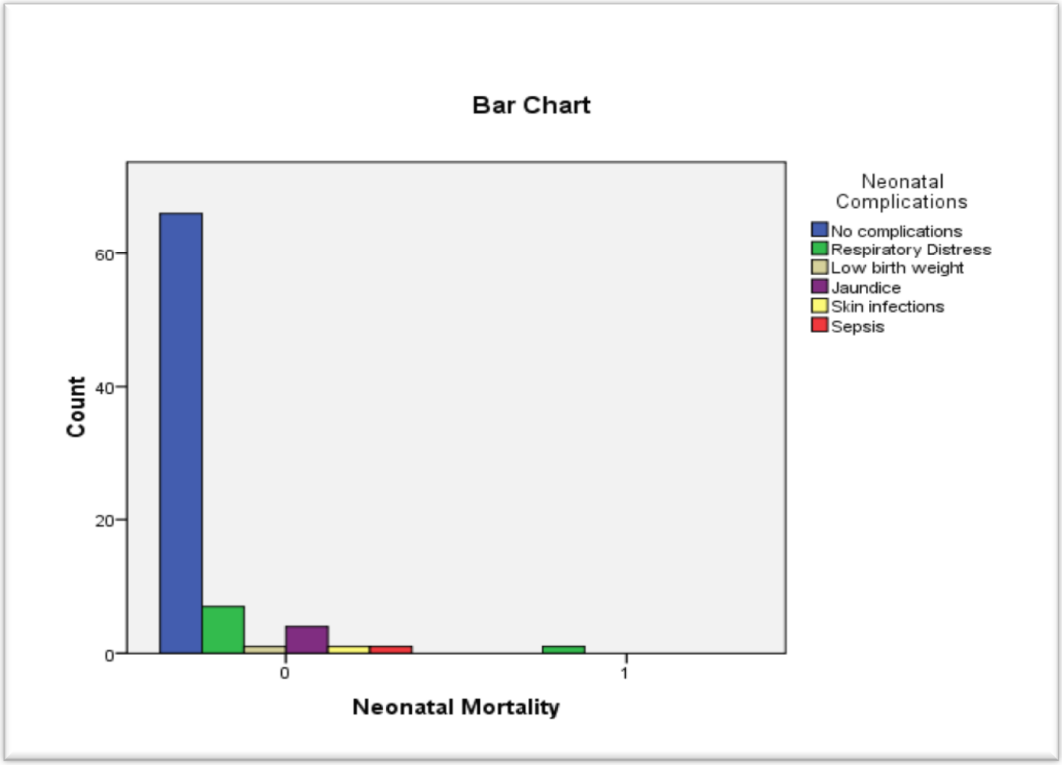
NEONATAL MORTALITY VS NEONATAL COMPLICATIONS

Crosstab					
			Neonatal Complications		
			No complications	Respiratory Distress	Low birth weight
Neonatal Mortality	0	Count	66	7	1
		% within Neonatal Complications	100.0%	87.5%	100.0%
		% of Total	81.5%	8.6%	1.2%
	1	Count	0	1	0
		% within Neonatal Complications	.0%	12.5%	.0%
		% of Total	.0%	1.2%	.0%
	Total	Count	66	8	1
		% within Neonatal Complications	100.0%	100.0%	100.0%
		% of Total	81.5%	9.9%	1.2%

Crosstab						
			Neonatal Complications			
			Jaundice	Skin infections	Sepsis	Total
Neonatal Mortality	0	Count	4	1	1	80
		% within Neonatal Complications	100.0%	100.0%	100.0%	98.8%
		% of Total	4.9%	1.2%	1.2%	98.8%
	1	Count	0	0	0	1
		% within Neonatal Complications	0.0%	0.0%	0.0%	1.2%
		% of Total	0.0%	0.0%	0.0%	1.2%
	Total	Count	4	1	1	81
		% within Neonatal Complications	100.0%	100.0%	100.0%	100.0%
		% of Total	4.9%	1.2%	1.2%	100.0%

Chi-Square Tests			
	Value	**Df**	**Asymp. Sig. (2-sided)**
Pearson Chi-Square	9.239[a]	5	0.100
Likelihood Ratio	4.748	5	0.447
Linear-by-Linear Association	.400	1	0.527
N of Valid Cases	81		

NEONATAL MORTALITY VS NEONATAL COMPLICATIONS



χ^2 =9.239 P=0.1000

There is no significant difference between neonatal mortality with respect to various neonatal complications.

GROUP STATISTICS AND INDEPENDENT SAMPLE TEST

BIOMARKER VS OUTCOME

Group Statistics					
	Outcome	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Progesterone 24 to 28 Weeks	Pre-term	12	3271.67	350.201	101.094
	Term	69	4391.70	315.002	37.922
Progesterone 29to 32 Weeks	Pre-term	12	2625.75	220.241	63.578
	Term	69	3735.52	272.550	32.811

Independent Samples Test				
		Levene's Test for Equality of Variances		**t-test for Equality of Means**
		F	Sig.	T
Progesterone 24 to 28 Weeks	Equal variances assumed	0.003	0.954	-11.186
	Equal variances not assumed			-10.373
Progesterone 29 to 32 Weeks	Equal variances assumed	0.822	0.367	-13.345
	Equal variances not assumed			-15.511

Independent Samples Test				
		t-test for Equality of Means		
		df	Sig. (2-tailed)	Mean Difference
Progesterone 24 to 28 Weeks	Equal variances assumed	79	0.000	-1120.029
	Equal variances not assumed	14.268	0.000	-1120.029
Progesterone 29to 32 Weeks	Equal variances assumed	79	0.000	-1109.772
	Equal variances not assumed	17.440	0.000	-1109.772

Independent Samples Test				
		t-test for Equality of Means		
			95% Confidence Interval of the Difference	
		Std. Error Difference	Lower	Upper
Progesterone 24 to 28 weeks	Equal variances assumed	100.129	-1319.331	-920.727
	Equal variances not assumed	107.973	-1351.201	-888.857
Progesterone 29to 32 Weeks	Equal variances assumed	83.161	-1275.299	-944.244
	Equal variances not assumed	71.545	-1260.430	-959.113

Progesterone 24-28 Weeks	t = -11.186	P =0.000
Progesterone 29-32 Weeks	t = -13.345	P =0.000

There is a statistical significance existing between labor outcome with respect to progesterone level between 24 to 28 weeks and 29 to 32 weeks.i.e., lower the progesterone level, higher the incidence of preterm labor.

BIOMARKER VS NEONATAL COMPLICATIONS

Group Statistics			
	Neonatal Complications	**N**	**Mean**
Progesterone 24 to 28 Weeks	Neonatal complications	15	3608.93
	No complications	66	4365.95
Progesterone 29to 32 Weeks	Neonatal complications	15	3000.27
	No complications	66	3700.85

Group Statistics			
	Neonatal Complications	**Std. Deviation**	**Std. Error Mean**
Progesterone 24 to 28 Weeks	Neonatal complications	626.924	161.871
	No complications	359.766	44.284
Progesterone 29to 32 Weeks	Neonatal complications	646.492	166.923
	No complications	311.924	38.395

Independent Samples Test				
		Levene's Test for Equality of Variances		t-test for Equality of Means
		F	Sig.	t
Progesterone 24 to 28 Weeks	Equal variances assumed	13.355	0.000	-6.306
	Equal variances not assumed			-4.511
Progesterone 29to 32 Weeks	Equal variances assumed	27.593	0.000	-6.239
	Equal variances not assumed			-4.090

Independent Samples Test				
		t-test for Equality of Means		
		df	**Sig. (2-tailed)**	**Mean Difference**
Progesterone 24 to 28 Weeks	Equal variances assumed	79	0.000	-757.021
	Equal variances not assumed	16.155	0.000	-757.021
Progesterone 29to 32 Weeks	Equal variances assumed	79	0.000	-700.582
	Equal variances not assumed	15.511	0.001	-700.582

Independent Samples Test				
		t-test for Equality of Means		
			95% Confidence Interval of the Difference	
		Std. Error Difference	Lower	Upper
Progesterone 24 to 28 Weeks	Equal variances assumed	120.050	-995.974	-518.068
	Equal variances not assumed	167.819	-1112.506	-401.537
Progesterone 29to 32 Weeks	Equal variances assumed	112.294	-924.098	-477.066
	Equal variances not assumed	171.282	-1064.616	-336.547

Progesterone 24-28 Weeks	t = -6.306	P =0.000
Progesterone 29-32 Weeks	t = -6.239	P =0.000

There is a statistical significance existing between neonatal complications and progesterone level between 24 to 28 weeks and 29 to 32 weeks .i.e., lower the progesterone level , greater the neonatal complications.

