

**COMPARISON OF ORAL NIFEDIPINE AND
TRANSDERMAL NITROGLYCERINE AS A
TOCOLYTIC FOR PRETERM LABOUR**

**A Dissertation Submitted to
THE TAMILNADU DR. M.G.R MEDICAL UNIVERSITY
CHENNAI**

In Partial Fulfilment of the Regulations
for the Award of the Degree of
M.S. (OBSTETRICS & GYNAECOLOGY) - BRANCH – II



**GOVERNMENT STANLEY MEDICAL COLLEGE
CHENNAI -600 001.**

April - 2015

CERTIFICATE

This is to certify that dissertation entitled **COMPARISON OF ORAL NIFEDIPINE AND TRANSDERMAL NITROGLYCERINE AS A TOCOLYTIC FOR PRETERM LABOUR** is a bonafide work done by **Dr. P.PADMINI PRIYA DARSHINI** at R.S.R.M Lying in Hospital, Stanley Medical College, Chennai. This dissertation is submitted to Tamil Nadu Dr. M.G.R. Medical University in partial fulfilment of university rules and regulations for the award of M.S. Degree in Obstetrics and Gynaecology.

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DECLARATION

I Dr. P. Padmini Priya Darshini, solemnly declare that the dissertation titled, **COMPARISON OF ORAL NIFEDIPINE AND TRANSDERMAL NITROGLYCERINE AS A TOCOLYTIC FOR PRETERM LABOUR** is a bonafide work done by me at R.S.R.M. Lying in Hospital, Stanley Medical College, Chennai during September 2013 – September 2014 under the guidance and supervision of **Prof. Dr.N.Thamizhselvi, M.D., D.G.O.**, Professor and Chief of the department of Obstetrics and Gynaecology.

This dissertation is submitted to the Tamil Nadu Dr. M.G.R. Medical University in partial fulfilment of University rules and regulations for the award of M.S. Degree (Branch-II) in obstetrics and Gynaecology.

Place: Chennai
Date: 14.10.2014

Dr. P. Padmini Priya Darshini

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I am very thankful to my parents, parents in-law and my husband for their continuous support and care.

Finally I thank Lord Almighty, who gave me the will power and showered blessings to complete my dissertation work.

Originality

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INTRODUCTION

Preterm or premature birth are terms used to define neonates born before 259 days is considered as largest contributor to infant mortality and morbidities. A variety of morbidities are largely due to organ system immaturity, are Significantly increased in infants born before 37 weeks gestation compared with those delivered at term.

13 Children who are born prematurely have a higher risk of cerebral palsy, sensory deficits, learning disabilities and respiratory illness than those born at term.

Beck and colleagues (2010) estimated that 9.6% of all births were preterm in 2005, which accounts about 12.9 million birth. About 85% of this were in Asia and Africa where 10.9 million births were preterm.

Very often, the diagnosis of preterm labour is made at too advanced stage in labour to effectively stop it or act upon it. This appears to be true in developed and in developing countries.

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INTRODUCTION Preterm or premature birth are terms used to define neonates born before 259 days is considered as largest contributor to infant mortality and morbidities. A variety of morbidities are largely due to organ system immaturity, are Significantly increased in infants born before 37 weeks gestation compared with those delivered at term.

Children who are born prematurely have a higher risk of cerebral palsy, sensory deficits, learning disabilities and respiratory illness than those born at term. 13

Beck and colleagues (2010) estimated that 9.6% of all births were preterm in 2005, which accounts about 12.9 million birth. About 85% of this were in Asia and Africa where 10.9 million births were preterm. Very often, the diagnosis of preterm labour is made at too advanced stage in labour to effectively stop it or act upon it. This appears to be true in developed and in developing countries. Despite advances in perinatal medicine recent decades the problem of Preterm birth continues to frustrate satisfactory reproductive outcomes with little progress having been made in identifying and reducing the frequency of Preterm. A real reduction in the preterm delivery rate will only take place through an improved understanding of the etiology, pathogenesis, identify the patient at risk, prediction of preterm labour and its early detection and effective tocolysis. Resources used to care for preterm infants are measure of the social Burden of preterm birth. Amount spend is immeasurable. So preterm labour should be prevented. Pharmacological inhibition of preterm labour remains the most effective means to delay delivery and improve the neonatal outcome until a more effective means of prevention is identified. Our study is concerned to detect a better drug among transdermal patch of nitroglycerine and oral nifedipine in the prevention of preterm labour. DEFINITION : Pre term labour is defined

as the presence of uterine contractions of sufficient strength and frequency to cause progressive effacement and dilatation of the cervix between 20 weeks and 37 weeks 10

or before 259 days (acc. To WHO). Based on the gestational age the preterm birth can be classified in to: Extremely preterm Very preterm Moderate preterm Late preterm - - - - < 28 weeks. 28 to <32 weeks. 32 to 34 weeks. 34 to 36 weeks Fetal viability period lower limit are the following : • UNITED STATES - 20 WEEKS (ACOG 1995) • ROYAL COLLEGE OF OBSTETRICIAN -24 WEEKS • FIGO- 22 WEEKS • INDIA- 28 WEEKS INCIDENCE : Preterm delivery rate : United states - 11%

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INTRODUCTION

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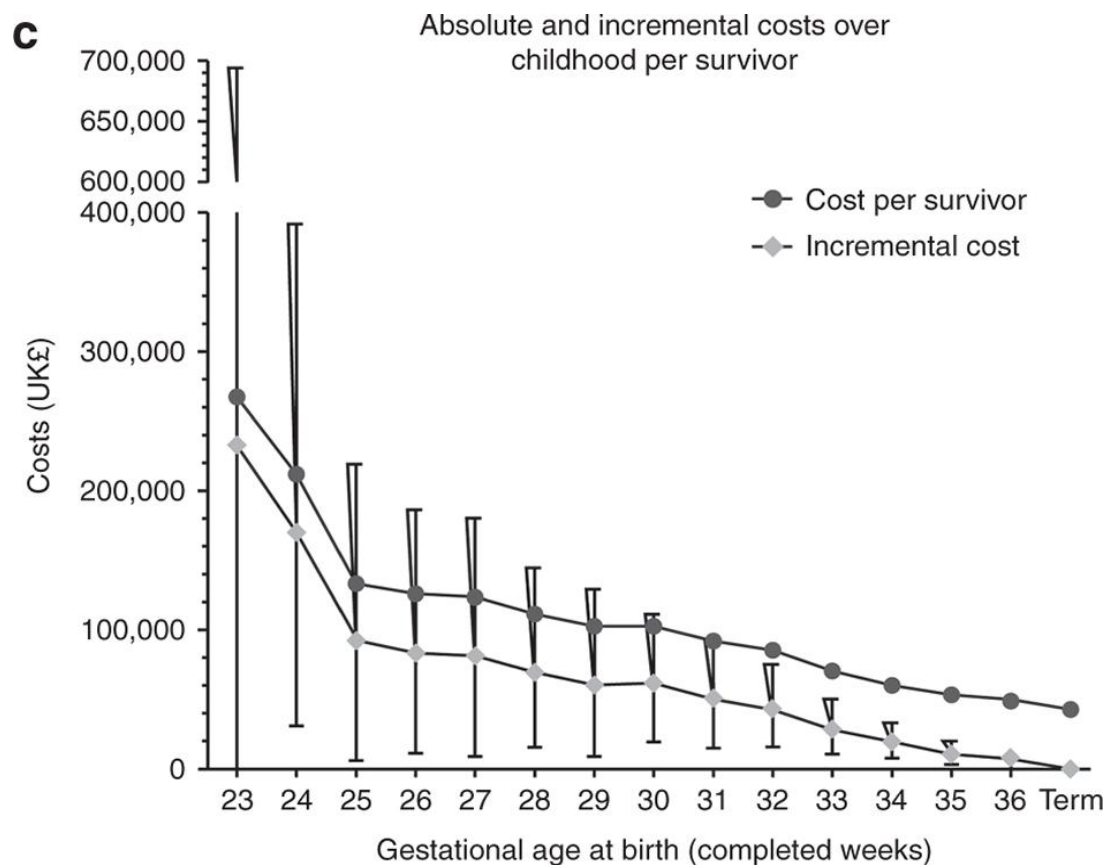
Beck and colleagues (2010) estimated that 9.6% of all births were preterm in 2005, which accounts about 12.9 million birth. About 85% of this were in Asia and Africa where 10.9 million births were preterm.

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Resources used to care for preterm infants are measure of the social burden of preterm birth. Amount spend is immeasurable. So preterm labour Should be prevented. Pharmacological inhibition of preterm labour remains the most effective means to delay delivery and improve the neonatal Outcome until a more effective means of prevention is identified.

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AIM OF THE STUDY

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To compare the safety and efficacy of oral nifedipine with transdermal patch of nitroglycerine in the tocolysis of preterm labour.

OBJECTIVE OF THE STUDY

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To detect a better drug in the achievement of the tocolysis of preterm labour.

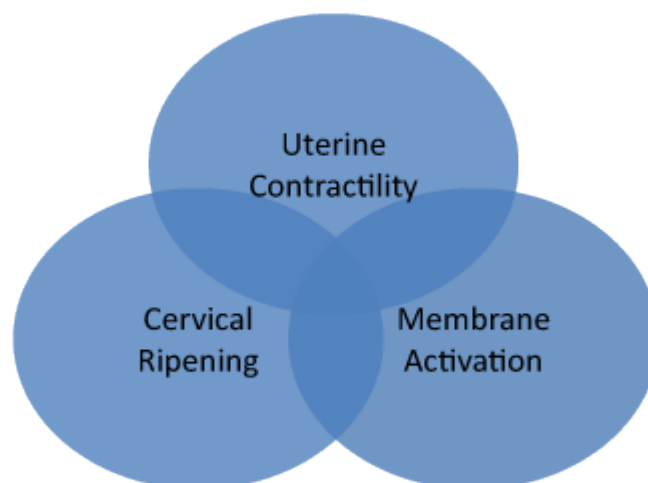
REVIEW OF LITERATURE

DEFINITION :

Pre term labour is defined as the presence of uterine contractions of sufficient strength and frequency to cause progressive effacement and dilatation of the cervix between 20 weeks and 37 weeks or before 259 days(acc. To WHO).⁷²

Based on the gestational age the preterm birth can be classified⁴⁴ in to:

| | | |
|-------------------|---|------------------|
| Extremely preterm | - | < 28 weeks. |
| Very preterm | - | 28 to <32 weeks. |
| Moderate preterm | - | 32 to 34 weeks. |
| Late preterm | - | 34 to 36 weeks |



Fetal viability period lower limit are the following ^{1,65} :

- UNITED STATES – 20 WEEKS (ACOG 1995)
- ROYAL COLLEGE OF OBSTETRICIAN -24 WEEKS
- FIGO- 22 WEEKS
- INDIA- 28 WEEKS

INCIDENCE :

Preterm delivery rate :

United states – 11%

Europe 5 – 7 %

India -12.3% (NNPD)

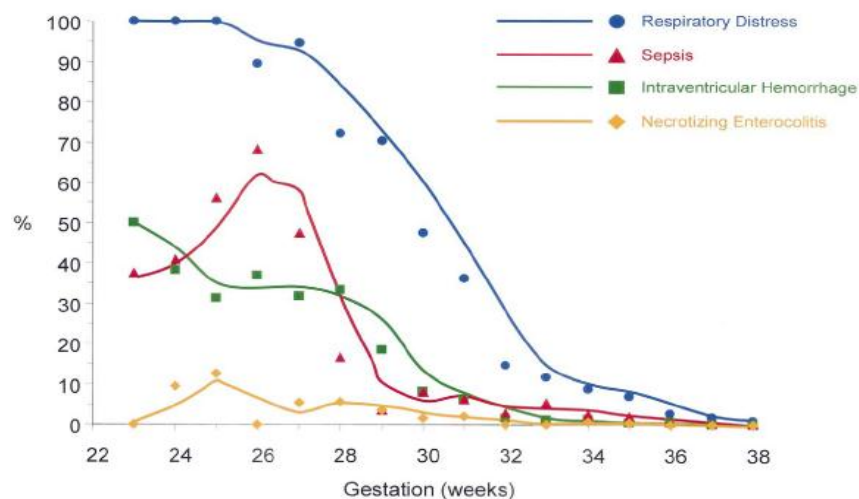
1 in 5 pregnant women exhibit signs and symptoms of preterm labour

MAGNITUDE OF THE PROBLEM :

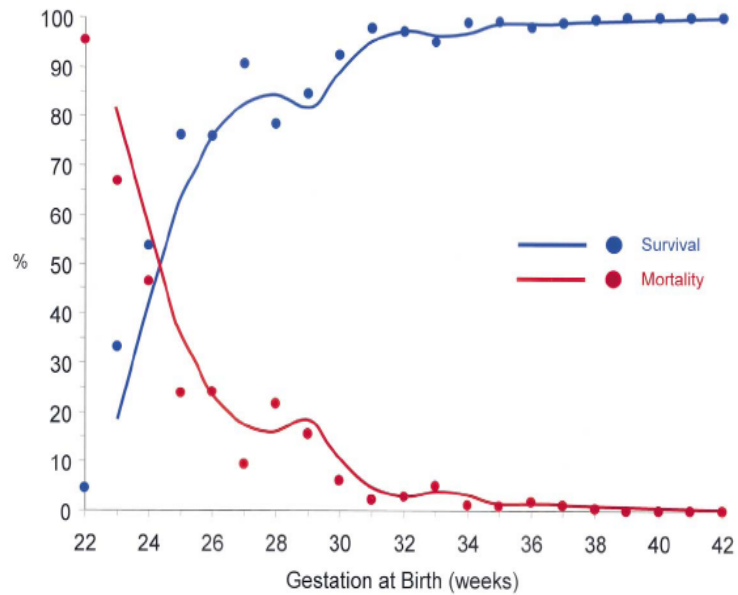
- ❖ Large no of perinatal mortality and morbidity occurs due to preterm labour
- ❖ About 75 – 90 % of neonatal death is due to preterm labour

- ❖ 20% of all infants born < 32 weeks do not survive the first year of life
- ❖ The infant mortality rate for very pre term infants (delivered <32 weeks of gestation) is nearly 75 times the rate for infant born at term.⁵³
- ❖ It is the second leading cause of death after pneumonia in children under five years of age.
- ❖ Recently the primary focus is on late preterm infants between 34 and 36 weeks because of increased morbidity rates compared with those at term.
- ❖ These infants predominantly suffer not only the immediate complications of prematurity but also long term disabilities like neurodevelopmental disabilities.

PRETERM MORBIDITY⁵⁵



PRETERM MORTALITY



ETIOPATHOGENESIS OF PRETERM LABOUR 51:

Activation of maternal or fetal HPA axis :

30 percentage of preterm labour are due to this mechanism.

This is mainly due to maternal fetal stress factor and premature

onset of physiological initiators

Infection :

This is the most common etiology which accounts for about 40 %.

Infections are mainly chorion –decidual and systemic infection

Decidual hemorrhage :

20% are due to this factor.

Main contributing factor in this is abruptio placenta

Pathological distension of uterus:

10% of preterm labour are due to pathological distension.

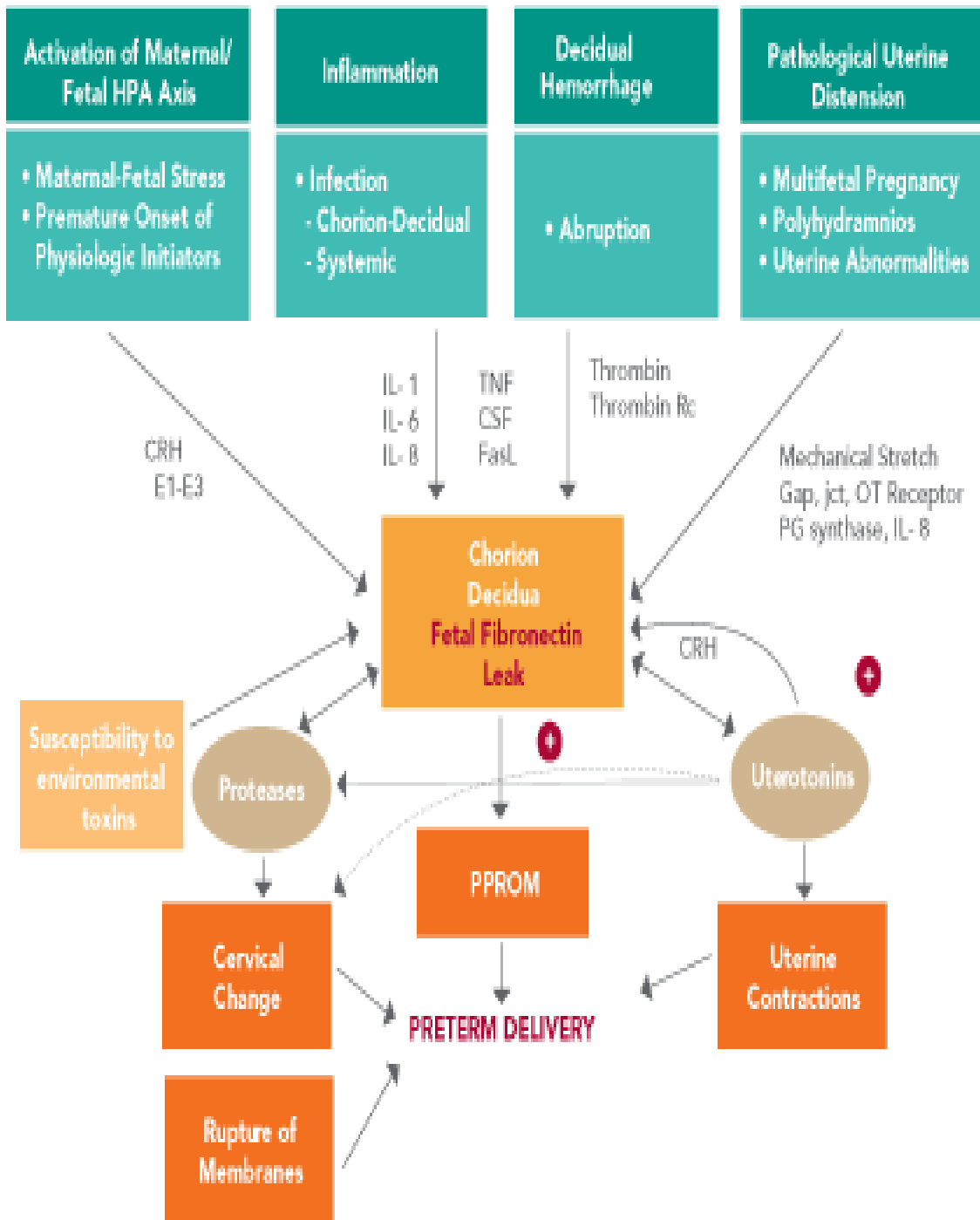
Causes of pathological distension are:

Multiple pregnancy.