CERVIX LENGTH VS OUTCOME

Group Statistics					
	Outcome	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
cx 24 to 28 Weeks	Pre term	12	2.917	0.1946	0.0562
	Term	69	3.555	0.2373	0.0286
cx 29 to 32 Weeks	Pre term	12	2.592	0.1379	0.0398
	Term	69	3.442	0.2366	0.0285

Independent Samples Test					
		Levene's Test for Equality of Variances		**t-test for Equality of Means**	
		F	Sig.	T	Df
cx 24 to 28 wks	Equal variances assumed	1.673	.200	-8.803	79
	Equal variances not assumed			-10.128	17.240
cx 29 to 32 wks	Equal variances assumed	4.723	.033	-12.057	79
	Equal variances not assumed			-17.372	24.130

Independent Samples Test			
		t-test for Equality of Means	
		95% Confidence Interval of the Difference	
		Lower	Upper
cx 24 to 28 weeks	Equal variances assumed	-0.7828	-0.4941
	Equal variances not assumed	-0.7713	-0.5056
cx 29 to 32 weeks	Equal variances assumed	-0.9908	-0.7100
	Equal variances not assumed	-0.9514	-0.7494

Independent Samples Test				
		t-test for Equality of Means		
		Sig. (2-tailed)	Mean Difference	Std. Error Difference
cx 24 to 28 wks	Equal variances assumed	.000	-.6384	.0725
	Equal variances not assumed	.000	-.6384	.0630
cx 29 to 32 wks	Equal variances assumed	.000	-.8504	.0705
	Equal variances not assumed	.000	-.8504	.0490

Cervix length 24-28 Weeks	t = -5.899	P =0.000
Cervix length 29-32 Weeks	t = -6.457	P =0.000

There is a statistical significant increase in the risk of preterm labor with respect to decrease in cervix length between 24 to 28 weeks and 29 to 32 weeks.

CERVIX LENGTH VS NEONATAL COMPLICATIONS

Group Statistics					
	Neonatal Complications	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
cx 24 to 28 weeks	Neonatal complications	15	3.087	0.3091	0.0798
	No complications	66	3.545	0.2632	0.0324
cx 29 to 32 weeks	Neonatal complications	15	2.853	0.4121	0.1064
	No complications	66	3.421	0.2798	0.0344

Independent Samples Test					
		Levene's Test for Equality of Variances		**t-test for Equality of Means**	
		F	**Sig.**	**t**	**Df**
cx 24 to 28 weeks	Equal variances assumed	1.469	0.229	-5.899	79
	Equal variances not assumed			-5.327	18.886
cx 29 to 32 weeks	Equal variances assumed	8.930	0.004	-6.457	79
	Equal variances not assumed			-5.078	17.048

Independent Samples Test				
		t-test for Equality of Means		
		Sig. (2-tailed)	Mean Difference	Std. Error Difference
cx 24 to 28 weeks	Equal variances assumed	0.000	-0.4588	0.0778
	Equal variances not assumed	0.000	-0.4588	0.0861
cx 29 to 32 weeks	Equal variances assumed	0.000	-0.5679	0.0879
	Equal variances not assumed	0.000	-0.5679	0.1118

Independent Samples Test			
		t-test for Equality of Means	
		95% Confidence Interval of the Difference	
		Lower	Upper
cx 24 to 28 weeks	Equal variances assumed	-0.6136	-0.3040
	Equal variances not assumed	-0.6391	-0.2784
cx 29 to 32 weeks	Equal variances assumed	-0.7429	-0.3928
	Equal variances not assumed	-0.8038	-0.3320

Cervix length 24-28 Weeks	t = -8.803	P =0.000
Cervix length 29-32 Weeks	t = -12.057	P =0.000

There is a statistical significant increase in the risk of neonatal complications with decreasing cervix length between 24 to 28 weeks and 29 to 32 weeks.

CORRELATION

BMI VS BIOMARKER/CERVIX LENGTH

	Progesterone 24-28 weeks	**Progesterone 29-32 weeks**	**Cervix length 24-28 weeks**	**Cervix length 29-32 weeks**
BMI	t = - 0.103	t = - 0.031	t = - 0.071	t = - 0.018
	P = 0.361	P = 0.785	P = 0.530	P = 0.875
	Not Significant	Not Significant	Not Significant	Not Significant

There is no statistical significance existing between BMI and pregnancyoutcome – term/preterm.

HEIGHT, WEIGHT, BMI VS OUTCOME

Group Statistics					
	Outcome	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Height	Pre-term	12	153.92	5.534	1.598
	Term	69	155.04	5.574	.671
Weight	Pre-term	12	54.42	11.912	3.439
	Term	69	57.87	10.492	1.263
BMI	Pre-term	12	23.01	4.874	1.407
	Term	69	24.11	3.976	.479

Independent Samples Test					
		Levene's Test for Equality of Variances		**t-test for Equality of Means**	
		F	Sig.	T	df
Height	Equal variances assumed	0.204	0.653	-0.647	79
	Equal variances not assumed			-0.650	15.148
Weight	Equal variances assumed	1.095	0.299	-1.032	79
	Equal variances not assumed			-0.943	14.127
BMI	Equal variances assumed	2.193	0.143	-0.854	79
	Equal variances not assumed			-0.739	13.663

Independent Samples Test				
		t-test for Equality of Means		
		Sig. (2-tailed)	Mean Difference	Std. Error Difference
Height	Equal variances assumed	0.520	-1.127	1.742
	Equal variances not assumed	0.525	-1.127	1.733
Weight	Equal variances assumed	0.305	-3.453	3.347
	Equal variances not assumed	0.362	-3.453	3.663
BMI	Equal variances assumed	0.396	-1.099	1.286
	Equal variances not assumed	0.472	-1.099	1.486

Independent Samples Test			
		t-test for Equality of Means	
		95% Confidence Interval of the Difference	
		Lower	Upper
Height	Equal variances assumed	-4.594	2.340
	Equal variances not assumed	-4.817	2.564
Weight	Equal variances assumed	-10.115	3.209
	Equal variances not assumed	-11.304	4.398
BMI	Equal variances assumed	-3.659	1.461
	Equal variances not assumed	-4.294	2.096

Height	Weight	BMI
t = - 0.647	t = - 1.032	t = - 0.854
P = 0.520	P = 0.305	P = 0.396
Not Significant	Not Significant	Not Significant

There is no statistical significance existing between height, weight and BMI with respect to pregnancy outcome – term/preterm.

HEIGHT, WEIGHT, BMI VS NEONATAL COMPLICATIONS

Group Statistics					
	Neonatal Complications	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Height	Neonatal complications	15	154.13	6.707	1.732
	No complications	66	155.05	5.296	.652
Weight	Neonatal complications				2.388
	No complications	66	58.26	10.872	1.338
BMI	Neonatal complications	15	22.593	4.0383	1.0427
	No complications	66	24.252	4.0886	.5033

Independent Samples Test					
		Levene's Test for Equality of Variances		**t-test for Equality of Means**	
		F	**Sig.**	**t**	**Df**
Height	Equal variances assumed	1.506	0.223	-0.572	79
	Equal variances not assumed			-0.493	18.170
Weight	Equal variances assumed	0.083	0.774	-1.602	79
	Equal variances not assumed			-1.774	23.670
BMI	Equal variances assumed	.126	.724	-1.421	79
	Equal variances not assumed			-1.432	21.037

Independent Samples Test				
		t-test for Equality of Means		
		Sig. (2-tailed)	Mean Difference	Std. Error Difference
Height	Equal variances assumed	0.569	-0.912	1.594
	Equal variances not assumed	0.628	-0.912	1.850
Weight	Equal variances assumed	0.113	-4.858	3.033
	Equal variances not assumed	0.089	-4.858	2.737
BMI	Equal variances assumed	0.159	-1.6582	1.1670
	Equal variances not assumed	0.167	-1.6582	1.1578

Independent Samples Test			
		t-test for Equality of Means	
		95% Confidence Interval of the Difference	
		Lower	Upper
Height	Equal variances assumed	-4.084	2.260
	Equal variances not assumed	-4.797	2.973
Weight	Equal variances assumed	-10.894	1.179
	Equal variances not assumed	-10.512	.796
BMI	Equal variances assumed	-3.9810	.6646
	Equal variances not assumed	-4.0657	.7493

Height	Weight	BMI
t = - 0.572	t = - 1.602	t = - 1.421
P = 0.569	P = 0.113	P = 0.159
Not Significant	Not Significant	Not Significant

There is no statistical significance existing between height, weight and BMI with respect to neonatal complications.

LOGISTIC REGRESSION

Dependent Y	GA_at_delivery
Independent X	progesterone_24_to_28_wks progesterone 24 to 28 wks
Sample size	81
Coefficient of determination R^2	0.5486
Residual standard deviation	1.2407

Regression Equation

y = 26.1645 + 0.002658 x					
Parameter	Coefficient	Std. Error	95% CI	t	P
Intercept	26.1645	1.1545	23.8665 - 28.4625	22.6629	<0.0001
Slope	0.002658	0.0002713	0.002118 - 0.003198	9.7977	<0.0001

Analysis of Variance

Source	DF	Sum of Squares	Mean Square
Regression	1	147.7583	147.7583
Residual	79	121.5998	1.5392

F-ratio	95.9945
Significance level	P<0.001

LOGISTIC REGRESSION

Dependent Y	GA_at_delivery
Independent X	progesterone_29to_32_wks progesterone 29to 32 wks
Sample size	81
Coefficient of determination R^2	0.5763
Residual standard deviation	1.2019

Regression Equation

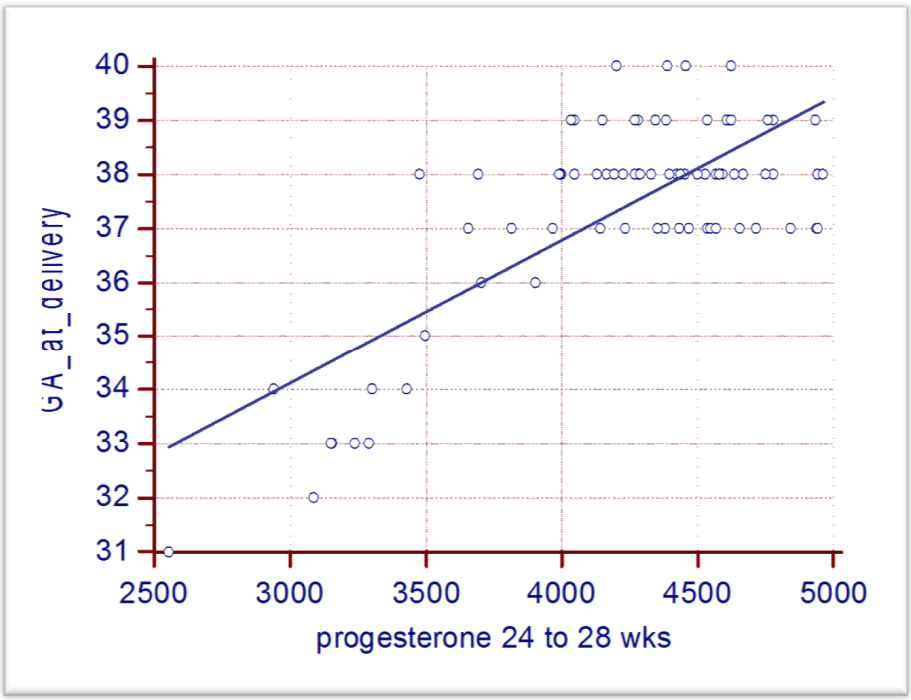
y = 26.9582 + 0.002923 x					
Parameter	Coefficient	Std. Error	95% CI	T	P
Intercept	26.9582	1.0156	24.9367 - 28.9797	26.5437	<0.0001
Slope	0.002923	0.0002819	0.002361- 0.003484	10.3664	<0.0001

Analysis of Variance

Source	DF	Sum of Squares	Mean Square
Regression	1	155.2374	155.2374
Residual	79	114.1206	1.4446

F-ratio	107.4631
Significance level	P<0.001

The scatter diagram shows that there exists a linear relationship between salivary progesterone level and cervix length with respect to labor outcome.


GA_at_delivery
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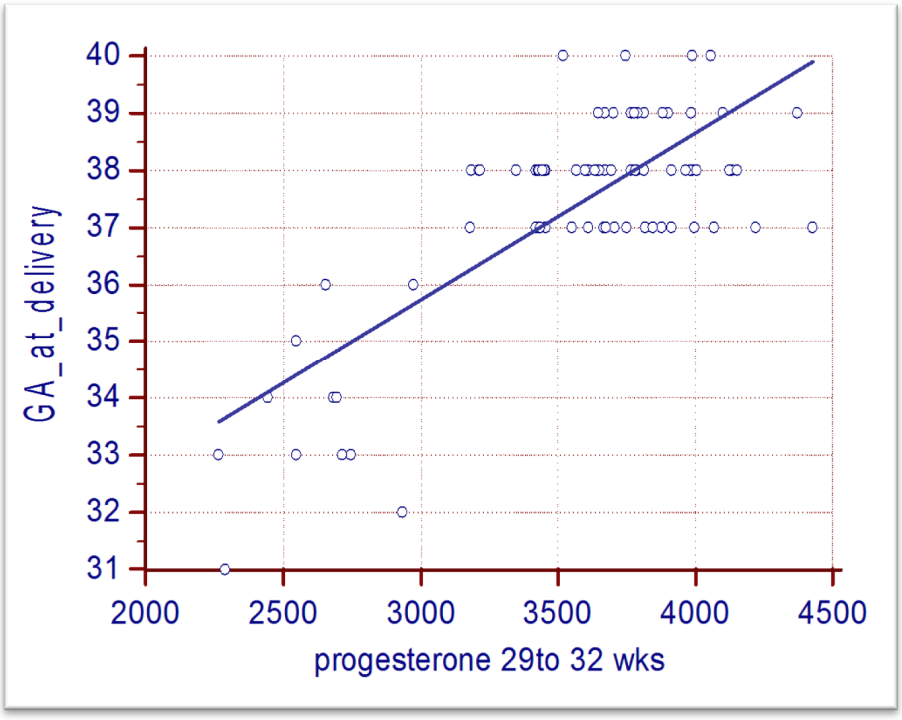
2500
3000
3500
4000
4500
5000
progesterone 24 to 28 wks


GA_at_delivery
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2500
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3500
4000
4500
progesterone 29to 32 wks

Discussion

DISCUSSION

A total of 90 women were enrolled in our study. Two women were diagnosed to have Hyperglycemia in pregnancy between 29-32 weeks and were excluded from the study. Three women developed hypertensive disorder of pregnancy and were excluded from the study. One woman was diagnosed by USG to have fetal growth restriction with oligohydramnios and was excluded from the study. Three women did not turn up between 29-32 weeks of gestation due to various reasons and were excluded from the study.