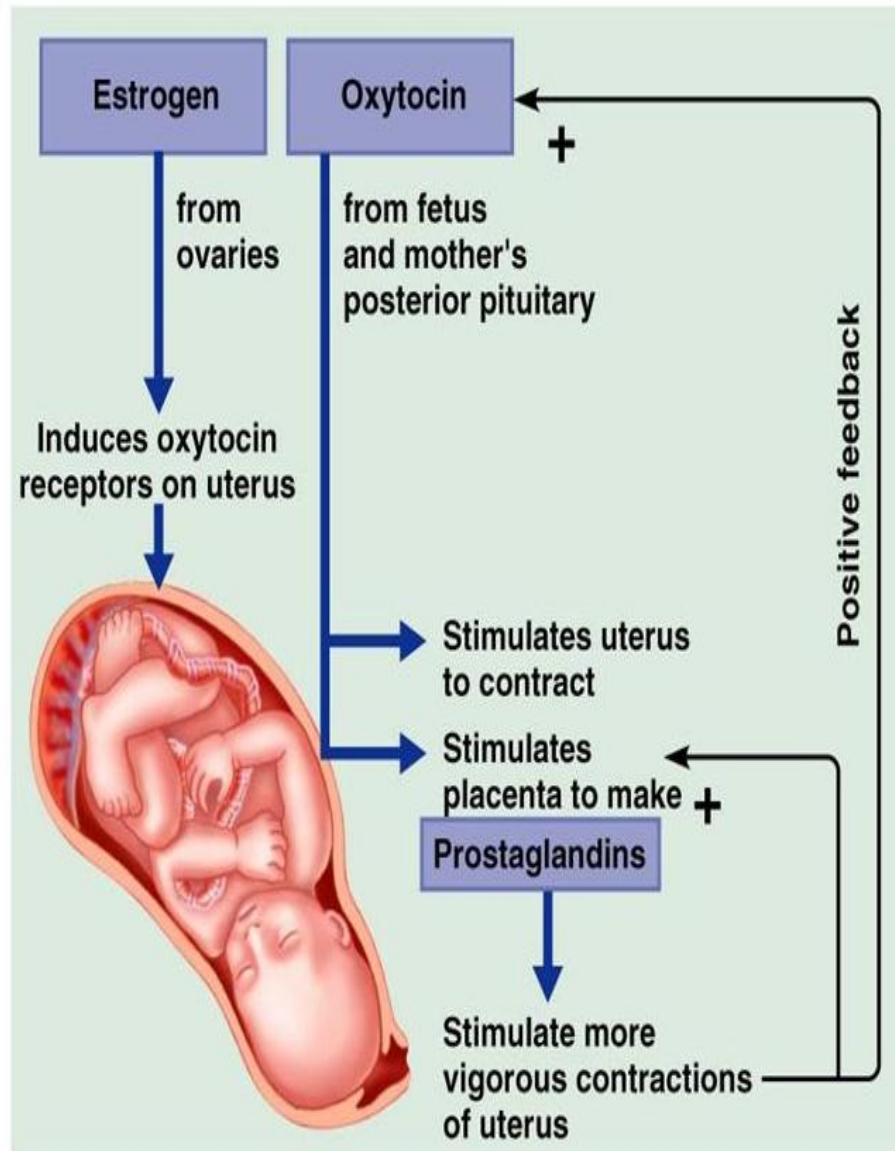
Polyhydramnios.

Uterine abnormalities

ETIOPATHOGENESIS OF PRETERM LABOUR :



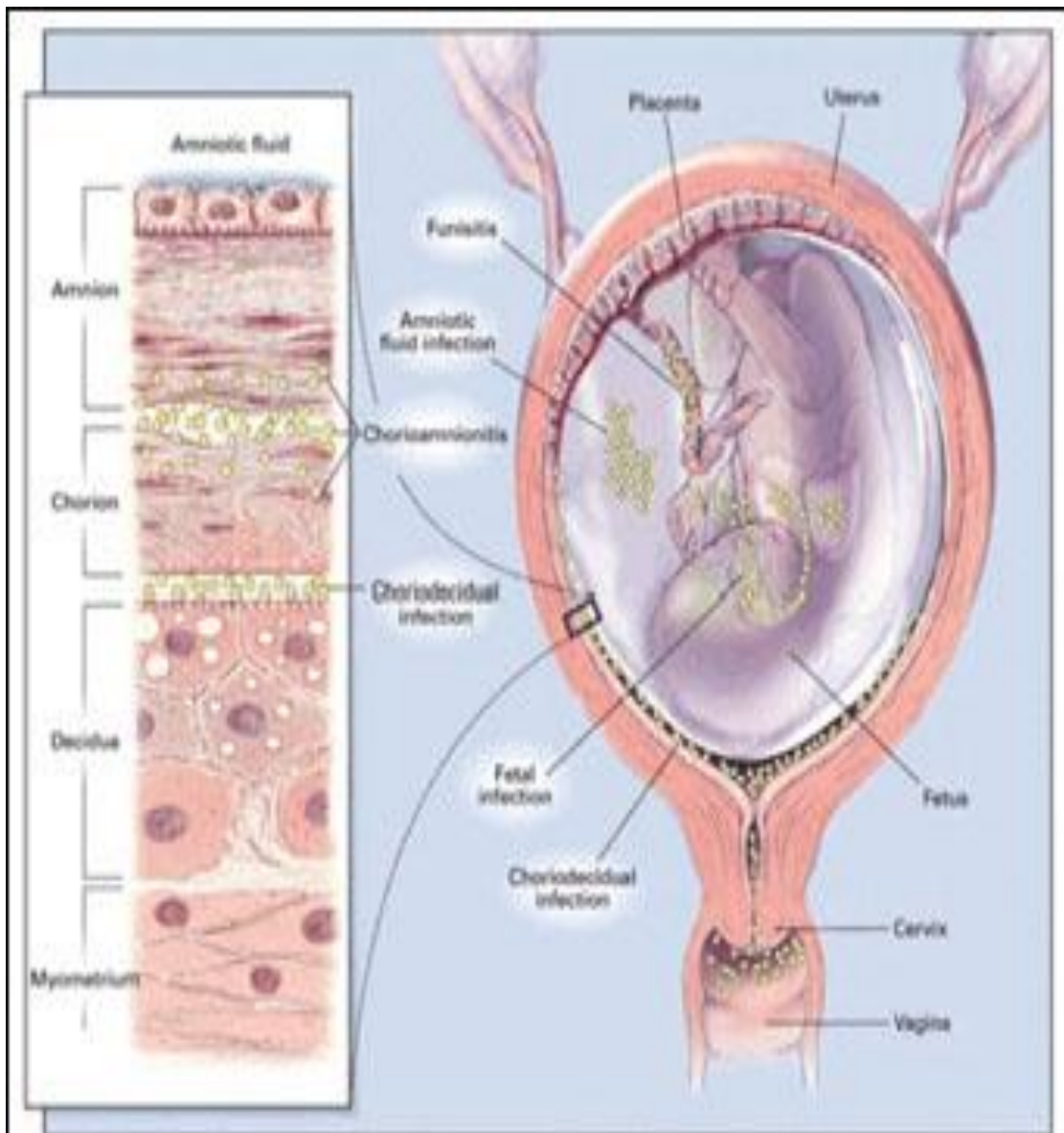
ACTIVATION OF MATERNAL OR FETAL HPA AXIS :



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INFECTION :

Infection or chorioamnionitis is associated with preterm labour was first recognized by Bobitt and Ledge^{18,19}



Intrauterine infection is considered to have following stages^{34,35,36} :

- ❖ STAGE I – infection in the vagina and cervix.
- ❖ STAGE II – deciduitis.
- ❖ STAGE III - choriovasculitis or amnionitis.
- ❖ STAGE IV - finally infection of the fetus.

12.8 % of preterm labour shows positive for infection of amniotic fluid by culture (e76 Neoreviews vol 3no 5.may 2002).

Two important pathogens:

Mycoplasma hominis

Ureaplasma urealyticum are associated with preterm labour.

Goldenberg and colleagues (2008a) reported that 23% of neonates born between 23 and 32 weeks have positive umbilical cord culture for the genital mycoplasma.

Colonization of genital tract with the following organisms are also found to be associated with preterm labour.

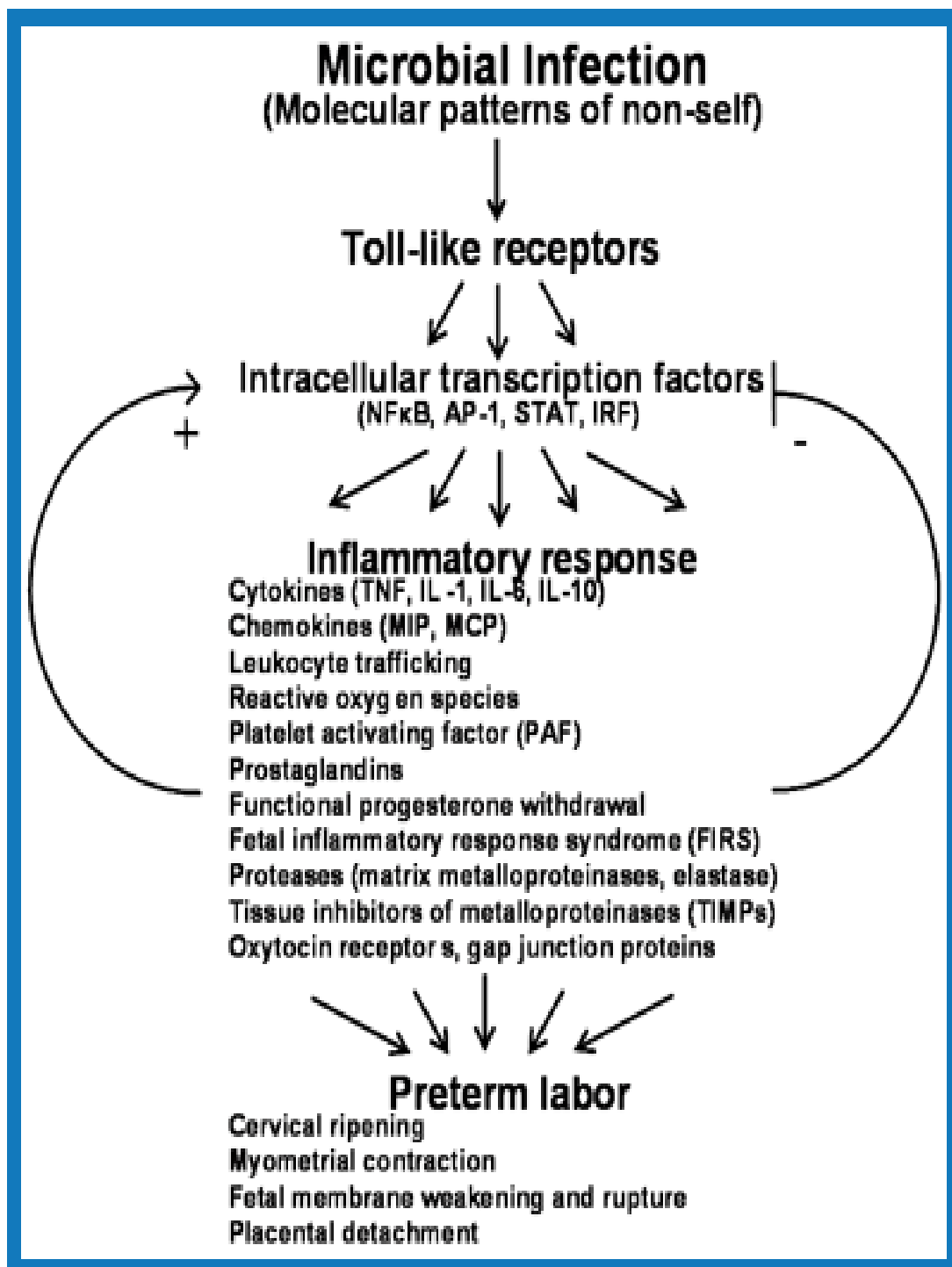
- Chlamydia trichomatis (Martin et al, Harrison et al)

- BACTERIAL VAGINOSIS – Gardnerella vaginalis , mobiluncus species mycoplasma hominis (Hiller and colleagues 1995).
- Niesseria gonorrhoea (Edward et al).
- Trichomonias.
- Group B streptococcal infection (Bobit et al ,Lamont et al).

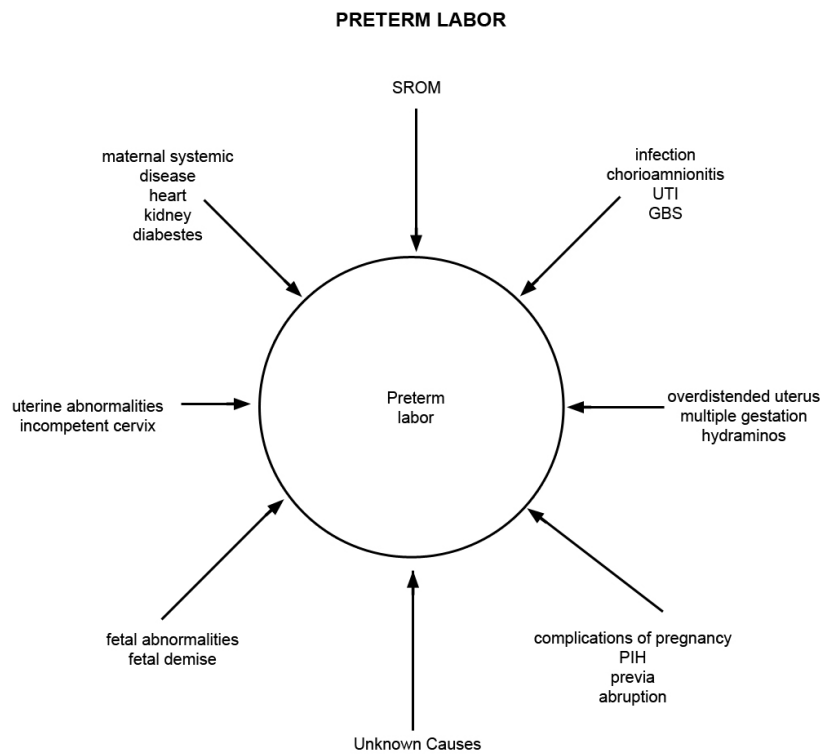
OTHER INFECTIONS :

Urinary tract infection associated with asymptomatic bacteriuria also associated with preterm labour.

PERIODONTITIS : Preterm birth is also associated with periodontitis by gram negative bacteria which mainly affect the connective tissue (Bogges KA obg gyn 2003).¹⁷



RISK FACTOR FOR PRETERM LABOUR :



RISK FACTORS : (Arias F, Obstet Gynecol 1982;14;361)¹¹

- Iatrogenic preterm delivery

MATERNAL :

systemic medical illness

substance abuse

Severe preeclampsia or eclampsia

- **UTERINE :**

Anomalous uterus

Overdistension

fibroids

- **PLACENTAL:**

Placental abruption,placenta previa

Marginal placental bleeding,

Large chorioangioma

- **AMNIOTIC FLUID :**

Preterm rupture of chorioamniotic membranes

Polyhydramnios

Clinical chorioamnionitis

- **FETAL :**

Fetal malformation

Multifetal gestation

Fetal hydrops

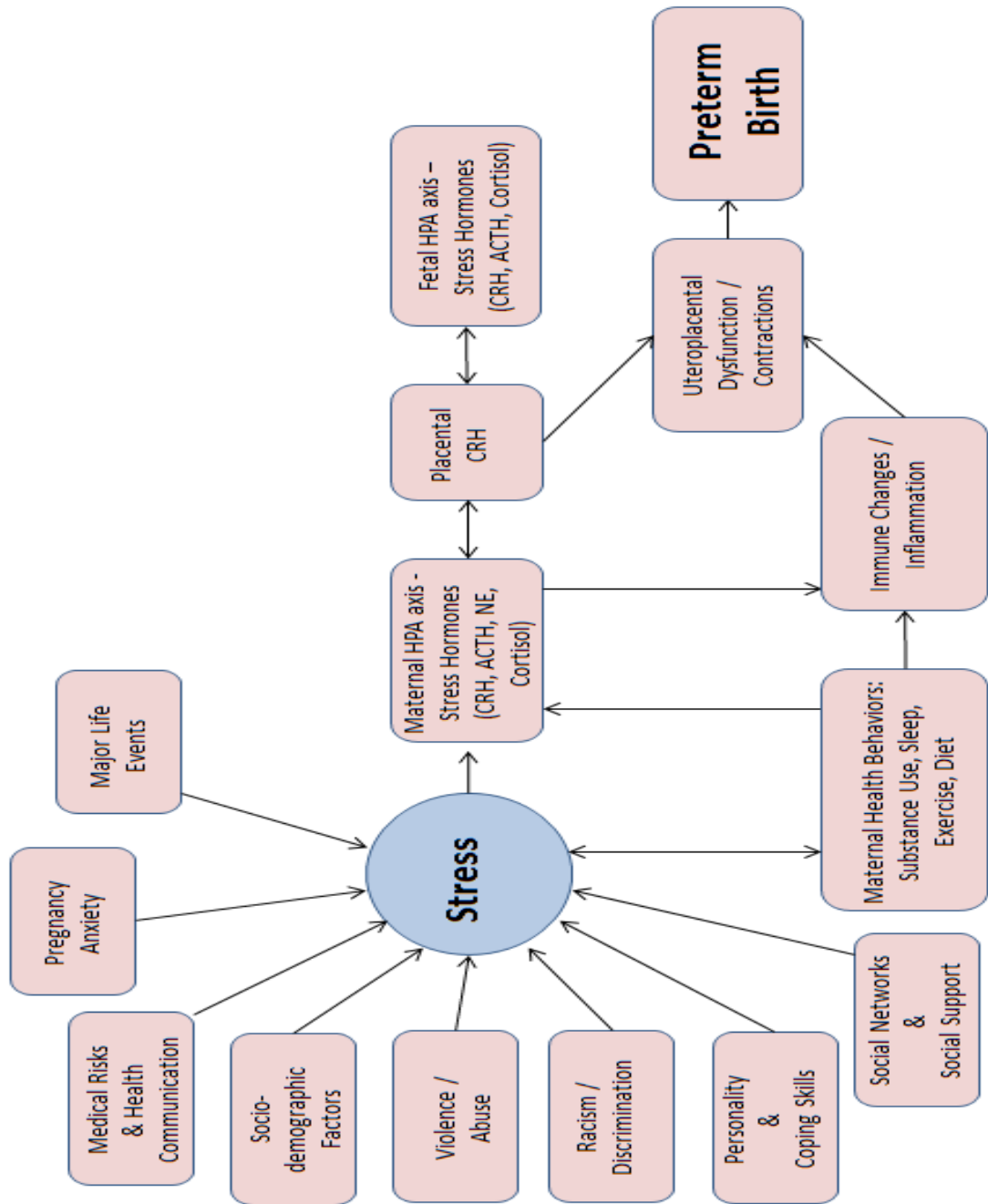
Fetal growth restriction

Fetal demise

- **CERVICAL**

Incompetence of cervix

ANTECEDENT AND CONTRIBUTING FACTORS:



The following are the antecedent and contributing factors :

1. RECURRENT PRETERM:

A previous occurrence of preterm labour before 34 weeks increases the chance of recurrence (Krymko et al).⁵⁵ Only ten percent of all preterm occur in women with previous preterm birth .

2. RACE :

Increased prevalence of preterm labour is seen in black women ^{35,51}. Bacterial vaginosis is more commonly seen in the black people may explain this increased prevalence of preterm labour .

Non-hispanic African American-17.8%

American Indians/Native Alaskans – 13.5%

Hispanics - 11.9%

Whites - 11.5%

Asian and Pacific Islander 10.5% (CDC : 2004 Birth)

3. LOW BODY MASS INDEX :

Over weight women are at decreased risk of preterm labour before 35 weeks when compared to women with normal weight (Ehrenberg and colleagues 2009).

4. ABSENT OR INADEQUATE PRENATAL CARE

Poor ante natal care is associated with increased risk of preterm birth.³¹

5. EXTREMES OF AGE :

It is more common in extremes of age group. incidence is more in age group ≤ 18 yrs and ≥ 35 years.

6. STRENOUS WORK:

This factor have increased risk of preterm birth (i.e) working for long hours like standing and walking and hard physical labour (Goldenberg and colleagues 2008b).³⁵

7. SUBSTANCE ABUSE:

Negger and co worker 2004 ⁵⁴ found that substance abuse and smoking is have increased risk for preterm labour.

Alcohol dependence syndrome ⁵⁹ is also important contributing factor.

8. THREATENED ABORTION:

Bleeding between 6 to 13 weeks have increased chance for preterm labour according to weiss and associates (2004). ⁷¹

9. BIRTH DEFECT :

Birth defects were associated with preterm birth and low birth weight according to Dolan and colleagues (2007) ²⁷ in FASTER TRIAL.

10. INTERVAL BETWEEN PREGNANCIES AND PRETERM BIRTH:

Conde Agudelo and co workers (2006) ²³ reported that interval between the pregnancies less than 18 months and more than 59 months were associated with more chance for both preterm birth and small for gestational age infants.

CLINICAL FACTORS USED TO PREDICT PRETERM LABOUR:

RISK ASSESMENT:

Risk assessment is a concept first proposed by Papernik (1969).⁶⁴

Risk scoring system devised by Papernik and modified by Creasy and Govik (1980) has been tested in several regions.

The purpose of this is to identify the women at increased risk to give birth early prior to the onset of labour would lead to interventions that could prevent preterm birth. The frequency of a large number of demographic and epidemiological markers in women who did and did not give birth were compared.

Unfortunately risk scores do not identify the majority of women who deliver Preterm. They are of limited clinical use.

CREASY AND COLLEGUES ⁴ : (ObGyn 1980,1982,birth defect 1983):

More simplified scoring system Scoring system is based on the factors which increases risk of preterm birth, the risk is more with recurrent preterm, bleeding in the pregnancy, UTI, high order pregnancies, body mass index < 20kg/m², previous low birth weight and stress factors.

Screening is performed during the prenatal care visits.

Several studies have failed to show any benefits from risk scoring systems

- ❖ ≥ 10 high risk
- ❖ 5-9 medium risk
- ❖ 0-5 low risk
- The prevalence of preterm labour was 6.1%
- The sensitivity was 64%
- Positive predictive value 30%

CERVICAL ASSESSMENT :

Asymptomatic cervical dilatation after midpregnancy is suspected as a risk factor.

The odds ratio of preterm delivery was 1.43 for each unit increase in bishop score for nulliparous women and 1.23 for multiparous women ($p < 0.0005$)

Cervical dilatation ≥ 1 cm, length < 2 cm and cervical score, 2, respective sensitivities and specificities of 8% and 99%, 13% and 93% and 20% and 93% respectively (Hartmann K, *Obstet Gynecol* 1999;93:504-9)³⁹.

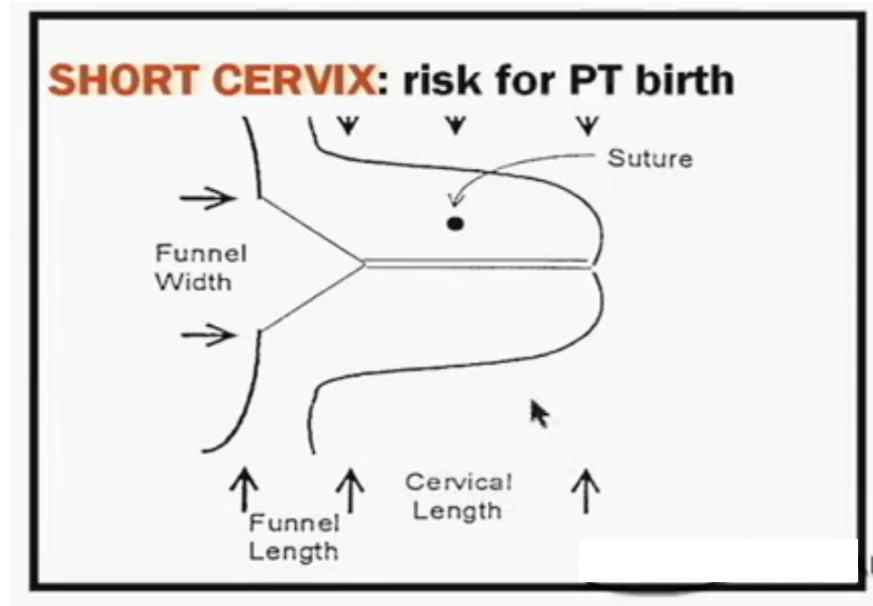
Iams and co workers (1996)⁴³ measured cervical length at approximately 35mm and those women with progressively shorter cervix experiences increased rate of preterm birth.

Ultrasound images of the cervix in preterm labour shows effacement as early as 16 to 24 weeks but this ultrasound finding is seen at 32 weeks in term pregnancy.

FUNNELING:

It is the ultrasound evidence of ballooning of the membranes into dilated internal os with closed external os. (Owen et al 2003).⁶²

A shortened cervix in association with funneling has been shown to be an indicator of greater risk of preterm delivery(Rust et al 2005).⁶⁶



Decarvalho and co workers(2005)²⁶ concluded from the study conducted by them on 1958 women by sonographic examination that short cervix was poorest predictor of preterm but funneling plus history or prior preterm birth was highly predictive.

ZILANTI ET AL⁷³ described the appearance of cervical effacement as seen by transvaginal sonography as following which describes the relationship of the cervical canal to the lower uterine segment.

T – Closed Uneffaced Cervix Y – partial effacement from internal os



v – further progression of effacement

u - membranes exposed through internal os in to the vagina



DOPPLER VELOCIMETRY IN PREDICTING PRETERM

LABOUR:(Rizzo et al 1996)

Decreased uteroplacental perfusion may predict preterm labour.

Decreased P I in MCA and increased RI in uterine artery.

These have poor positive predictive value.

FETAL BREATHING MOVEMENT :

Absence of fetal breathing movement in the ultrasound predicts preterm birth. labour within 48 hrs.

- Sensitivity - 96.7%
- Specificity – 80%
- Positive predictive value -87.9%
- Negative predictive value- 94.1%

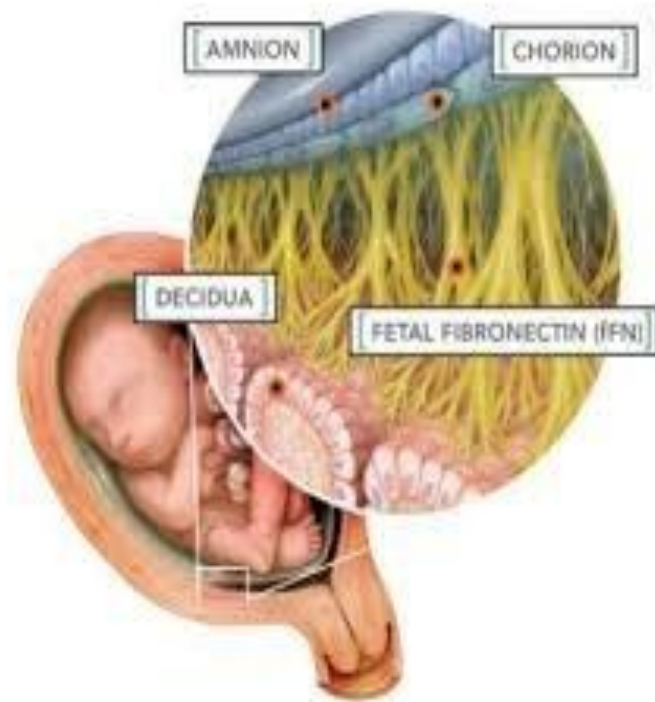
HOME UTERINE ACTIVITY MONITORING:

In 1950, Alvarez and Caldeyro Barcia reported simply that “the uterus never sleeps”; “Alvarez waves” . Zahn identified an increase in uterine contractility between 10pm and 2 am among 54 normal women performing continuous 24 hour tocodynametry . Clinical trials have generally involved four different study methodologies:

1. Self identification of preterm labour signs or symptoms.
2. Frequent perinatal nursing contact.
3. HUAM alone .
4. Frequent perinatal nursing contact with HUAM.

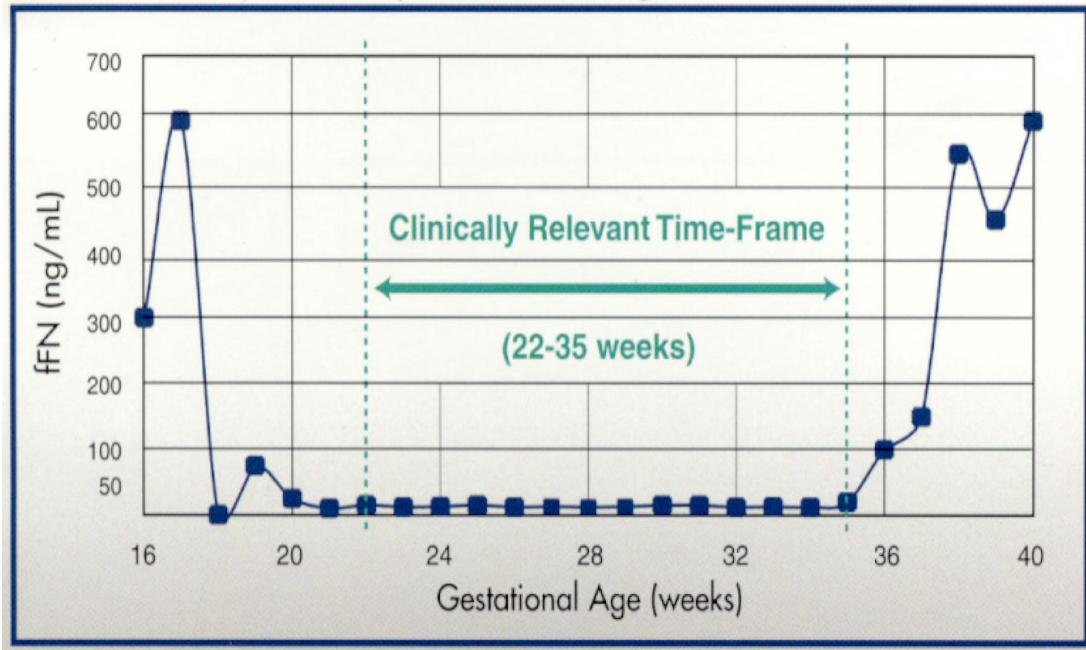
This system is not recommended by ACOG²

FETAL FIBRONECTIN :



Glycoprotein found in extracellular matrix of amniotic membranes
Act as glue that binds chorion to deciduas.

Normally found in cervico vaginal secretions until 20weeks of gestation and again at the term released in to vaginal/cervical fluid in response to inflammation or separation of amniotic membranes from deciduas. Presence after 24 weeks is indicative of imminent labour. Fetal fibronectin immunoassay detects concentrations of fetal fibronectin protein in cervicovaginal fluid. Presence of fetal fibronectin $>50\text{ng/ml}$ ^{50,51,53} after 22 weeks is considered positive



OTHER MARKERS:

SALIVARY ESTRIOL:

Normally there is increase in the level of estriol through out the pregnancy. This increase accelerates five weeks prior to uneventful delivery. Estriol level greater than 2.1ng/ml⁴⁸ is considered positive. This test becomes unsuitable due to suppression by antenatal steroids and diurnal variation.

ACTIVIN AND INHIBIN:

Releases the local prostaglandins

RELAXIN: involved in collagen remodeling with in amnion and chorion. Plevyak et al noted a significant effect with activin and inhibin levels only at 31-34 weeks further research is required.

CORTICOTROPIN RELEASING HORMONE:

Before the onset of preterm labour the level of CRH is increased. Increased level of CRH 1.9MOM is used to anticipate the preterm birth (Dudley DJ,AJOG 1999).

PRO INFLAMMATORY CYTOKINES IL 6 :

Cervical IL 6 and serum IL6 increased at a very high level at 24 weeks of gestation in women withspontaneous preterm labour before 35 weeks of gestation.

Cervical IL 6 has strong association with levels >410pg/ml and has an RR of 7.7 for intraamniotic infection(Reece and hobbins 2007).⁶⁷

OTHER INVESTIGATIONAL MARKERS:

The NICHD MFMU'S preterm prediction study(1993-1996):

This study found the predictors of preterm labour:

1. fetal fibronectin > 50ng/ml
- 2.cervical length </= 25 mm

Between 32 to 35 weeks predictors are:

- Serum alpha feto protein
- Alkaline phosphatase
- G-CSF above 75th percentile.

DIAGNOSIS OF PRETERM LABOUR:

Preterm labour can be classified as threatened or actual the basis for such classification is the difference in prognosis. Approximately 85% of patients with threatened preterm labour deliver after 37 weeks ,whereas 40-50% of all patients in actual preterm labour deliver at term.

THREATENED PRETERM LABOUR:

Absence of cervical change in the presence of contractions.

SYMPTOMS OF PRETERM LABOUR:

Table 62.8 Chief symptoms of preterm labor.

| |
|-----------------------------|
| Abdominal pain |
| Back pain |
| Pelvic pain |
| “Gas pain” |
| Menstrual-like cramps |
| Vaginal bleeding |
| Pinkish staining |
| Increased vaginal discharge |
| Pelvic pressure |
| Urinary frequency |
| Diarrhea |

INGEMARSSON'S CRITERIA FOR PRETERM LABOUR:

- Gestation between 28-36 weeks
- Painful, regular, uterine contractions occurring at interval of less than 10 min, for atleast 30 min, by external tocography
- Intact membranes
- Effacement of cervix with cervical dilatation between 1 and 4 cms

CREASY CRITERIA:

- ❖ Gestation age of 20 to 37 weeks
- ❖ Documented uterine contractions 4 in 20 min or 8 in 60 min
- ❖ Documented cervical changes or cervical effacement of 80% or dilatation of cervix greater than or equal to 2 cm
- ❖ Intact membranes.

SPECULUM EXAMINATION:

- To determine the length of the cervix and extent of dilatation of cervical os.
- To determine the presence of amniotic fluid.

DIGITAL EXAMINATION:

- To be avoided if membranes have ruptured
- Effacement and dilatation are looked for.

PREVENTION OF PRETERM LABOUR

As preterm labour is the major cause for the perinatal morbidity and mortality its prevention is an important strategy in the management of patients at high risk for preterm.