The study analyzed the values of salivary progesterone estimation as a predictor of preterm birth. Salivary progesterone levels were compared with transvaginal cervical length during the same gestational age. Other variables-socioeconomic status, working status, height, weight, body mass index, passive smoking, neonatal complications and neonatal mortality were also analyzed.

- ROC curve was drawn for salivary progesterone between 24-28 weeks and 29-32 weeks with respect to term and preterm deliveries. Sensitivity and specificity of salivary progesterone in predicting preterm labor, when done between 24-28 weeks was 100% and 94.2% respectively,

when the criterion was set as ≤3903pg/ml. The same when repeated between 29-32 weeks, sensitivity and specificity was 100% and 100% respectively when the criterion was set as ≤2975pg/ml.

- Similarly, ROC curve was drawn for transvaginal cervical length between 24-28 weeks and 29-32 weeks with respect to term and preterm deliveries. Sensitivity and specificity of transvaginal cervical length in predicting preterm labor was 91.7% and 95.7% respectively at 24-28 weeks when the criterion was set as ≤ 3.1cm and 100% and 98.6% respectively, when done at 29-32 weeks, and the criterion set as ≤ 2.9cm.

- The sensitivity and specificity for both salivary progesterone and transvaginal cervical length in prediction of preterm labor were greater when done at a later gestational age.

- ROC curve was drawn for salivary progesterone between 24-28 weeks and 29-32 weeks with respect to neonatal complications. Sensitivity and specificity were 100% and 93.9% respectively when done between 24-28 weeks and criterion set as ≤3703pg/ml. Sensitivity and specificity were 100% and 98.5% respectively when done between 29-32 weeks and criterion set as ≤2935pg/ml.

- ROC curve was drawn for transvaginal cervix length between 24-28 weeks and 29-32 weeks with respect to neonatal complications. Sensitivity and specificity were 100% and 93.9% respectively when done between 24-28 weeks and criterion set as ≤3.1cm. Sensitivity and specificity were 100% and 97%, when done between 29-32 weeks and criterion set as ≤2.7cm.

- The relation of age with respect to labor outcome describes the chi-square =0.787 and P=0.675 which is not significant. Thus age did not have any impact on labor outcome.

- The relation of BMI with respect to labor outcome describes the chi-square= 3.027 and P = 0.387 which is not significant.. Thus BMI did not have any impact on labor outcome.

- The relation of socioeconomic status with respect to preterm labor describes the chi square = 2.051 and P = 0.562 which is not significant. Thus socioeconomic status did not have any impact on the prediction for preterm labor.

- The relation of socioeconomic status with respect to neonatal complications describes the chi square = 13.108 and P = 0.594 which is not significant. Thus socioeconomic status did not have any impact on neonatal complications.

- The relation of women in working group for risk of preterm labor describes the chi square = 0.875 and P =0.350 which is not significant. Thus women who belonged to the working group did not have a predilection for preterm labor.

- The relation of women in working group for risk of neonatal complications describes chi square = 4.754 and P = 0.447 which is not significant. Thus women who belonged to the working group did not have a predilection for neonatal complications.

- The relation of different inclusion criteria with respect to preterm labor describes the chi square=5.366 and P = 0.068 which is not significant. Thus percentage of recurrence of preterm labor does not vary among the group with different inclusion criteria.

- The relation of different inclusion criteria with respect to neonatal complications describes the chi square =19.176 and P = 0.038 which is significant. Thus the neonatal complications did have a significant relationship with history of abortion and preterm group i.e 38.3% with preterm labor and abortion group and 23.5% with PPROM group.

- The relation of passive smoking with preterm labor describes the chi square = 4.348 and P = 0.037 which is significant. There is an increased

incidence of preterm labor in group with history of passive smoking i.e 66.7% in preterm group and 34.8% in term group.

- The relation of passive smoking with neonatal complications describes the chi square = 7.315 and P = 0.198 which is not significant. There is no increased incidence of neonatal complications in group with history of passive smoking.

- The relation of NICU admission with respect to pregnancy outcome, term/preterm describes the chi square = 45.960 and P = 0.000 which is significant. Thus neonates belonging to preterm birth group had higher incidence of NICU admissions i.e 13.6% in preterm labor group vs 6.2% in term labor group.

- The relation of NICU admission with respect to neonatal complications describes the chi square = 74.787 and P = 0.000 which is significant. 99% - Respiratory distress syndrome, 4.9% Jaundice, 1.2% Low birth weight, 1.2% skin infections, 1.2% sepsis.

- The relation of neonatal mortality with respect to preterm labor describes the chi square = 5.822 and P = 0.016 which is significant. Incidence of neonatal mortality is1.2% in the preterm group.

- The relation of neonatal mortality with respect to neonatal complications describes the chi square = 9.239 and P = 0.100 which is not significant.

- The t-test showed a good correlation between salivary progesterone and transvaginal cervical length with respect to pregnancy outcome and neonatal complications as they describe P = 0.000 which is significant. i.e., lower the progesterone, higher the incidence of preterm labor and neonatal complications.

- The correlation between BMI with salivary progesterone and cervix length between 24 to 28 weeks and 29-32 weeks. (Progesterone 24-28 weeks- P = 0.361; Progesterone 29-32 weeks- P = 0.785; cervix 24-28 weeks- P = 0.530; cervix 29-32 weeks- P = 0.875) is not significant. Thus pre pregnancy BMI had no impact on pregnancy outcome in this study.

- The t-test done for correlating height, weight and BMI with pregnancy outcome describes P value (height- P = 0.520; weight- P = 0.305 and BMI- P = 0.396) which is not significant. Height, weight and BMI did not have significant impact on pregnancy outcome i.e term or preterm.

- The t-test done for correlating height, weight and BMI with neonatal complications describes P value (height - P = 0.569; Weight -P = 0.113; BMI- P = 0.159) which is not significant. Thus height, weight and BMI did not have significant impact on neonatal complications.

- The logistic regression curve relating salivary progesterone level to gestational age at delivery shows a statistically significant linear relationship. i.e., lower the salivary progesterone level, lesser is the gestational age of delivery.

- The regression equation thus derived i.e., multiplying the estimated salivary progesterone level by a constant value and adding another constant value for that gestational age, at which salivary progesterone level is estimated, gives the gestational age of delivery.

Y= 26.1645 + 0.002658 x Salivary progesterone level at 24 to 28 weeks.

Y = 26.9582 + 0.002923 x Salivary progesterone level at 29 to 32 weeks.

Where, Y is the gestational age at delivery.

Summary

SUMMARY

1. The age, pre- pregnancy height, weight and Body mass index was not useful in predicting the preterm labor and neonatal complications.
2. The risk of preterm labour were not increased in working women.
3. Socio economic status did not have a significant impact on labor outcome and neonatal complications.
4. The incidence of recurrence of preterm labor did not vary among patients with previous history of spontaneous abortion between 20-28 weeks, preterm labor and PPROM.
5. The risk of neonatal complications in women with preterm labor were more in those with previous history of spontaneous abortion between 20-28 weeks and previous history of preterm labor. A similar association was not seen in those with previous history of PPROM.
6. Women with passive smoking (i.e history of smoking among family members) were at a greater risk for preterm labor.
7. Neonates of women with passive smoking were not more prone for neonatal complications.
8. Risk of NICU admissions were more in preterm deliveries.
9. Most common cause for admission in NICU, in preterm deliveries being respiratory distress syndrome followed by jaundice.