Table 62.24 Primary prevention strategies.

| |
|---|
| Delay childbearing until age 17 years |
| Delay interpregnancy interval |
| Eliminate low maternal weight for height |
| Smoking prevention and cessation |
| Prevent and detect sexually transmitted diseases, and treat to cure |
| Detect bacteriuria and treat to cure |
| Manage fertility to avoid multifetal gestation |
| Provide or refer for preconceptional counseling |
| Detect and treat iron-deficiency anemia |
| Provide or refer for drug abuse prevention and treatment |

Table 62.25 Secondary prevention strategies.

| |
|--|
| Risk assessment in prenatal care |
| Improved sufficiency of the content of prenatal care |
| Repeated education regarding warning signs and symptoms of preterm labor |
| Early-diagnosis programs |
| Home uterine activity monitoring, cervical length, oncofetal fibronectin |
| Early medical intervention |
| Medications, surgery, early referral |
| Reduced maternal physical activity |
| Maternal work leave |
| Eliminate barriers to care (access, access, access) |
| Education, education, education |

This prevention is achieved by:

1. Antibiotics
2. Cervical encerclage
3. Progesterone.

ANTIBIOTICS:

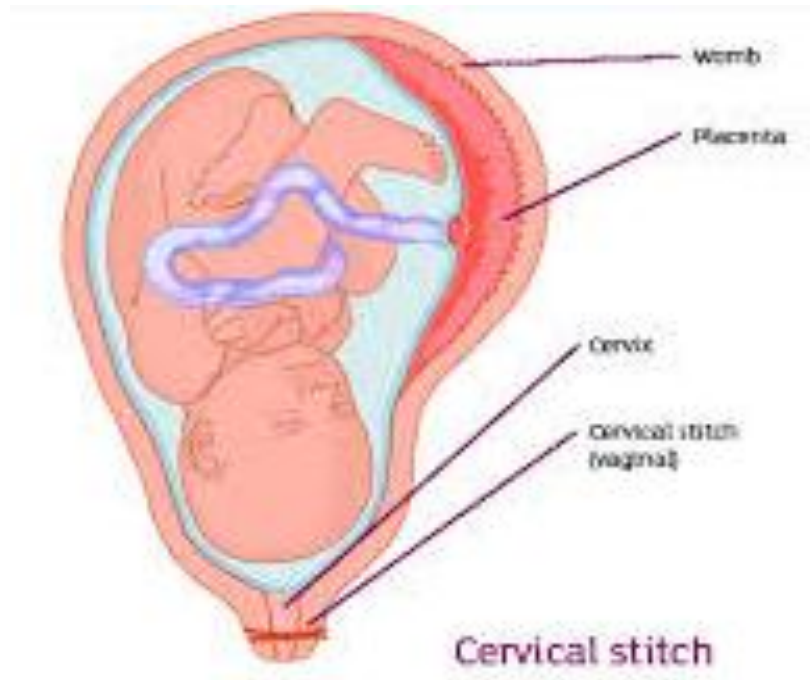
Goldenberg et al 2008 ³⁵ postulated that infection may trigger by activating the innate immune system so control of infection plays an important role in the prevention of preterm labour.

A meta analysis by Bujold and Morency (2007) ⁵⁶ proposed that recurrence of preterm labour is reduced by administering antibiotics in the second trimester for women with history of preterm labour

Carey et al (2000) ²¹ and okun et al (2005) found that when women treated with metranidazole for bacterial vaginosis there was no significant reduction in preterm labour but reduction in persistant infection is found.

CERVICAL ENCERCLAGE:

Encerclage as treatment for the preterm labour is found to be Controversial.



THREE TYPES OF CERCLAGE:

PRIMARY CERCLAGE:

Done prophylactically in high risk patient

SECONDARY CERCLAGE:

Done in patients with USG evidence of cervical insufficiency

TERTIARY OR RESCUE CERCLAGE:

Done as emergency procedure in patients with established cervical incompetence.

In CIPRACT TRIAL 2001 proved that cerclage reduced the rate of preterm labour in patient with gestational age < 34 weeks (Althusius et al)³.

Berghella and colleagues 2005¹⁵ proposed that in patient with prior history of preterm labour cerclage reduced the rate of preterm labour.

Daskalakis et al 2006 proved that the group who received cerclage benefitted with prolongation of pregnancy. Dor et al 1982 proved that cerclage provides no benefit in twin pregnancy and Triplets (Roman et al 2005.)

PROGESTERONE:

Intramuscular injection of 250 mg of 17 hydroxyprogesterone reduced the rate of preterm birth before 37 weeks when administered between 16 to 20 weeks (Meis et al).⁵⁴

No benefit in twin gestation according to Rouse et al 2007.

Intravaginal progesterone :

Micronized progesterone capsules 200 mg vaginally have been used in trial in asymptomatic patient with cervix length less than 15 mm and appears to be effective (da fonseca et al 2007)^{.25}

PROGESTERONE IS NOT RECOMMENDED :

- ✓ As supplementary in cervical encerclage for suspected cervical insufficiency.
- ✓ As a preventive for asymptomatic women with a positive fetalfibronectin screening.
- ✓ As a tocolytic agent

MANAGEMENT

STEP 1:

THE EVALUATION PHASE:

- The need and the specific nature for tocolytic therapy is assessed
- An etiological diagnostic workup is carried out
- To seek to rule out contraindications to substantially prolonging the pregnancy.

Table 62.11 Contraindications to tocolysis.

| Absolute contraindications | Relative contraindications |
|---|--|
| Fetal demise | Fetal heart rate abnormalities |
| Lethal fetal anomaly | Fetal growth restriction |
| Severe preeclampsia or eclampsia requiring immediate delivery | Preeclampsia not requiring immediate delivery |
| Chorioamnionitis | Stable late second or third trimester vaginal bleeding |
| Severe hemorrhage | Significant maternal disease |
| | Cervical dilation ≥ 5.0 cm |
| | Progressive structural but nonlethal fetal anomalies |

STEP 2 :

Next step is the decision about tocolytic to give.

STEP 3 :

Ultrasound examination done in this step

Table 62.13 Fetal and maternal assessment via ultrasonography.

Fetal evaluation

Age, weight, and growth status

Life and fetal number

Lie, presentation, and position

Well-being

Behavior

Anatomy and sex

Blood and sampling (funicentesis) for rapid karyotype, blood gases, disease-specific hematologic profiles

Amniotic fluid evaluation

Polyhydramnios

Oligohydramnios

Amniocentesis for infection, fetal pulmonary maturation, fetal hemolysis

Placental and funic evaluation

Previa

Abruption

Marginal bleed with membrane separation

Location, internal anatomy, contour, thickness, and grade

Umbilical cord insertion sites

Funic presentation

Umbilical artery Doppler

Uterine and cervical evaluation

Defective uterine scar

Uterine septum

Weak lower uterine segment

Cervical length

Cervical dilation

Myomatous uterus

ROLE OF BED REST ,HYDRATION AND SEDATION IN PRETERM LABOUR:

BED REST:

This is one of the most prescribed intervention during pregnancy. Many studies have proved no role of bed rest in the inhibition of preterm labour.³²

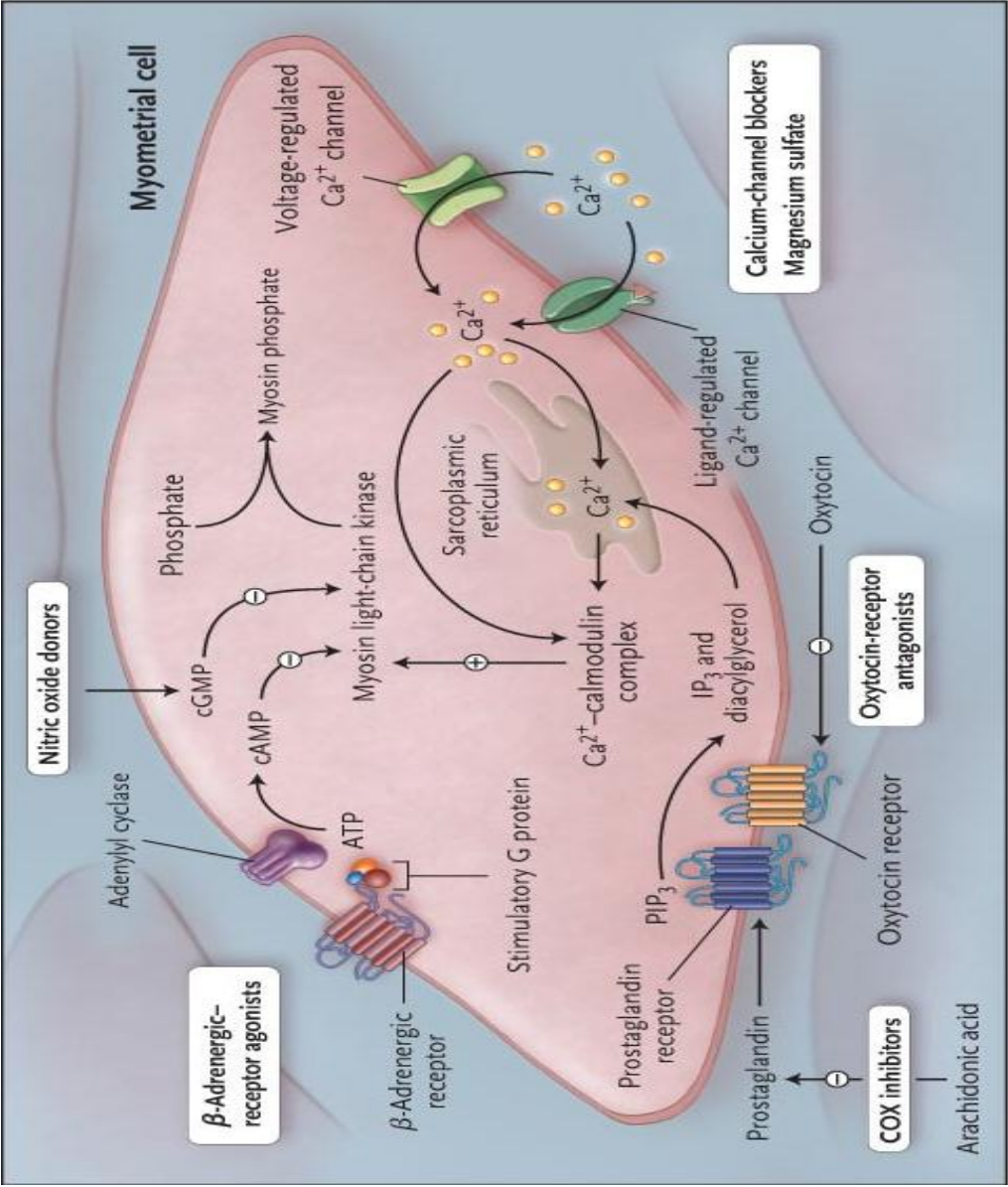
HYDRATION AND SEDATION :

Helfgott ⁴⁰ and associates compared hydration ,sedation with bed rest and found no difference.

TOCOLYTICS :

- Drugs used in the suppression of preterm labour.
- BETA ADRENERGIC AGONIST
- MAGNESIUM SULFATE
- PROSTAGLANDIN INHIBITORS
- OXYTOCIN ANTAGONIST
- CALCIUM CHANNEL BLOCKER AND NITRIC OXIDE DONORS.

MECHANISM OF TOCOLYTICS :



BETA-SYMPATHOMIMETIC AGENTS

Ritodrine, terbutaline, salbutamol ⁵ are the commonly used drugs.

These are often associated with serious maternal side effects

- ❖ Pulmonary edema.
- ❖ Arrhythmia.

The cause of pulmonary edema is multifactorial, and risk factors, include tocolytic therapy with beta agonist, multiple pregnancy, steroid therapy, Tocolysis for more than 24 hours, large intravenous crystalloid volume infusion.

These drugs are potent cardiovascular stimulants and can cause serious complications such as maternal myocardial ischemia, metabolic derangements like hyperglycemia and hypokalemia and fetal cardiac effects.

BETA-SYMPATHOMIMETIC AGENTS(ADMINISTRATION)

- **Ritodrine infusions** (Caritis and colleagues)

50-100microgm/min, increase 50 microgm/min every 10 min until contraction ceases.

Ritodrine is no longer recommended as first line of drug by RCOG.⁶⁵

Terbutaline :

- ✓ In a commonly used regimen, 0.25 mg is given subcutaneously every 20 to 60min until contractions have subsided.
- ✓ Oral: The usual daily dose ranges from 10 to 30mg,max:40mg

PROSTAGLANDIN SYNTHETASE INHIBITORS

Indomethacin⁷⁴ is commonly used drug

- 50 to 100 mg of indomethacin administered once in 8 hrs for 24 hrs. total.
- dose should not exceed 200mg
- After oral administration serum concentration peaks in 1 to 2 hours

MATERNAL SIDE EFFECTS:

- ✚ Nausea
- ✚ Vomiting
- ✚ Headache
- ✚ Diarrhea

FETAL COMPLICATION:

- Closure of ductus arteriosus
- Pulmonary hypertension
- Interventricular hemorrhage
- Necrotizing enterocolitis

MAGNESIUM SULFATE^{28,68}:

Mostly it act as calcium antagonist. It uncouple depolarization contraction coupling. It affects neural transmission modifying acetylcholine release and sensitivity at motor end plate.

DOSAGE:

Loading dose 4 gm over 20 min followed by continuous infusion 2g/hr.

CRITICAL SERUM LEVEL OF Mgso4 :

- Therapeutic range – 6-8 mg/dl
- Loss of deep tendon reflexes – 8 -12 mg/dl
- Respiratory paralysis – 10 -15 mg / dl
- Cardiac arrest - >20mg/dl

SIDE EFFECTS:

- a. Loss of deep tendon reflexes
- b. Warmth during infusion
- c. Increase in skin temperature
- d. Chest tightness
- e. Hypocalcemia
- f. Pulmonary edema

According to Grimes and Nanda 2006 magnesium sulfate is ineffective as tocolytic

Magnesium Sulfate has Cerebro Protective Action

CALCIUM CHANNEL BLOCKERS:

The most commonly used calcium channel blocker is nifedipine.^{46,63} It acts by inhibiting the influx of extracellular calcium across the cell membrane during inward calcium current of action potential. They block the voltage sensitive L type of calcium channels. They also inhibit the release of intracellular calcium from sarcoplasmic reticulum. Thus they reduce the tone of smooth muscles.

DOSAGE OF NIFEDIPINE: most commonly used

- 20 mg orally stat
- Followed by 20 mg orally after 60 min if contractions persist
- Maintenance dose of 20 mg orally every 3-8 hrs for 48-72hrs
- Maximum dose is 160 mg /day

Onset of action after oral nifedipine is less than 20 min with peak plasma concentration in 1 hour(15-90 min) and half life of 1.5 to 3 hrs. duration of action of single dose is 6 hrs. Elimination is mainly through kidney(70%) and bowel (30%) nifedipine doesnot adversely affect uteroplacental and fetal blood flow when evaluated by Doppler

SIDE EFFECTS:

- a. Facial flushing
- b. Nausea
- c. Headache
- d. Hypotension, Tachycardia

NITROGLYCERIN^{20,22,47}:

It causes smooth muscle relaxation

Short duration of action. $t_{1/2}$ is 2 min

By following route it can be administered:

- i. Sublingual
- ii. Transdermal
- iii. Ointment
- iv. Oral capsule extended form.

DOSAGE:

10 mg transdermal patch is applied over abdomen ,if contraction persist another patch applied for 24 hrs. Not more than 2 patches should be applied simultaneously. It does not reach the fetal circulation.

OXYTOCIN RECEPTOR BLOCKADE:

Atosiban³⁷ is licensed in the UK for treatment of tocolysis preterm labour.

The recommended dosage and administration schedule for atosiban is a three-step procedure.

The initial bolus dose is 6.75 mg over one minute, followed by an infusion of 18 mg/hour for three hours and then 6 mg/hour for up to 45 hours.

Duration of treatment should not exceed 48 hours and the total dose given during a full course should preferably not exceed 330 mg of atosiban.

CORTICO STEROIDS IN PRETERM LABOUR;

The incidence and severity of neonatal respiratory distress syndrome has significantly reduced with the use of antenatal steroids according to Cochrane database (Crowther CA 2007).²⁴

The effects of corticosteroids are mediated by way of intracellular corticosteroid receptors or corticosteroid-induced paracrine effects between cells.

- Corticosteroids have been shown to stimulate the cyto differentiation in fetal lungs and at least 14 other tissues.
- Short-term neonatal benefits of maternal administration of antenatal corticosteroids include a decrease in the frequency of RDS, IVH, and neonatal mortality.

BETAMETHASONE OR DEXAMETHASONE:

Betacode trial by Elimian and colleagues (2007) ³⁰ found that the two drugs were comparable in reducing in major neonatal morbidities in premature infant.

DOSAGE :(RCOG 2004) ⁶⁵

BETAMETHASONE: 2 doses of 12 mg given in IM 24 hours apart.

DEXAMETHASONE: 4 doses of 6mg ,given IM 12 hours apart.

- There is increased incidence of interventricular hemorrhage in the betamethasone group compared to dexamethasone group.
- Antenatal exposure of betamethasone is associated with decreased incidence of periventricular leukomalacia but dexamethasone is associated with an increased incidence of periventricular leukomalacia.
- single dose of corticosteroid is recommended according to ACOG (committee opinion 402,2008).

what is rescue therapy ?

Administration of repeated corticosteroid dose when delivery becomes imminent and more than seven days elapsed since the initial dose.

Rescue therapy should not be routinely used recommended by 2000 consensus development.^{57,58}

MATERIALS AND METHODS

MATERIALS AND METHODS

STUDY DESIGN:

It is a prospective study conducted in Government RSRM lying in Hospital attached to Stanley medical college, Royapuram from September 2013 to 2014.

The study population comprised of patients who attended either the hospital outpatient department or causality.

There were 100 patients in transdermal NTG group in which 3 patient lost follow up and one patient is still continuing pregnancy.

There were 100 patient in oral nifedipine group in which 3 patient lost follow up and 2 patients are still continuing pregnancy.

Both the group received intramuscular corticosteroids.

In view of ethical issue informed written consent is obtained.

INCLUSION CRITERIA:

1. Gestational age between 28 and 36 completed weeks as determined by menstrual dates ,clinical examination, ultrasonogram abdomen.
2. Singleton pregnancy.

3. Uterine contractions – regular and painful ,3 per 10 min each lasting for more than 40 to 45 secs.
4. Progressive cervical effacement up to 75%.
5. Cervical dilatation up to 3 cm.
6. Intact membranes.

EXCLUSION CRITERIA:

Maternal Conditions:

1. Rupture of membranes
2. Infection.
3. Cervical dilatation greater than 3 cm
4. Antepartum hemorrhage
5. Polyhydramnios /oligohydramnios
6. Hypertension complicating pregnancy.
7. Cardiac disease.
8. Renal disease

9. Pulmonary disorder- asthmatics, ARDS
10. Uncontrolled diabetes mellitus
11. Cervical incompetence
12. Treatment with another tocolytic agent in the previous 24 hours.

Fetal Factors:

1. Multiple gestation
2. Fetal death
3. Fetal distress
4. Intra uterine growth restriction
5. Congenital anomalies.

INVESTIGATIONS:

- Urine analysis
- Complete blood count
- Vaginal swab
- Ultrasound abdomen

DRUG PROTOCOL:

On admission , patients are put in left lateral position and measured for blood pressure , pulse rate. cardio vascular system and respiratory system examined.

Each patients received 12 mg of betamethasone intramuscularly, first dose is given at the time of admission and after 24 hours second dose is repeated to accelerate the fetal lung maturity.

GROUP I

Patients in this group receives transdermal NTG patch which delivers 10mg of NTG over 24 hours.

If contraction persist after 1 hour an additional patch is applied.

Two patches (10 mg) should not be applied simultaneously.

At the end of 24 hours fresh patches are applied.

Mild headaches are treated with oral paracetamol.

When the contraction ceases patches remain in the place for 12 hours.

If the uterine contraction doesnot stops with two patches tocolysis is not achieved and treatment stopped.

Achievement of tocolysis is considered when the contraction ceases and Prolongation of pregnancy atleast for 48 hours.

GROUP II :

Patients receive 20 mg of nifedipine as loading dose.

When contraction persist even after one hour another 20 mg is given.

If the contraction stops after the first or the second dose, maintenance dose of oral nifedipine 20 mg every 6 hours is given for the next 48hours. Maintenance dose started 6 hours after the last dose. If the uterine contraction doesnot arrest even after the 40 mg of Nifedipine then tocolysis is not achieved.

Tocolysis is achieved when the contraction stops and no progression of cervical effacement and dilatation and prolongation of pregnancy atleast for 48 hours.

Antibiotic treatment should be given to the patient whenever necessary to control the infection.

VITALS TO BE MONITORED:

1. BP, PR , Temperature, RR hourly in both groups.
2. Systolic B.P <100 mm of Hg or P.R > 100 or increase in temperature will be reported.
3. Adverse effects are carefully monitored.
4. Fetal heart rate should be monitored hourly in the initial hours of Stabilisation and fourth hourly for the first 48 hours.

ACHIEVEMENT OF TOCOLYSIS:

In this study achievement of tocolysis is considered when the contraction stops with 20 mg of transdermal nitroglycerin or 40 mg of nifedipine and the pregnancy is prolonged for atleast 48 hours.

FALIURE OF ACHEIVEMENT OF TOCOLYSIS:

When the contraction does not stops with 20 mg of transdermal patch of nitroglycerine and 40 mg of nifedipine and inability to prolong the pregnancy for atleast 48 hours .

OUTCOME ARE NOTED AS :

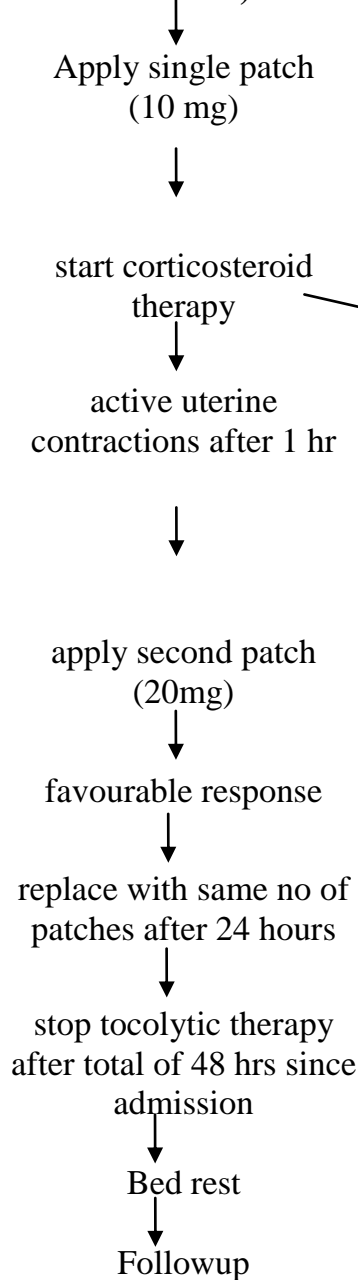
- Delay in the delivery for 48 hrs, 7 days, and more than 7 days.
- Gestational age of delivery.
- Any side effect of each drug.
- Neo natal out come.
- Birth weight
- Respiratory distress.
- Need and duration of NICU care.
- Neonatal complication.
- Perinatal mortality

Hence this study confines itself to the comparison of two drugs namely transdermal patch of nitroglycerine and oral nifedipine in prolongation of pregnancy for atleast 48 hours and studying the maternal and fetal effects.

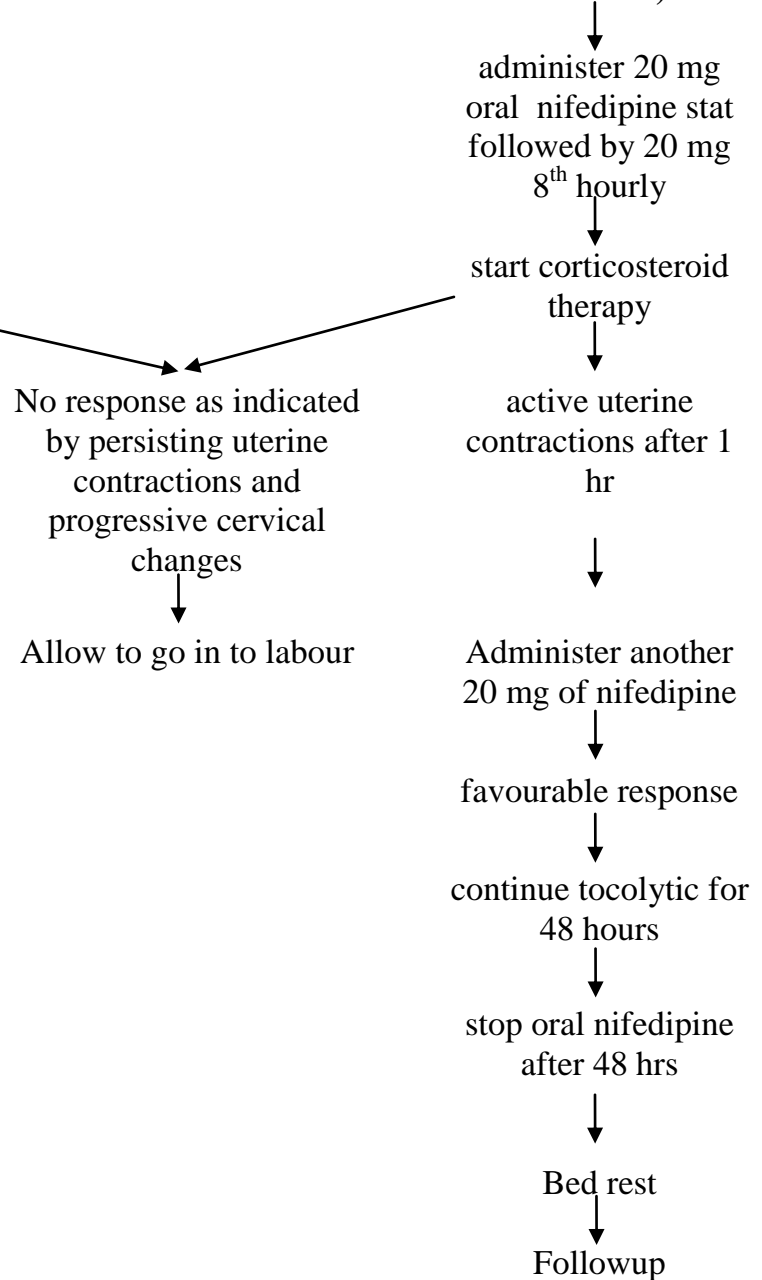
TOCOLYTIC THERAPY FOR PRETERM LABOUR

- Women at 28 to 37 weeks of gestation presenting with preterm labour.
- Regular painful uterine contractions(3/10 min).
- Progressive cervical changes like effacement and dilatation (<4cm)

GROUP I (NITROGLYCERINE GROUP)



GROUP II (NIFEDIPINE GROUP)

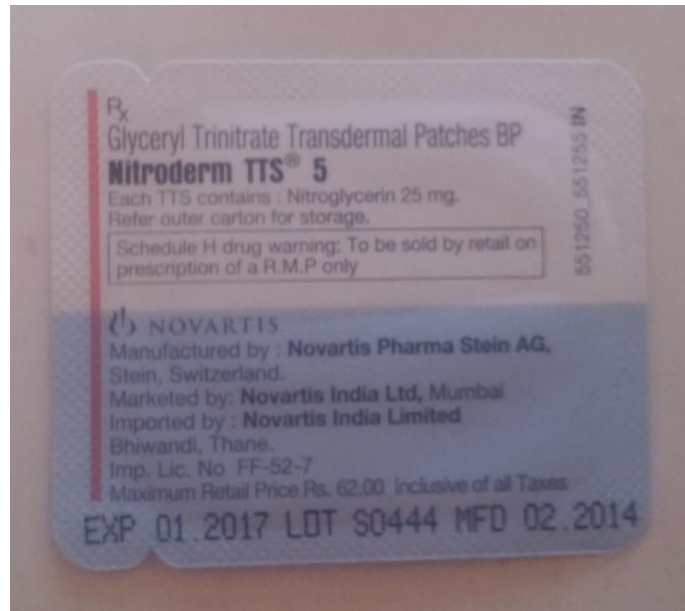


No response as indicated by persisting uterine contractions and progressive cervical changes

↓

Allow to go in to labour

NITRO GLYCERINE PATCH USED IN THIS STUDY



RESULTS AND OBSERVATION

RESULTS AND OBSERVATIONS

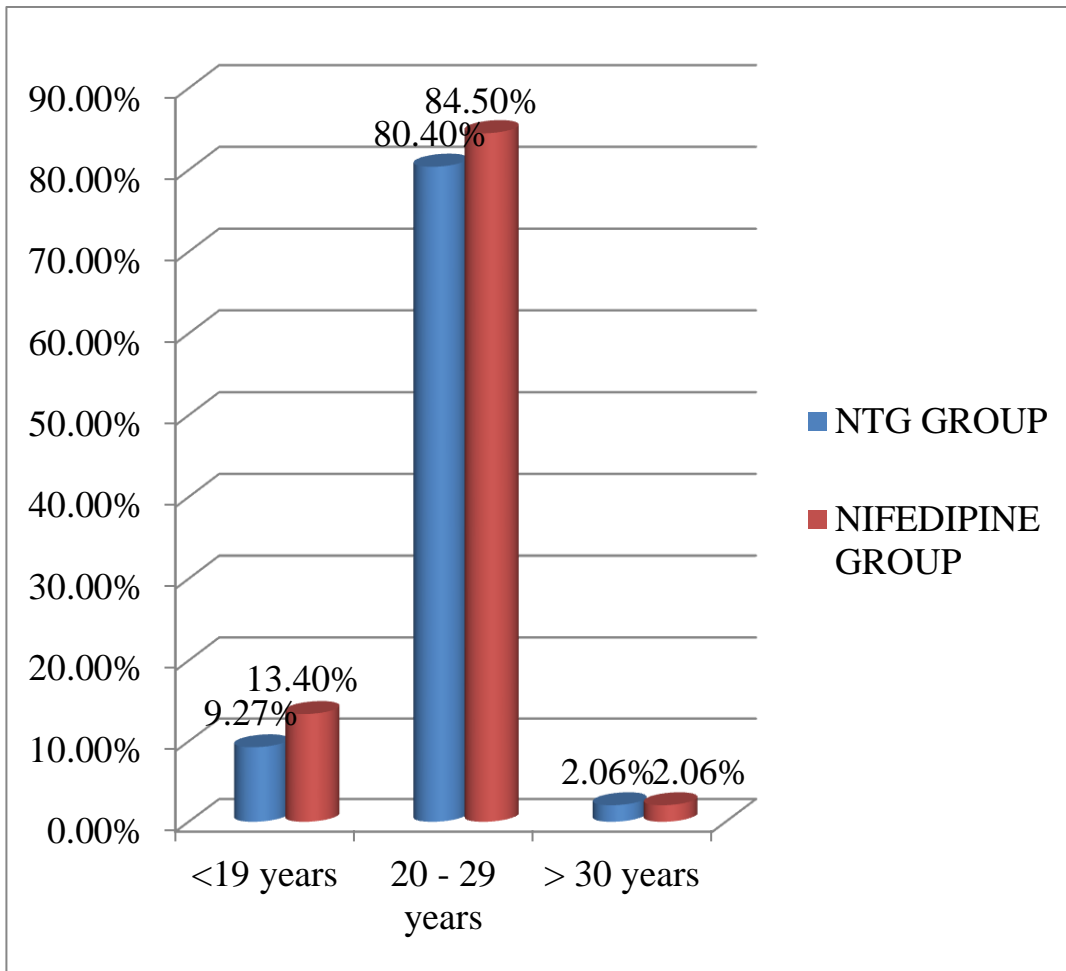
AGE DISTRIBUTION

TABLE - 1

| AGE IN YRS | NTG GROUP | | NIFEDIPINE GROUP | |
|------------|-----------|-------|------------------|-------|
| | NO | % | NO | % |
| <19 YRS | 9 | 9.27% | 13 | 13.4% |
| 20-29 YRS | 78 | 80.4% | 82 | 84.5% |
| >30YRS | 2 | 2.06% | 2 | 2.06% |

The incidence of preterm labour is about 9.27% in <19 yrs in NTG group and 13.4% in nifedipine group. In the 20 to 29 yrs category the incidence is 80.4% in the NTG group and 84.5% in the nifedipine group. but above the age of 30 years the incidence is 2.06% both in NTG and nifedipine group. The mean age in the NTG group 22.86 and nifedipine 22.32. Maximum incidence occurs in the age group of 20 to 29 yrs.

AGE DISTRIBUTION

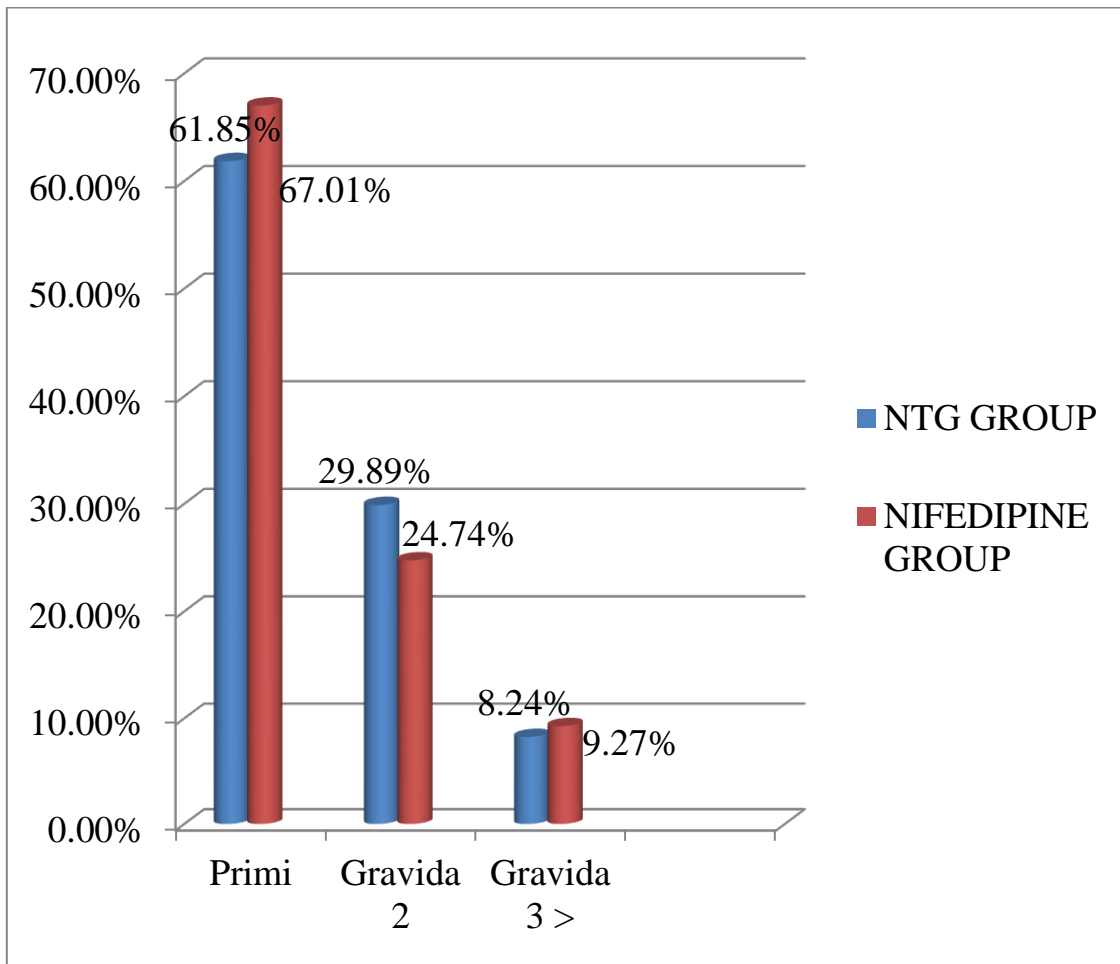


PARITY
TABLE - 2

| PARITY | NTG GROUP | | NIFEDIPINE GROUP | |
|---------------------|------------------|----------|-------------------------|----------|
| | NO | % | NO | % |
| PRIMI | 60 | 61.85% | 65 | 67.01% |
| GRAVIDA 2 | 29 | 29.89% | 24 | 24.74% |
| GRAVIDA 3 AND ABOVE | 8 | 8.24% | 9 | 9.27% |

The incidence in primi is 61.85% in NTG group and 67.01% in nifedipine group and in 2nd gravid incidence is 29.89% in NTG group and 24.74% in nifedipine group in multigravida incidence is 8.24% in NTG group and 9.27% in nifedipine group. Maximum incidence is in primigravida.