10. Neonatal mortality is more in preterm deliveries, the prime cause being respiratory distress.
11. Salivary progesterone estimation at 24-28 weeks and then at 29-32 weeks in asymptomatic high risk AN mothers was a valuable predictor of preterm labor when the cut off was fixed at ≤ 3903pg/ml at 24-28 weeks and ≤ 2975 pg/ml at 29-30 weeks.
12. Transvaginal cervical length measured at 24-28 weeks and then at 29-32 weeks, at the time of salivary progesterone estimation also, had similar sensitivity and specificity in predicting preterm labor when the cut off was fixed at ≤3.1cm at 24-28 weeks and ≤2.9cm at 29-32 weeks.

Conclusion

CONCLUSION

Salivary progesterone is a better predictor of preterm labor when compared to transvaginal cervical length, as it has better sensitivity and specificity, is a non-invasive method and sample collection is easier. Though transvaginal scan is available in every antenatal unit, it needs technical expertise and further , it shows inter-observer variability.

An ideal biochemical marker must be able to predict the problem at an earlier GA for appropriate interventions to be done. Hence it is justified in doing the salivary progesterone estimation at 24-28 weeks though it has comparatively lesser sensitivity and specificity than at 29-32 weeks.

In utero transfer can be advised for antenatal women whose salivary progesterone level are $\leq$3903pg/ml at 24-28 weeks and $\leq$2975pg/ml at 29-32 weeks for better obstetric outcome and better neonatal salvageability.

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Annexures

PROFORMA

Name :

Age :

Address :

S.No :

Occupation :

Height :

Weight :

Body mass index :

Obstetric code :

Last menstrual period :

Expected date of delivery :

Socio economic status :

Menstrual History :

Marital History :

Obstetric History :

Dating scan done or not :

Anomaly scan done or not :

Past History :

H/O abortion/preterm labour/prelabour rupture of membrane.

DM/HT/Twins/Heart disease/on any drugs.

TB/epilepsy/renal disease :

Family History H/O smoking among family members in her residence

Personal History :

General Examination :

Pallor

Edema

Vitals

Temperature :

Pulse rate :

Blood pressure :

Respiratory rate :

Systemic Examination

Cardiovascular System :

Respiratory System :

Central Nervous System

Abdominal Examination

INVESTIGATIONS

1. Urine - Sugar/Albumin/Microscopy/culture and sensitivity
2. Complete haemogram
3. OGCT
4. Blood Urea
5. High vaginal swab culture and sensitivity
6. Dating USG
7. Anomary USG
8. Salivary progesterone estimation-twice 1st sample between 24 to 28 weeks of GA and 2nd 3-4 weeks after 1st sample
9. Transvaginal cervical length measurement-done along with salivary
10. progesterone estimation

Delivered at

Gestational age in weeks

Mode of delivery

NICU Admissions:

Birth weight

Neonatal morbidity

Neonatal morality

MASTER CHART

S.NO	Name	Age	SE Status	Working/Not working	Ht	Wt	BMI	Obstetric Code	Inclusion criteria	H/O Smoking among family members	1st sample		2nd Sample		GA at delivery (in Wks)	B.WT	NICU Admission	Neonatal Mortality	Outcome	Neonatal Complications
											prog	cx	Prog	cx						
1	Amutha	29	4	1	155	75	31.2	G4P2L1A1	2	1	3150	2.7	2748	2.4	33+4	2.24	1	0	1	0
2	Dhana lakshmi	27	5	0	148	45	20.5	G2P1L0	2	1	2942	2.8	2696	2.5	34+2	1.9	1	0	1	1
3	Rukayal	27	4	1	153	60	25.6	G2A1	1	0	4268	3.5	3596	3.5	38+2	2.8	0	0	0	0
4	Kalpana	29	4	0	149	42	18.9	G3P1L1A1	1	0	4751	3.8	4124	3.6	38+6	3.1	0	0	0	0
5	Gomathi	25	5	0	154	49	20.7	G3P1L1A1	2	0	3903	3.4	2975	2.9	36+3	2.46	0	0	1	0
6	Amalu	34	4	0	158	53	21.3	G4P1L1A2	1	0	4223	4	3643	3.8	38+1	2.9	0	0	0	0
7	Renuka	28	3	0	163	50	18.9	G4A3	1	1	4939	3.9	3815	3.7	37+5	3.1	0	0	0	0
8	Sumathi	24	4	0	164	58	21.6	G3P1L1A1	1	1	4779	3.6	4367	3.5	39+1	2.78	0	0	0	0
9	Sufiya	30	4	0	153	63	26.9	G4P1L1A2	2	1	3703	3	2654	2.7	36+2	2.45	1	0	1	1
10	Sameena	29	4	1	159	75	29.6	G4P1L1A2	2	0	4280	3.2	3186	3	38+1	2.4	0	0	0	0
11	Amsa Lekha	29	5	0	160	44	17.2	G3P1L1A1	3	0	4150	3.3	3768	3.3	39+1	2.8	0	0	0	0
12	Meenakshi	31	4	0	159	47	18.6	G3P1L1A1	3	0	3088	2.8	2935	2.6	32+1	1.8	1	0	1	1
13	Prema	32	4	1	142	55	27.5	G4P3L1D2	3	0	4269	3.3	3786	3.2	38	2.45	1	0	0	2
14	Maha lakshmi	32	4	0	149	56	25.5	G3P1L1A1	1	0	4536	3.8	3549	3.6	37+2	2.7	0	0	0	0
15	Sufaija	23	4	0	148	52	23.6	G4A3	1	0	4454	3.9	3987	3.8	40+2	3	0	0	0	0
16	Maria	38	3	0	156	70	29.2	G2P1L1	3	0	3497	3.1	2548	2.6	35+5	2.1	1	0	1	1
17	Selvi	26	4	0	162	68	26.2	G4P1L1A2	3	0	4045	3.6	3216	3.4	38+4	2.65	0	0	0	0
18	Sasi kala	29	3	0	150	50	22.2	G3P2L1A1	2	0	3814	3.5	3418	3.4	37+3	2.55	0	0	0	0
19	Nirmala	28	3	0	153	70	29.9	G2A1	1	0	3476	3.5	3212	3.5	38+3	2.64	0	0	0	0
20	Sudha	23	4	1	155	58	24.2	G4P1L1A2	3	1	2554	2.7	2292	2.6	31+2	1.5	1	1	1	1
21	Rangeela	22	5	0	151	48	21	G2A1	1	0	4931	4	3775	3.8	39+5	3.2	0	0	0	0
22	Vallithai	27	4	0	148	62	28.2	G4P1L1A2	1	1	4280	3.5	3668	3.2	39	2.54	0	0	0	0
23	Sathya	28	4	0	154	65	27.4	G3P1L1A1	3	0	3156	2.9	2549	2.5	33+3	1.75	1	0	1	1
24	Sameeja	24	3	1	159	55	21.8	G2A1	1	1	4635	3.8	3814	3.6	38+3	3	0	0	0	0
25	Nisha	18	5	0	150	45	20	G2A1	1	0	3693	3.2	3347	3.1	38+2	2.7	0	0	0	0

26	Vinothini	26	4	0	155	67	27.9	G2P1L1	3	1	3994	3.4	3456	3.3	38	2.3	0	0	0	0
27	Deepa	33	5	0	157	96	39	G2A1	1	1	3658	3.3	3434	3.2	37+3	2.94	0	0	0	0
28	Kokila	26	3	0	168	93	32.9	G4P1L1A2	3	0	4193	3.1	3564	2.7	38+3	3.3	0	0	0	0
29	Susuma	19	5	0	150	55	24.4	G2A1	1	0	4546	3	4425	3	37+5	2.75	0	0	0	0
30	Jeya pratha	28	5	0	153	60	25.6	G3P2L2	3	0	4712	3.4	3912	3.4	37+5	2.6	0	0	0	0
31	Nathiya	24	5	0	151	54	23.7	G2A1	1	1	4534	3.5	4097	3.4	39	2.65	1	0	0	3
32	Anjali	33	5	0	153	48	20.5	G2P1L1	2	0	4567	4	3843	3.9	37+6	3.4	0	0	0	0
33	Sumathi	25	4	0	162	55	21	G3P2L1	2	0	4959	3.7	3987	3.6	38+3	2.7	0	0	0	0
34	Sowmiya	25	4	0	156	53	21.8	G2P1L0	2	0	4389	3.5	3745	3.4	40+2	2.8	0	0	0	0
35	Aachal	21	5	1	158	46	18.5	G2A1	3	0	4467	3.5	3705	3.4	37+1	2.7	1	0	0	4
36	Amala	26	3	0	153	53	22.6	G3P1L1A1	3	1	4608	3.8	3984	3.2	39+2	3.1	0	0	0	0
37	Nazreen	32	3	0	158	50	20	G4P2L2A1	2	0	4328	3.6	3668	3.5	38+2	2.95	0	0	0	0
38	Periyanayaki	33	3	0	159	62	24.6	G3A2	1	0	4577	3.4	3632	3.4	38+4	2.75	0	0	0	0
39	Saritha	25	4	1	154	53	22.4	G3P1L1A1	2	1	4045	3.6	3814	3.6	39	2.55	0	0	0	0
40	Sowmiya	26	3	1	156	48	19.7	G3P2L1	3	0	4623	3.8	3517	3.5	40+3	3.3	0	0	0	0
41	Ajitha	24	4	1	150	46	20.4	G2A1	1	1	4667	3.5	3426	3.4	38+1	2.87	0	0	0	0
42	Nandhini	23	4	1	154	58	24.5	G2P1L1	2	0	4290	3.3	3912	3.3	38+6	2.65	0	0	0	0
43	Devi	29	4	1	156	60	24.7	G3P2L2	2	0	4528	3.5	3432	3.2	38+2	2.75	0	0	0	0
44	Shanthi	28	4	0	160	64	26	G2P1L1	3	1	4269	3.2	3901	3.2	39+2	3	0	0	0	0
45	Elayaka	29	4	0	154	60	25.3	G3P2L0	2	0	4233	3	3431	3	37+2	2.8	0	0	0	0
46	Sathya	20	5	0	142	36	18	G2A1	1	1	3241	2.9	2714	2.6	33+6	2	1	0	1	3
47	Nithya	24	5	0	156	51	20.9	G2P1L0	3	1	4352	3.7	3876	3.7	37+5	2.82	0	0	0	0
48	Jeevitha	25	3	0	158	52	20.9	G2P1L1	2	1	4777	3.5	3607	3.4	38+1	3.3	0	0	0	0
49	Archana	26	5	0	154	52	21.9	G3A2	1	1	4758	3.4	3879	3.2	39+5	2.69	0	0	0	0
50	Kavitha	26	4	1	164	59	22	G3A2	1	0	4434	3.6	3980	3.5	38+3	3.3	1	0	0	3
51	Vimal;a	28	4	1	152	46	20	G3P1L1A1	1	0	4653	3.3	3610	3.1	37+4	2.83	0	0	0	0
52	Rajeeswari	42	3	1	155	64	26.7	G4P1L1A2	1	1	4432	3.7	3453	3.7	37+1	2.8	0	0	0	0
53	Sasikala	29	4	1	162	56	21.4	G3P2L1	3	0	3967	3.7	3747	3.4	37+3	3.4	0	0	0	0
54	Santhanalakshmi	30	4	1	152	56	24.3	G3P2L1A1	2	0	4346	3.8	3703	3.5	39	2.7	0	0	0	0
55	Vinothini	27	4	0	149	56	25.2	G3A2	1	1	4936	3.6	4217	3.6	37+3	3.02	0	0	0	0
56	Muneeswari	19	5	0	152	42	18.3	G2A1	1	0	4351	3.7	3673	3.6	37+6	2.6	0	0	0	0
57	Srividhya	28	5	0	159	58	23	G3P1L1A1	3	1	4223	3.5	3650	3.5	38+3	2.55	1	0	0	5

58	Saranya	24	4	0	150	54	24	G3P1L0A1	2	1	3998	3.4	3419	3.3	38	2.8	0	0	0	0
59	Pramela	38	4	1	154	72	30.4	G4P2L1A1	2	0	4129	3.8	3780	3.7	38+4	3.15	0	0	0	0
60	Kamatchi	26	4	1	156	69	28.4	G2A1	1	1	4141	3.4	3997	3.4	37+4	2.64	0	0	0	0
61	Jerina	23	3	0	152	60	26	G2P1L1	2	0	4534	3.7	3645	3.6	39+1	3.08	0	0	0	0
62	Sarumathy	25	4	0	149	54	24.3	G3P2L0	2	1	3291	3	2268	2.7	33+5	2.1	1	0	1	1
63	Deepthi	26	3	1	164	68	25.4	G4P1L1A2	1	1	4396	3.6	3695	3.5	38+4	3.1	0	0	0	0
64	Fausya	24	3	1	154	72	30.4	G2A1	1	0	4592	3.8	3765	3.8	38+1	3.2	0	0	0	0
65	Dhanalakshmi	23	4	1	162	49	18.7	G3P1L1A1	2	1	3303	2.9	2685	2.6	34+1	2.2	1	0	1	1
66	Vijaya	23	4	1	154	60	25.3	G4P2L1A1	3	1	4270	3.2	3442	3.2	38+2	3.3	0	0	0	0
67	Jakera	21	4	0	151	46	20.2	G2A1	1	0	4621	3.7	3789	3.6	39+3	2.94	0	0	0	0
68	Hemavathy	21	4	0	160	42	16.4	G2P1L0	2	1	3432	2.8	2445	2.4	34+3	2.4	1	0	1	3
69	Gayathri	24	3	0	152	60	25.9	G4P1L1A2	1	0	4200	3.7	4054	3.6	40+4	3.4	0	0	0	0
70	Geethalakshmi	25	4	1	156	58	23.8	G4P2L2A1	3	0	3989	3.2	3609	3.2	38+1	2.7	0	0	0	0
71	Kamala	22	4	0	163	46	17.3	G2P1L0	2	0	4380	3.7	3180	3.4	37+2	2.6	0	0	0	0
72	Logeshwari	28	4	1	156	60	24.7	G3P1L0A1	2	0	4498	3.5	4150	3.4	38+6	2.89	0	0	0	0
73	Mohana	27	4	0	153	62	26.4	G5P1L1A3	1	1	4165	3.8	3965	3.7	38+3	2.78	0	0	0	0
74	Seetha	25	4	0	154	65	27.4	G2P1L1	2	1	4452	3.4	3986	3.4	38	2.9	0	0	0	0
75	Devika	35	3	0	161	61	23.5	G3P2L1	2	1	4566	3.5	4005	3.5	38+3	3.3	0	0	0	0
76	Anjali	28	3	0	146	54	25.3	G3P1L1A1	2	0	4034	3.6	3645	3.4	39+4	3.2	0	0	0	0
77	Parameswari	32	4	1	160	62	24.2	G2P1L0	2	0	4536	3.3	3665	3.1	37+5	3.08	0	0	0	0
78	Jothi	28	4	1	163	87	32.8	G2A1	1	0	4841	3.9	4067	3.8	37+6	2.65	0	0	0	0
79	Bhavani	24	5	1	143	50	25	G2P1L0	2	0	4425	3.6	4130	3.7	38+2	3.15	0	0	0	0
80	Murugeshwari	30	3	1	142	55	27.5	G4P2L1A1	2	0	4382	3.8	3763	3.8	39+4	3.2	0	0	0	0
81	Deepa	26	2	1	166	56	20.4	G2P1L1	2	0	4939	3.7	3449	3.6	38+1	2.95	0	0	0	0

Working	1	Smoking	1		NICU Admission	1	Neonatal Complication
Not Working	0	Not Smoking	0		Not admitted	0	(i) Respitatory Distress
Inclusion Criteria		Pregnancy Outcome					(ii) Low birth weight
(i) Abortion between 20 to 28							
Weeks	1	(i) Term	0				(iii) Jaundice
(ii) Preterm labor	2	(ii) Preterm	1				(iv) Skin infections
PPROM	3						(v) Sepsis

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. M.Mahalakshmi
Postgraduate M.S.(Obstetrics & Gynaecology)
Madras Medical College
Chennai – 600 003.