PARITY



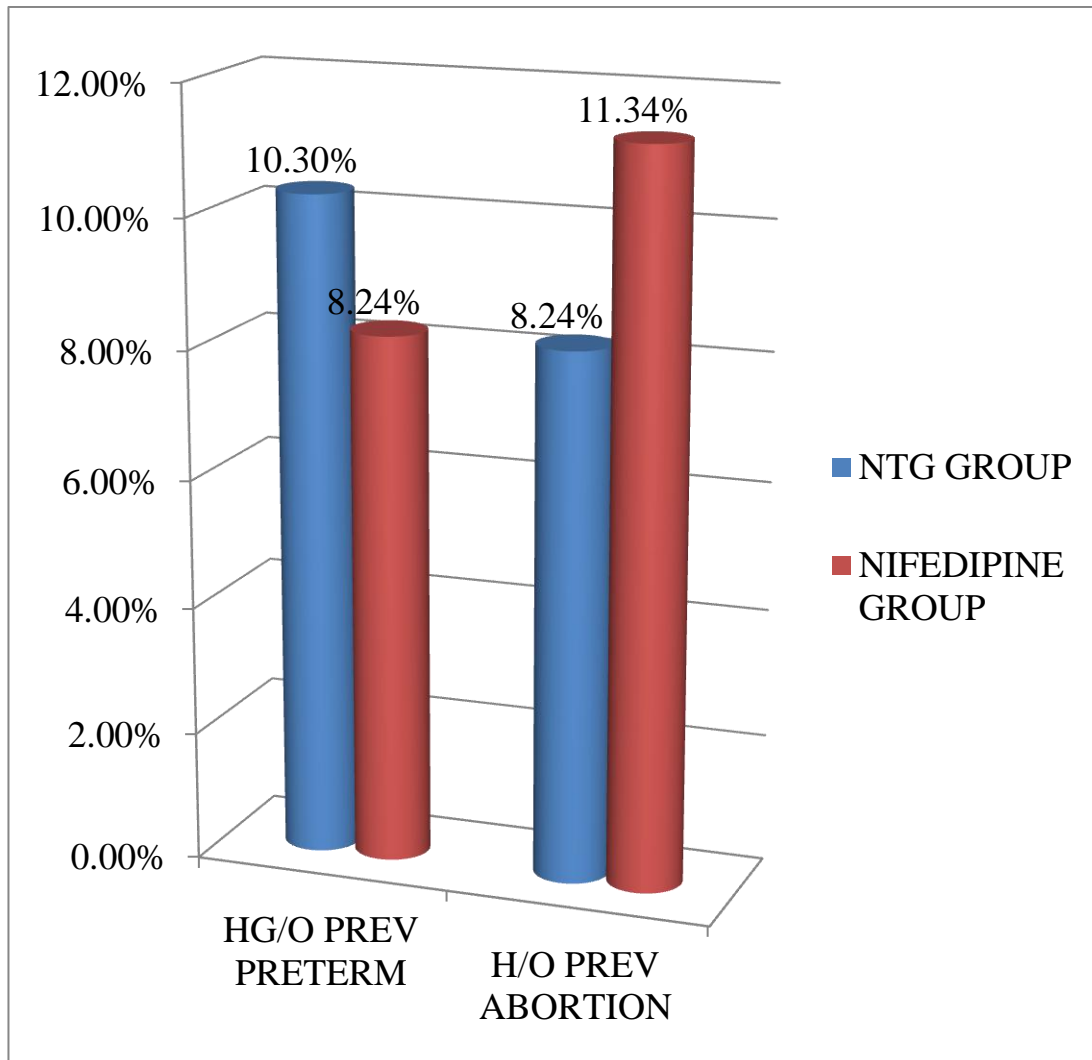
PREDISPOSING FACTORS

TABLE - 3

| PREDISPOSING FACTOR | NTG GROUP | | NIFEDIPINE GROUP | |
|---------------------|-----------|-------|------------------|--------|
| | NO | % | NO | % |
| H/O PREV PRETERM | 10 | 10.3% | 8 | 8.24% |
| H/O PREV ABORTION | 8 | 8.24% | 11 | 11.34% |

10.3% and 8.24% had history of previous preterm labour in NTG group and nifedipine group respectively. 8.24% and 11.34% had previous history of one or more abortions.

PREDISPOSING FACTORS



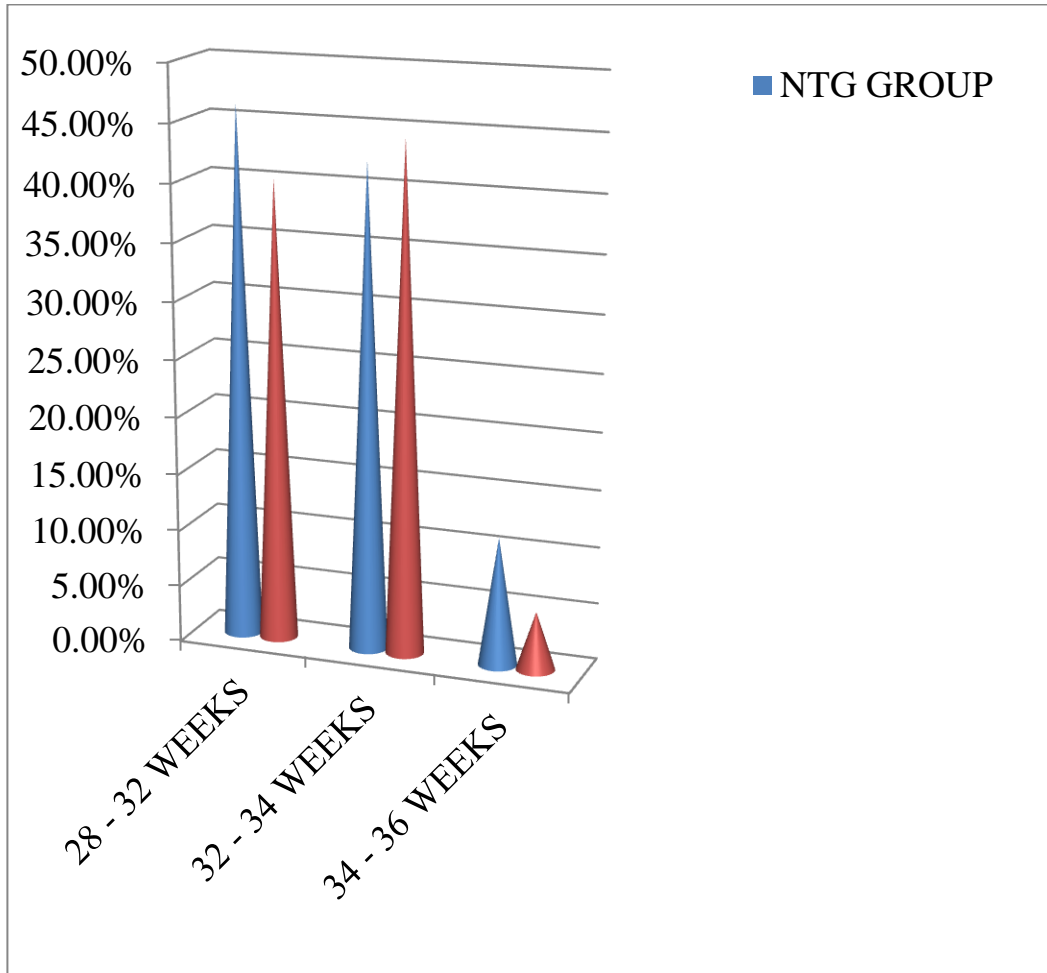
GESTATIONAL AGE

TABLE - 4

| AGE IN WEEKS | NTG GROUP | | NIFEDIPINE GROUP | |
|---------------|-----------|--------|------------------|--------|
| | NO | % | NO | % |
| 28 – 32 WEEKS | 45 | 46.4% | 39 | 40.2% |
| 32- 34 WEEKS | 41 | 42.26% | 43 | 44.33% |
| 34-36 WEEKS | 11 | 11.34% | 5 | 5.15% |

46.4% and 40.2% of preterm labour is observed in gestational age between 28 to 32 weeks ,42.26% and 44.33% of preterm labour observed in 32 to 34 weeks ,11.43% and 5.15% was observed in 34 to 36 weeks in NTG patch group and nifedipine group respectively.

GESTATIONAL AGE



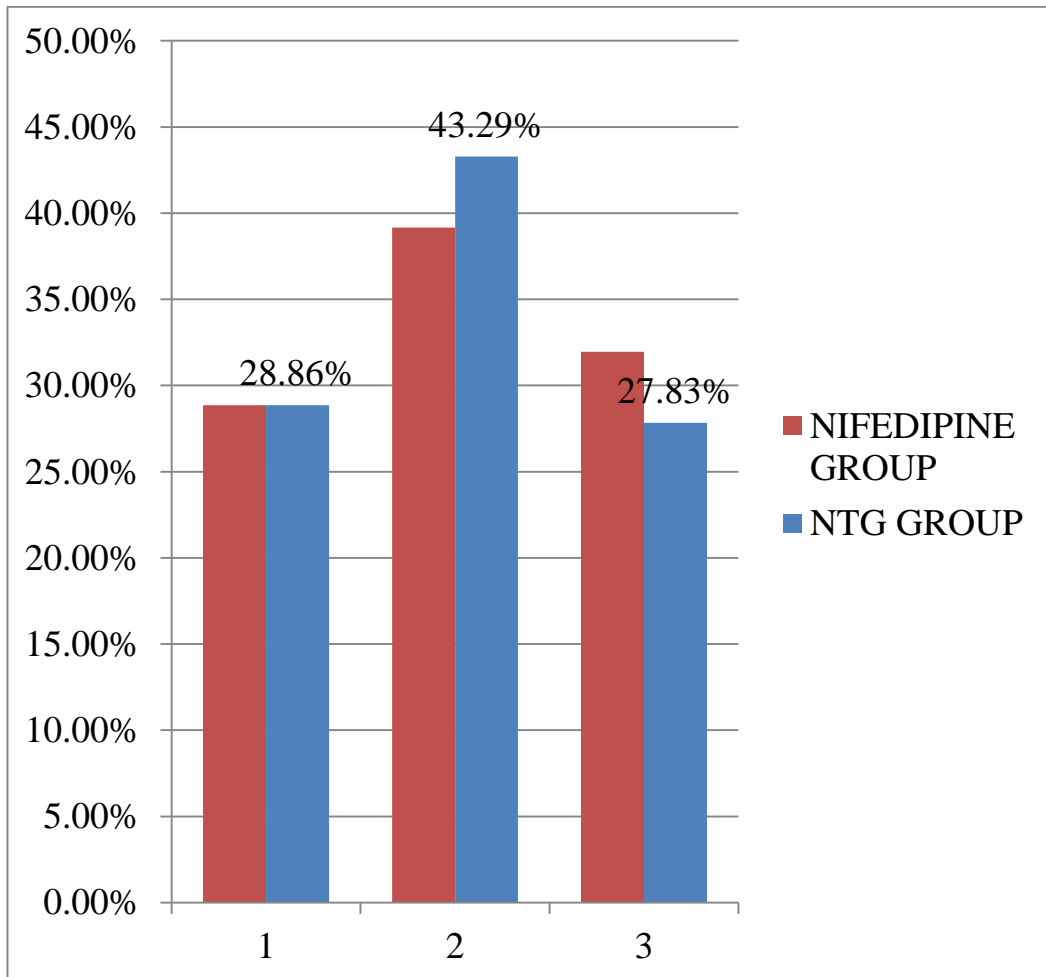
CERVICAL DILATATION

TABLE - 5

| CD IN CMS | NTG GROUP | | NIFEDIPINE GROUP | |
|-----------|-----------|--------|------------------|--------|
| | NO | % | NO | % |
| 1 | 28 | 28.86% | 28 | 28.86% |
| 2 | 42 | 43.29% | 38 | 39.17% |
| 3 | 27 | 27.83% | 31 | 31.95% |

The cervix was 1 cm dilated in 28.86% both in NTG and nifedipine group, 2cm dilated in 43.29% and 39.17% in NTG group and nifedipine group respectively and 27.83% and 31.95 % in 3 cm dilated in NTG and nifedipine group respectively.

CERVICAL DILATATION



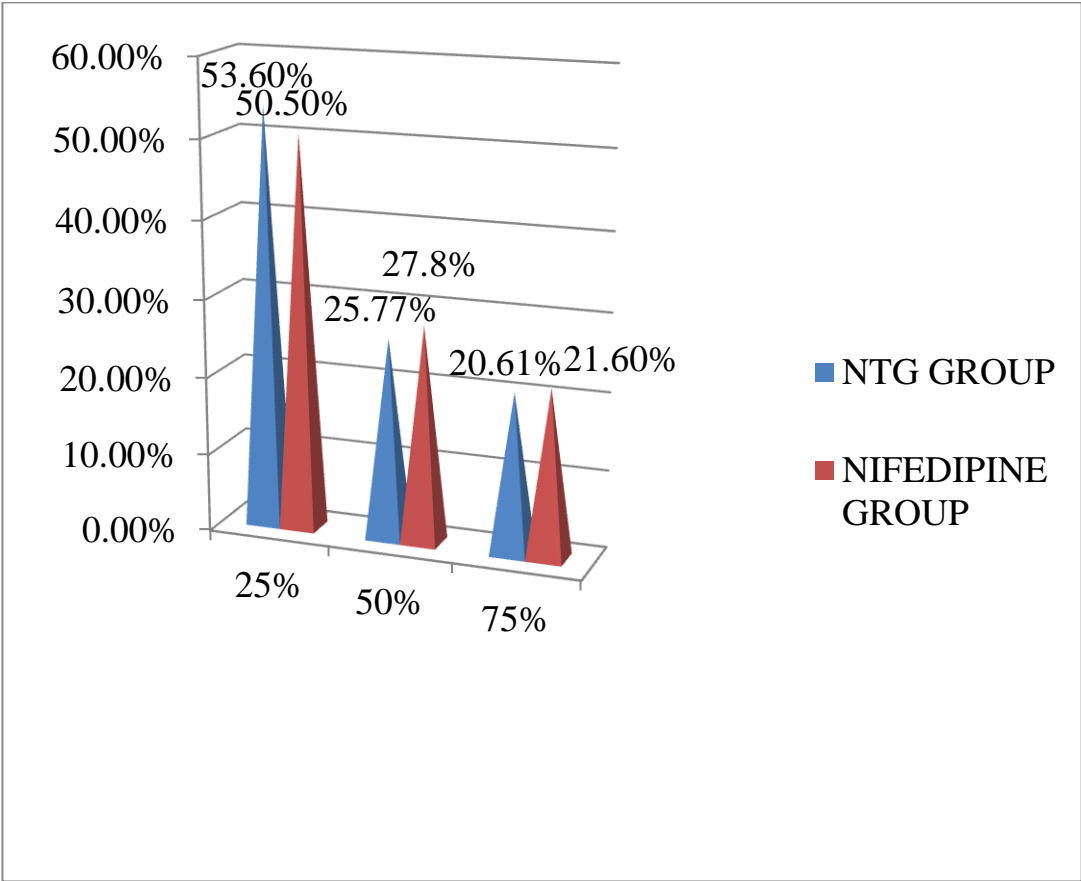
CERVICAL EFFACEMENT

TABLE - 6

| % OF EFFACEMENT | NTG GROUP | | NIFEDIPINE GROUP | |
|-----------------|-----------|--------|------------------|--------|
| | NO | % | NO | % |
| 25% | 52 | 53.60% | 49 | 50.51% |
| 50% | 25 | 25.77% | 27 | 27.83% |
| 75% | 20 | 20.61% | 21 | 21.64% |

The cervix was 25% effaced in 53.60% of cases and 50.51% of cases in NTG group and nifedipine group respectively, 50% effaced in 25.77% of cases and 27.83% of cases in NTG group and nifedipine group respectively, 20.16% and 21.64% of cases in NTG group and nifedipine group respectively.

CERVICAL EFFACEMENT



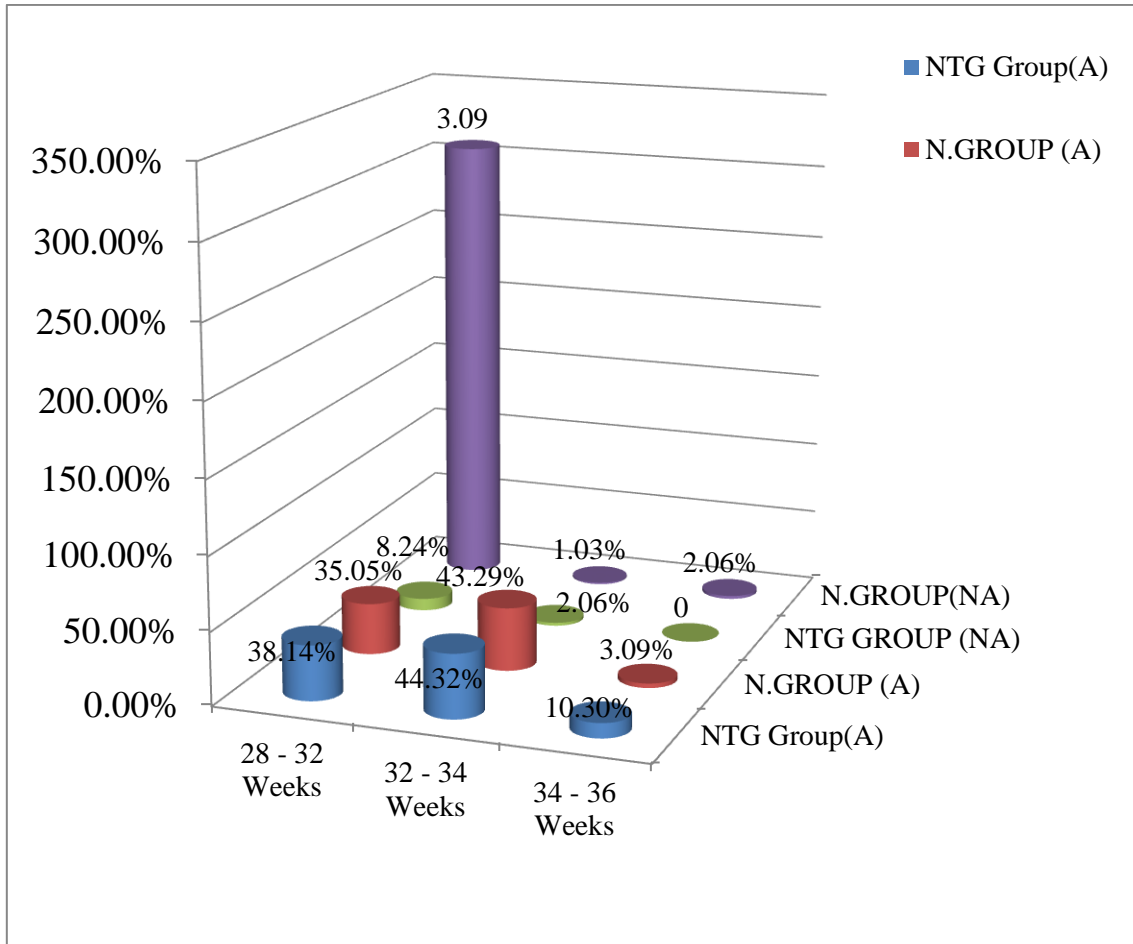
RESPONSE ACCORDING TO GESTATIONAL AGE

TABLE - 7

| GA IN WEEKS | NTG GROUP | | | | NIFEDIPINE GROUP | | | |
|-------------|-----------|--------|----|-------|------------------|--------|----|-------|
| | A | % | NA | % | A | % | NA | % |
| 28-32 WEEKS | 37 | 38.14% | 8 | 8.24% | 34 | 35.05% | 3 | 3.09% |
| 32-34 WEEKS | 43 | 44.32% | 2 | 2.06% | 42 | 43.29% | 1 | 1.03% |
| 34-36 WEEKS | 10 | 10.3% | 0 | 0 | 3 | 3.09% | 2 | 2.06% |

The prolongation of pregnancy more than 48 hrs is 44.32% and 43.29% in 32- 34 weeks gestational age group , 38.14% and 35.05% in 28 to 32 weeks of gestational age and 10.3% and 3.09% in 34 to 36 weeks gestational group in NTG and nifedipine group .p value is 0.42.