Dear Dr.M.Mahalakshmi,

The Institutional Ethics Committee has considered your request and approved your study titled **"Salivary progesterone as a biochemical marker to predict preterm birth in asymptomatic high risk women" No.24122014.**

The following members of Ethics Committee were present in the meeting held on 02.12.2014 conducted at Madras Medical College, Chennai-3.

1. Dr.C.Rajendran, M.D.,	: Chairperson
2. Dr.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
3. Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
4. Prof.R.Nandini, M.D., Inst.of Pharmacology, MMC	: Member
5. Prof.P.Ragumani, M.S., Professor, Inst.of Surgery, MMC	: Member
6. Prof.Md.Ali, M.D., D.M., Prof. & HOD of Medl.G.E., MMC	: Member
7. Prof.K.Ramadevi, Director, Inst.of Biochemistry, MMC	: Member
8. Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3	: Member
9. Prof.S.G.Sivachidambaram, M.D., Director i/c, Inst.of Internal Medicine, MMC	: Member
10. Thiru S.Rameshkumar, Administrative Officer	: Lay Person
11. Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
12. Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

8/12/14

Member Secretary, Ethics Committee

INFORMATION TO PARTICIPANTS

- We are conducting a study on the level of salivary level of progesterone, a hormone and length of cervix by transvaginal ultrasonogram and its effect on preterm labour i.e. delivery before 37 weeks of pregnancy.
- We are selecting antenatal women according to the need for the study. We wish that you participate in this study.
- In this study, we shall collect your saliva twice(1) between 24 to 28 weeks, 2) 3 to 4 weeks later) and do special test to measure the progesterone hormone level. Simultaneously, we shall measure the length of the cervix by transvaginal ultrasonogram. The tests you are subjected to, shall not affect you or your baby in uterus.
- Your participation in this study will not affect your AN care or any treatment if needed .
- The privacy of the patients in the research will be maintained throughout the study.
- In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.
- Taking part in this study is voluntary. You are free to decide whether to participate in this study or withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.
- The results of the special study may be intimated to ypu at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of the Investigator

Signature of the Participant

Date:

INFORMED CONSENT FORM

Title: "SALIVARY PROGESTERONE AS A BIOCHEMICAL MARKER TO PREDICT PRETERM BIRTH IN ASYMPTOMATIC HIGH RISK WOMEN''

Name of the Investigator **: Dr.M. Mahalakshmi**
Name of the Participant :
Name of the Institution : **INSTITUTE OF OBSTETRICS AND GYNAECOLOGY, EGMORE, CHENNAI**

I _____ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in this study.

1. I have read and understood this consent form and the information provided to me.
2. I have had the consent document explained to me.
3. I have been explained about the nature of the study.
4. I have been explained about my rights and responsibilities by the investigator.
5. I have informed the investigator of all the treatments I am taking or have taken in the past months/years including any native (alternative) treatments.
6. I have been advised about the risks associated with my participation in the study.*****
7. I agree to cooperate with the investigator and I will inform him /her immediately if I suffer unusual symptoms. *****
8. I have not participated in any research study within the past. *****
9. I am aware of the fact that I can opt out of the study at any time without having to give any reasoned this will not affect my future treatment in this hospital. *****
10. I am also aware that the investigators may terminate my participation in the study at any time, for any reason, without my consent. *****
11. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC if required.
12. I understand that my identity will be kept confidential if my data are publicly presented.
13. I have had my questions answered to my satisfaction.
14. I consent voluntarily to participate in the research/study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form, I attest that the information given in this document has been clearly explained to me and understood by me. I will be given a copy of this consent document.

For adult participants

1. Name and signature / thumb impression of the participant (or legal representative if participant incompetent)

Name _____ Signature_____ Date_____

2. Name and Signature of impartial witness (required for illiterate patients):

Name _____ Signature_____ Date_____

Address and contact number of the impartial witness:

3. Name and Signature of the investigator or his representative obtaining consent:

Name _____ Signature_____ Date_____

ஆராய்ச்சி தகவல் தாள்

சென்னை எழும்பூரில் உள்ள அரசு தாய் சேய் நல மருத்துவமனைக்கு வரும் முந்தைய கர்ப்பத்தில் குறைமாதத்தில் பிரசவித்து தற்போது கர்ப்பமுற்றிருக்கும் தாய்மார்களுக்கு இந்த கர்ப்பத்திலும் குறை மாதத்தில் பிரசவிக்க வாய்ப்பு உள்ளதா என்பது பற்றி ஆராய்ச்சி நடைபெற்று வருகின்றது.

நமது உமிழ்நீரில் பல உட்சுரப்பி இயக்குநீர் வகைகள் (ஹார்மோன்) உள்ளன. அவற்றில் புரஜெஸ்டிரோன் என்ற உட்சுரப்பி இயக்குநீர் அளவினைக் கொண்டும், மற்றும் கர்ப்பப்பை வாயின் நீளத்தை யோனி வழியாக செய்யும் ஸ்கேன் மூலம் அளப்பதன் மூலமும், குறைமாதத்தில் பிரசவமாகக்கூடிய வாய்ப்பை எளிதில் கண்டறிய முடியும் என்பதே இந்த ஆராய்ச்சியின் நோக்கமாகும்.

நீங்களும் இந்த ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம். இந்த ஆராய்ச்சியில் உங்களுடைய உமிழ்நீரை இருமுறை (I-24-28 வாரங்களில் II-3-4 வாரங்கள் கழித்து) சேகரித்து சில சிறப்பு பரிசோதனைக்கு உட்படுத்தி அதன் தகவல்களை ஆராய்வோம். அதே சமயத்தில் உங்கள் கர்ப்பப்பை வாயின் நீளத்தை யோனி வழியாக ஸ்கேன் செய்து அளப்போம். இதில் பங்கேற்பதால் தங்களுக்கு கிடைக்க வேண்டிய கவனிப்பிற்கோ, சிகிச்சைக்கோ எந்தவித பாதிப்பும் ஏற்படாது என்பதை தெரிவித்துக் கொள்கிறோம். மேலும் இந்த பரிசோதனைகளால் வயிற்றில் உள்ள குழந்தைக்கோ அல்லது உங்களுக்கோ எந்தவித பாதிப்பும் ஏற்படாது என்பதை தெரிவித்துக் கொள்கிறோம்.

முடிவுகளை அல்லது கருத்துக்களை வெளியிடும்போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியிலிருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த சிறப்புப பரிசோதனைகளின் முடிவுகளை ஆராய்ச்சியின்போது அல்லது ஆராய்ச்சியின் முடிவின்போது தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் பங்கேற்பாளர் கையொப்பம்

தேதி:

ஆராய்ச்சி ஒப்புதல் கடிதம்

ஆராய்ச்சி தலைப்பு:-

உமிழ்நீரில் உள்ள புரஜெஸ்டிரோன் என்ற உட்சுரப்பி இயக்குநீர் (ஹார்மோன்) அளவைக் கொண்டும் மற்றும் கர்ப்பப்பை வாயின் நீளத்தை ஸ்கேன் மூலம் அளந்தும், ஏற்கனவே குறைமாதத்தில் பிரசவித்து தற்போது கர்ப்பமாக இருக்கும் தாய்மார்களுக்கு இந்த முறையும் குறைமாதத்தில் பிரசவிக்க வாய்ப்புள்ளதா என்பதை தெரிந்து கொள்வது.