RESPONSE ACCORDING TO GESTATIONAL AGE



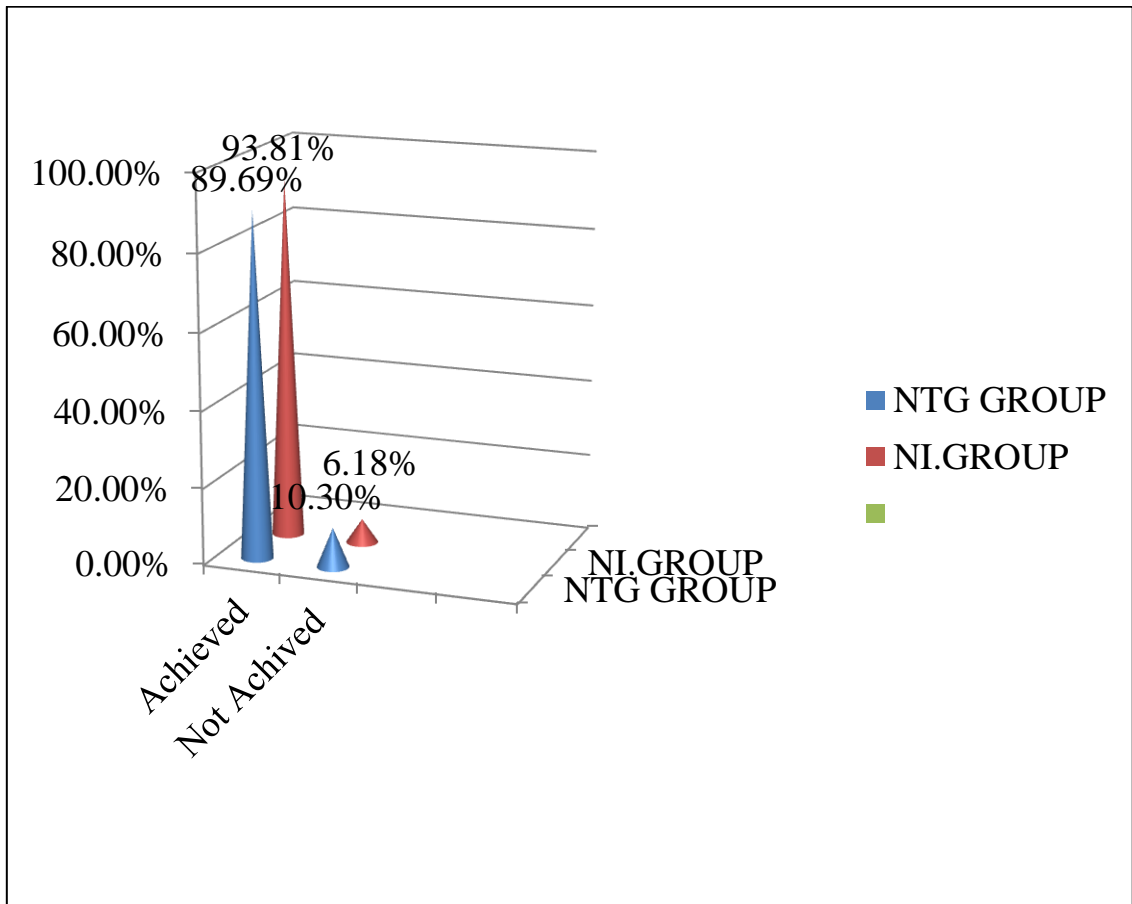
ACHIEVEMENT OF TOCOLYSIS

TABLE - 8

| ACHIEVED/NOT ACHIEVED | NTG GROUP | | NIFEDIPINE GROUP | |
|--------------------------|-----------|--------|---------------------|--------|
| | NO | % | NO | % |
| ACHIEVED | 87 | 89.69% | 91 | 93.81% |
| NOT ACHIEVED | 10 | 10.3% | 6 | 6.18% |

The achievement of tocolysis is 89.69 % in NTG group and 93.81% in nifedipine group and the p value is 0.2.

ACHIEVE MENT OF TOCOLYSIS



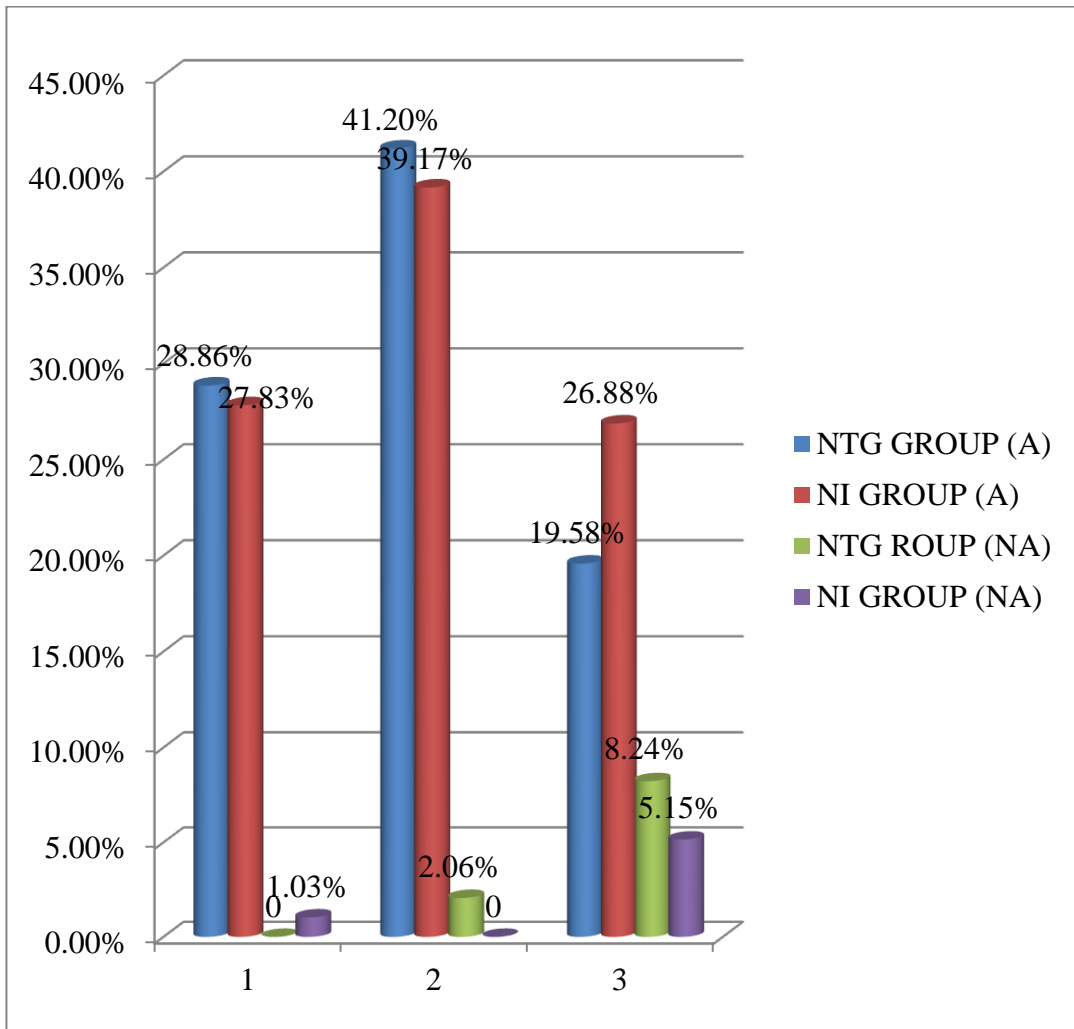
RESPONSE ACCORDING TO CERVICAL DILATATION

TABLE - 9

| CD IN CMS | NTG GROUP | | | | NIFEDIPINE GROUP | | | |
|-----------|-----------|--------|----|-------|------------------|--------|----|-------|
| | A | % | NA | % | A | % | NA | % |
| 1 | 28 | 28.86% | 0 | 0 | 27 | 27.83% | 1 | 1.03% |
| 2 | 40 | 41.2% | 2 | 2.06% | 38 | 39.17% | 0 | 0 |
| 3 | 19 | 19.58% | 8 | 8.24% | 26 | 26.88% | 5 | 5.15% |

The patients who delivered after 48 hours in NTG and nifedipine group with cervical dilatation 2cm is 41.2% and 39.17% respectively and 28.86% and 27.83% in patients with 1 cm dilatation respectively. p value is 0.03.

RESPONSE ACCORDING TO CERVICAL DILATATION



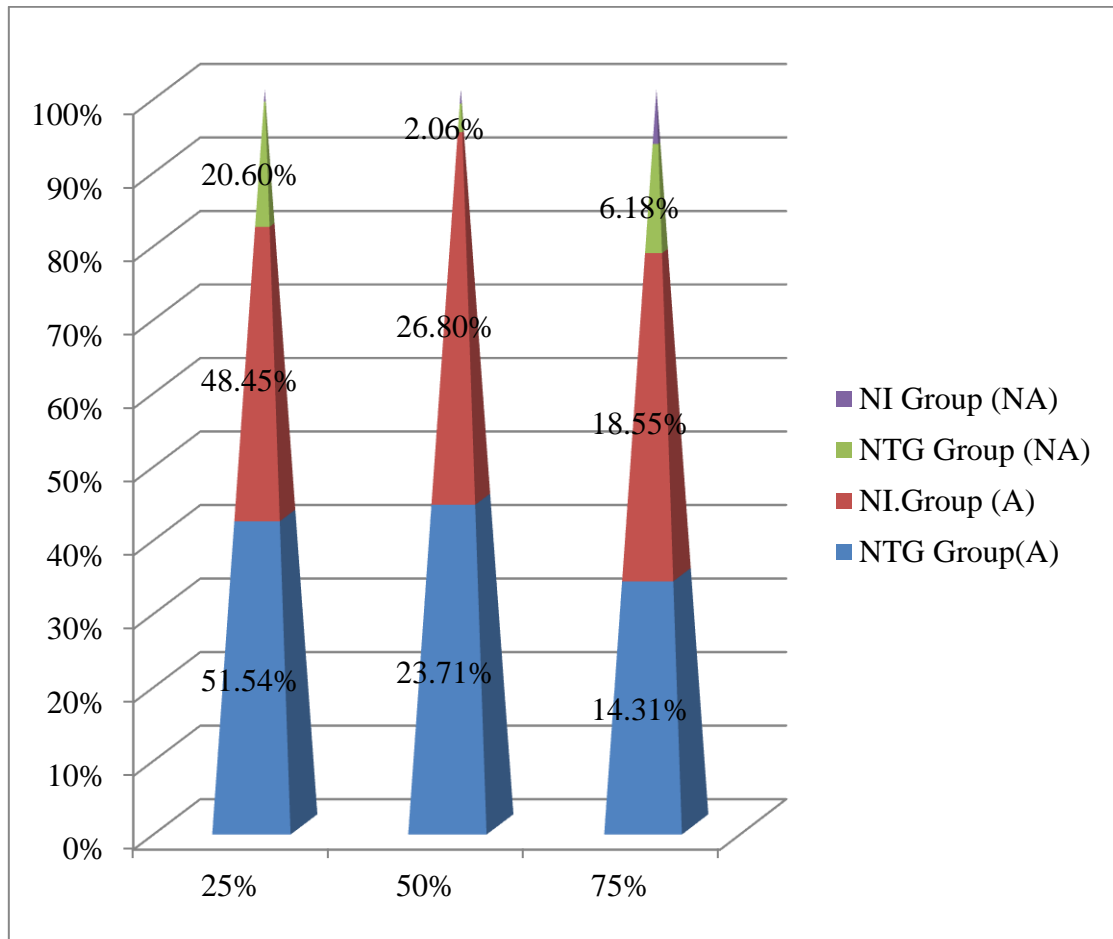
RESPONSE ACCORDING TO CERVICAL EFFACEMENT

TABLE - 10

| CERVICAL EFFACEMENT | NTG GROUP | | | | NIFEDIPINE GROUP | | | |
|--------------------------------|------------------|----------|-----------|----------|-------------------------|----------|-----------|----------|
| | A | % | NA | % | A | % | NA | % |
| 25% | 50 | 51.54% | 2 | 2.06% | 47 | 48.45% | 2 | 2.06% |
| 50% | 23 | 23.71% | 2 | 2.06% | 26 | 26.80% | 1 | 1.03% |
| 75% | 14 | 14.31% | 6 | 6.18% | 18 | 18.55% | 3 | 3.09% |

Among the patients who delivered successfully in the NTG group and nifedipine group the cervix was 25 % effaced in 51.54 % and 48.45% and 50 % effaced in 23.71% and 26.80% and 75% effaced in 14.31% and 18.55% respectively. P value is 0.9.

RESPONSE ACCORDING TO CERVICAL EFFACEMENT



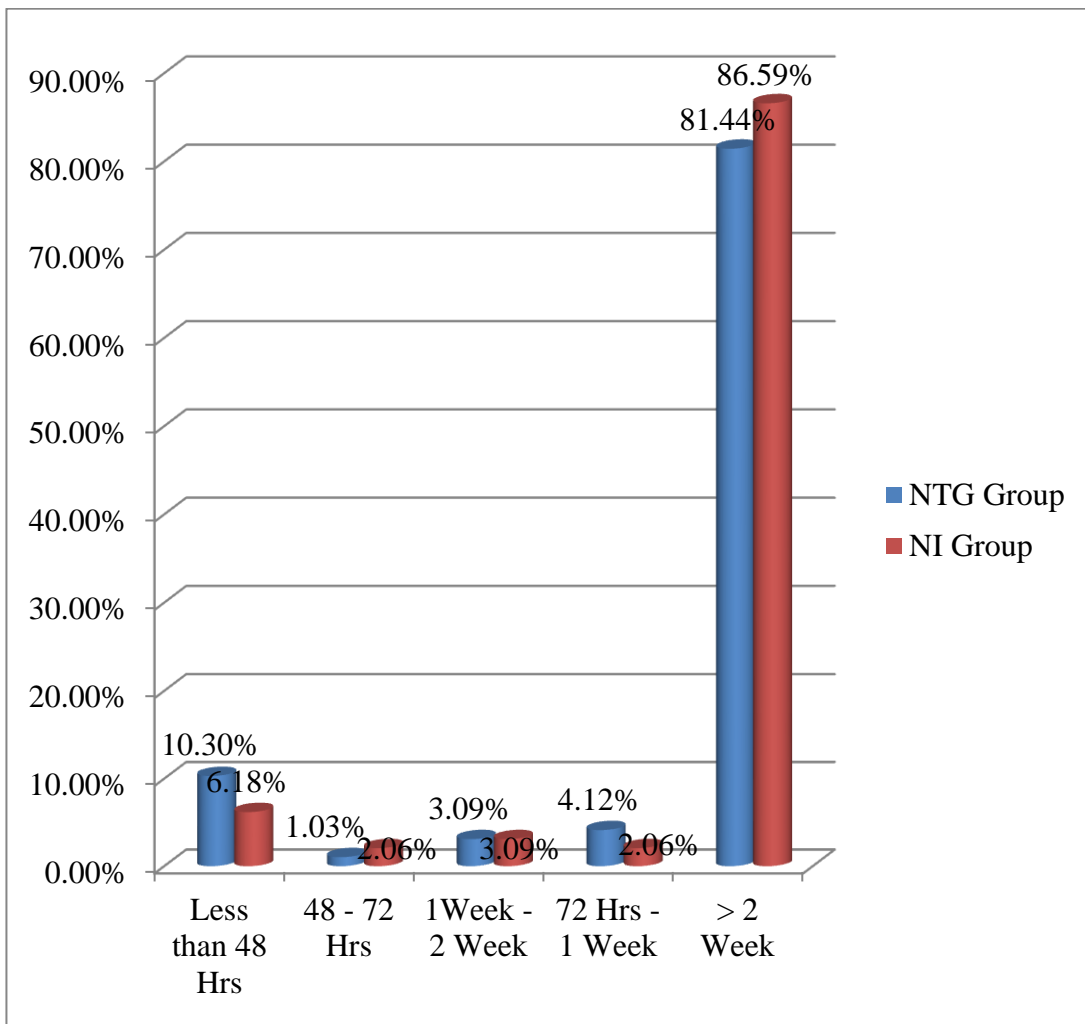
DURATION OF PROLONGATION

TABLE - 11

| DAYS | NTG GROUP | | NIFEDIPINE GROUP | |
|-----------------|-----------|--------|------------------|--------|
| | NO | % | NO | % |
| LESSTHAN 48 HRS | 10 | 10.3% | 6 | 6.18% |
| 48 – 72 HRS | 1 | 1.03% | 2 | 2.06% |
| 72HRS-1 WEEK | 3 | 3.09% | 3 | 3.09% |
| 1WEEK – 2 WEEK | 4 | 4.12% | 2 | 2.06% |
| >2 WEEK | 79 | 81.44% | 84 | 86.59% |

The prolongation of pregnancy beyond 2 weeks is 86.59% and 81.44% in nifedipine and nitroglycerine patch group respectively.