பெயர் தேதி

வயது நோயாளி எண்.

இனம் ஆராய்ச்சி சேர்க்கை எண்.

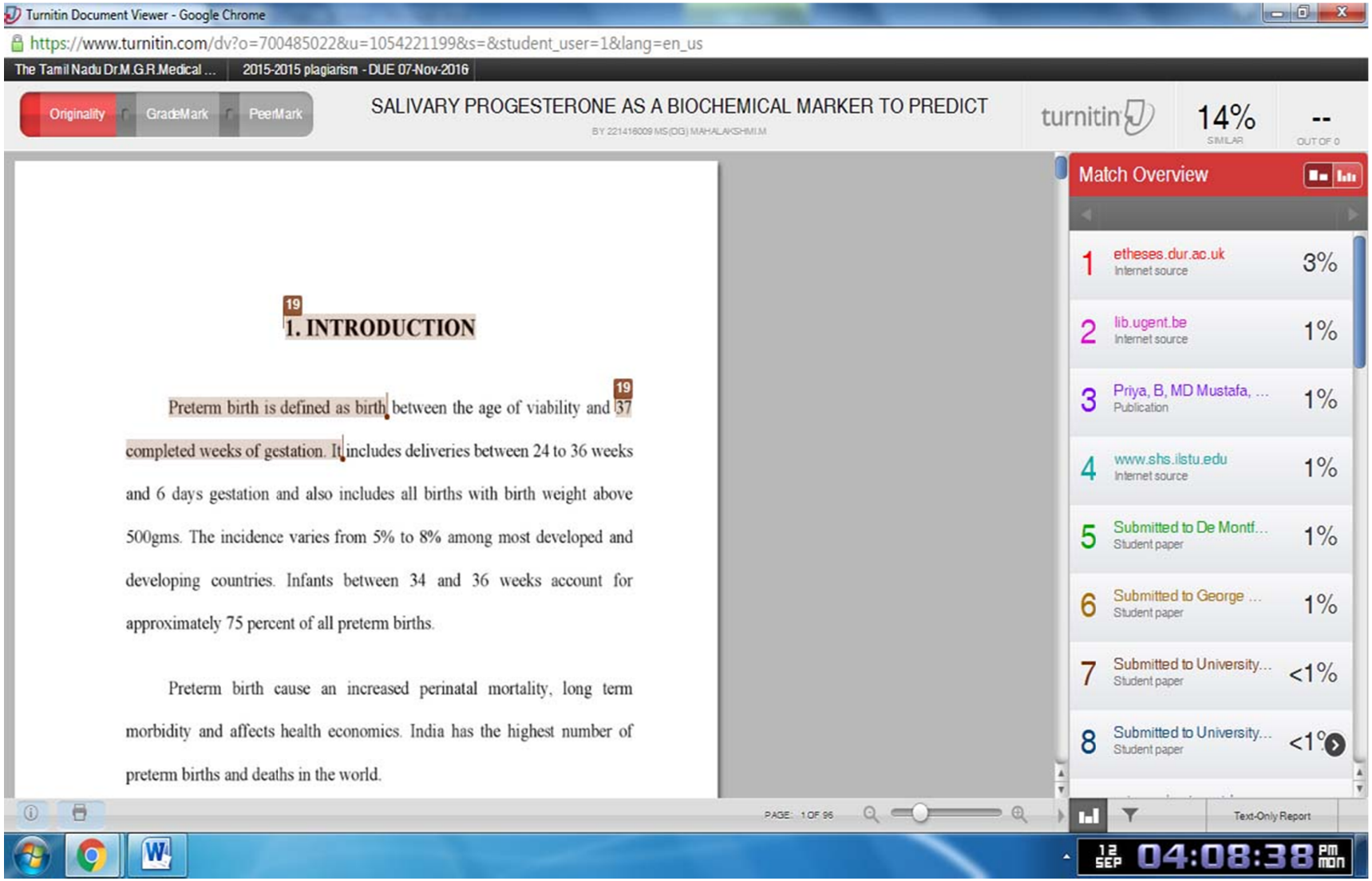
எனது உமிழ்நீரை பரிசோதனைக்கு உட்படுத்தவும் மற்றும் என் கர்ப்பப்பை வாயின் நீளத்தை யோனி வழியாக செய்யும் ஸ்கேன் (USG) மூலமாக அளக்கவும் எனக்கு சம்மதம்.

நான், குறைமாத பிரசவம் ஆகக்கூடிய வாய்ப்பினை கண்டறியும் இந்த ஆராய்ச்சியின் விபரங்களைக் கொண்ட தகவல் தாளைப் பெற்றுக் கொண்டேன்.

மேற்கூறிய பரிசோதனைகளால் வயிற்றில் இருக்கும் குழந்தைக்கோ அல்லது எனக்கோ எந்தவித பாதிப்பும் ஏற்படாது என்பதை மருத்துவர் மூலம் தெரிந்து கொண்டேன்.

நான் என்னுடைய சுயநினைவுடன் மற்றும் முழு சுதந்திரத்துடன் இந்த மருத்துவ ஆராய்ச்சியில் என்னை சேர்த்துக் கொள்ள சம்மதிக்கின்றேன்.

கையொப்பம்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Preterm birth is defined as birth between the age of viability and 37 completed weeks of gestation. It includes deliveries between 24 to 36 weeks and 6 days gestation and also includes all births with birth weight above 500gms. The incidence varies from 5% to 8% among most developed and developing countries. Infants between 34 and 36 weeks account for approximately 75 percent of all preterm births.
Preterm birth cause an increased perinatal mortality, long term morbidity and affects health economics. India has the highest number of preterm births and deaths in the world.
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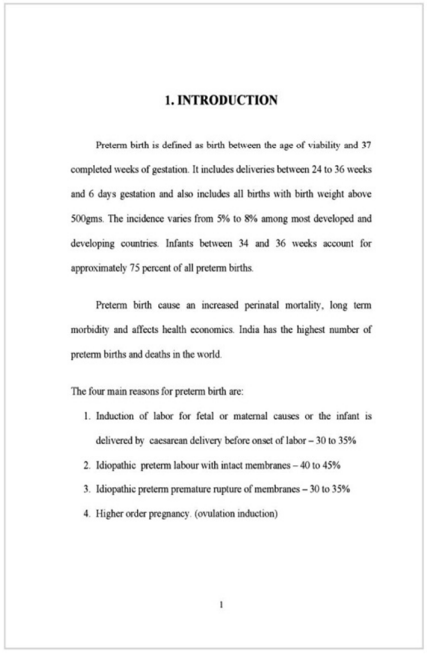

1. INTRODUCTION

Preterm birth is defined as birth between the age of viability and 37 completed weeks of gestation. It includes deliveries between 24 to 36 weeks and 6 days gestation and also includes all births with birth weight above 500gms. The incidence varies from 5% to 8% among most developed and developing countries. Infants between 34 and 36 weeks account for approximately 75 percent of all preterm births.

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The four main reasons for preterm birth are:

1. Induction of labor for fetal or maternal causes or the infant is delivered by caesarean delivery before onset of labor – 30 to 35%
2. Idiopathic preterm labour with intact membranes – 40 to 45%
3. Idiopathic preterm premature rupture of membranes – 30 to 35%
4. Higher order pregnancy. (ovulation induction)

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