DURATION OF PROLONGATION



MODE OF DELIVERY

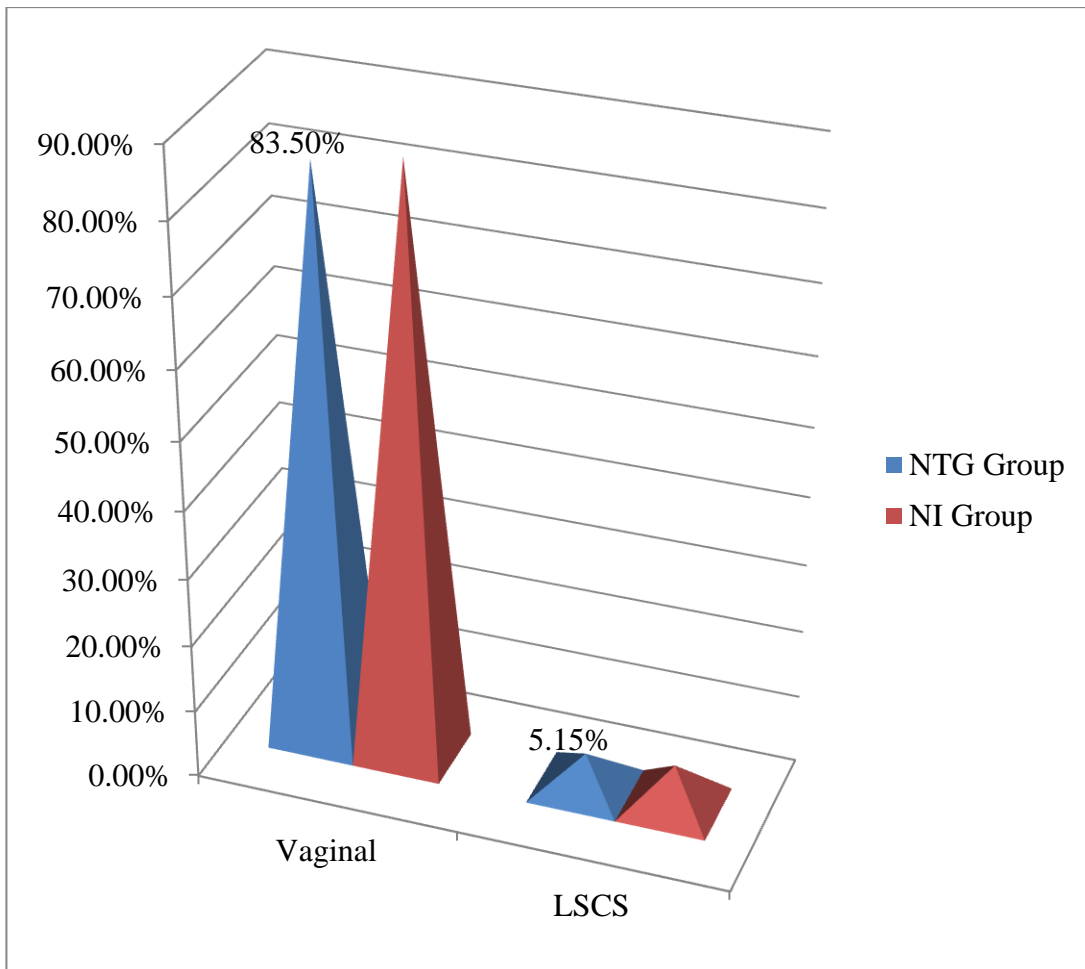
TABLE - 12

| MOD | NTG GROUP | | | | NIFEDIPINE GROUP | | | |
|---------|-----------|--------|----|-------|------------------|--------|----|-------|
| | A | % | NA | % | A | % | NA | % |
| VAGINAL | 81 | 83.50% | 10 | 10.3% | 83 | 85.56% | 6 | 6.18% |
| LSCS | 5 | 5.15% | 0 | 0 | 6 | 6.18% | 0 | 0 |

85.56% and 83.50% of cases delivered vaginally in nifedipine group and nitroglycerine group respectively .p value is 0.985 is insignificant. 6 cases in nifedipine group underwent LSCS (lower segment caesarean section) 3 cases PROM (premature rupture of membrane) with no response to oxytocin and 2 cases for fetal distress with meconium stained liquor and 1 case with breech in labour.

5 cases in NTG group underwent caserean section of these 3 cases fetal distress with meconium stained liquor and 2 cases PROM with no respon oxytocin.

MODE OF DELIVERY



MATERNAL MORBIDITY

TABLE - 13

| NTG GROUP | | NIFEDIPINE GROUP | |
|------------|----|-----------------------------|----|
| IRRITATION | 14 | HYPOTENSION | 4 |
| RASH | 1 | TACHYCARDIA | 12 |
| HEADACHE | 25 | HYPOTENSION, TACHYCARDIA | 5 |
| | | NAUSEA,VOMITTING | 4 |
| | | FACIAL FLUSHING | 7 |

This table represent the maternal morbidity in both the groups. The p value is 0.0001 which is statistically significant . no cases of maternal mortality.no cases of postpartum hemorrhage noted in both groups.

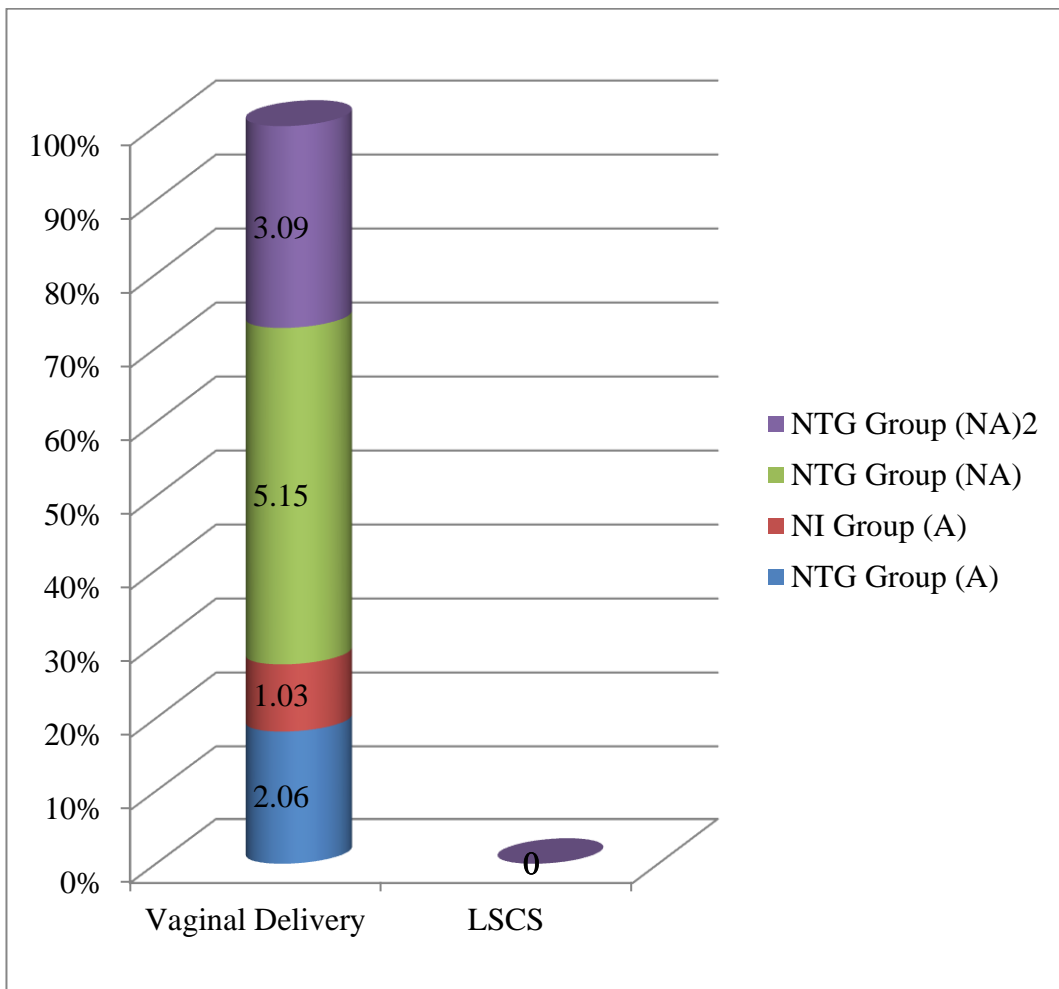
NEONATAL MORTALITY

TABLE - 14

| MOD | NTG GROUP | | NIFEDIPINE GROUP | |
|------------------|------------------|-----------|-------------------------|-----------|
| | A | NA | A | NA |
| VAGINAL DELIVERY | 2(2.06%) | 5(5.15%) | 1(1.03%) | 3(3.09%) |
| LSCS | - | - | - | - |

The neonatal mortality was 5.15% in NTG group and 3.09% in nifedipine. Not achieved group in vaginal delivery. No neonatal mortality in caesarian Group.

NEONATAL MORTALITY



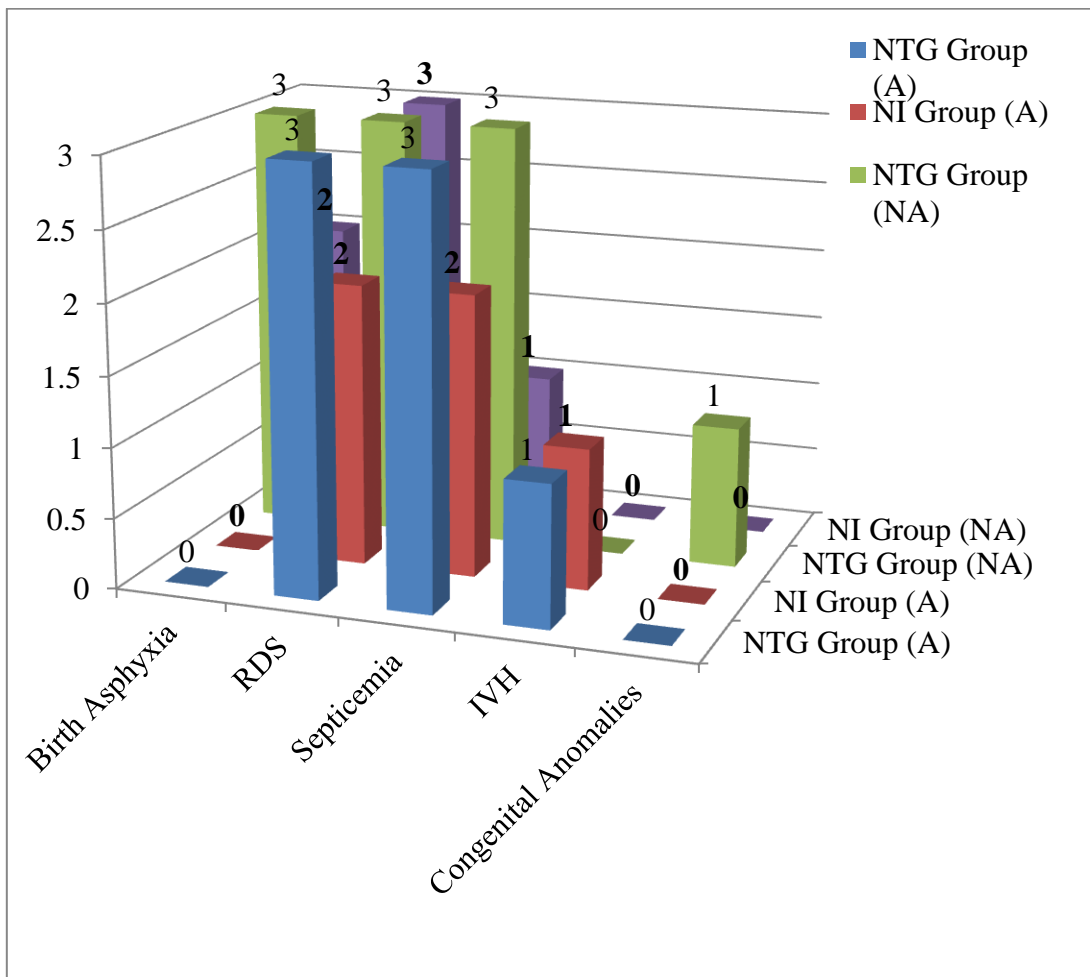
NEONATAL MORBIDITY

TABLE - 15

| MORBIDITY | NTG GROUP | | NIFEDIPINE GROUP | |
|----------------------|-----------|----|------------------|----|
| | A | NA | A | NA |
| BIRTH ASPHYXIA | 0 | 3 | 0 | 2 |
| RDS | 3 | 3 | 2 | 3 |
| SEPTICEMIA | 3 | 3 | 2 | 1 |
| IVH | 1 | 0 | 1 | 0 |
| CONGENITAL ANOMALIES | - | 1 | - | - |

Better neonatal outcome as to the decrease in the presence of respiratory distress syndrome and other complication in neonates is more nifedipine success group.

NEONATAL MORBIDITY



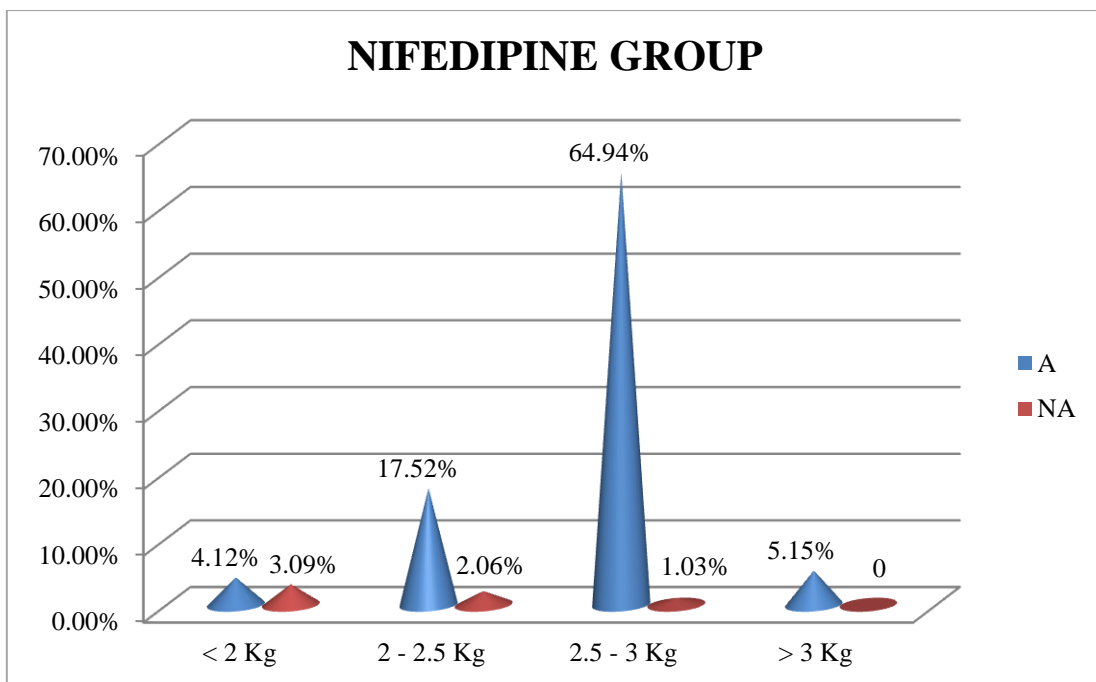
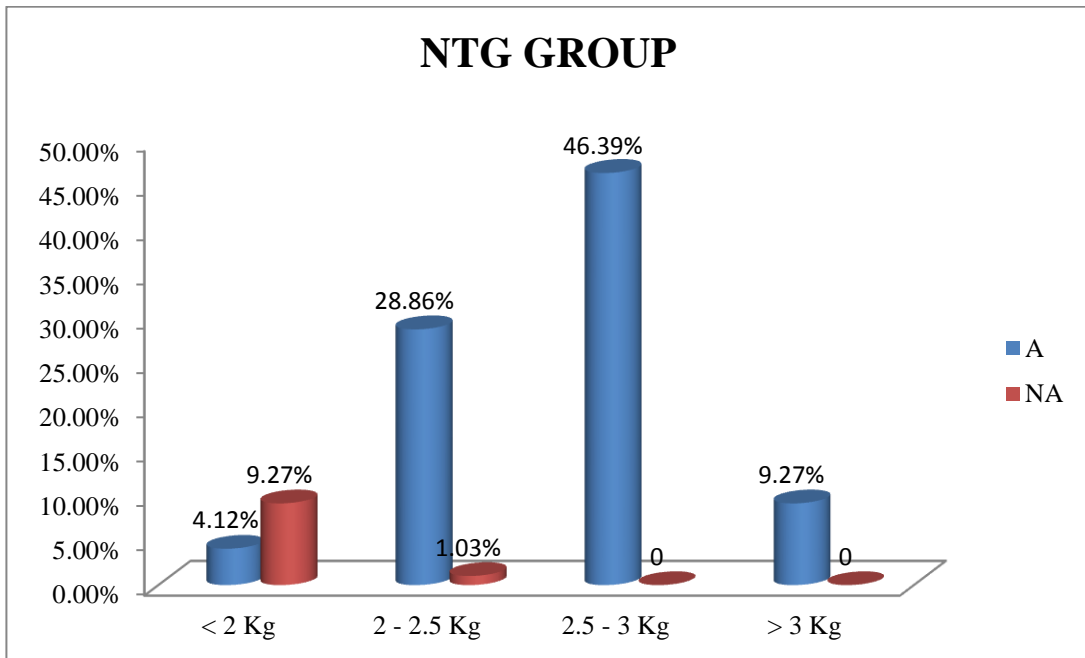
WEIGHT OF BABY AT BIRTH

TABLE - 16

| BIRTH WEIGHT IN KG | NTG GROUP | | | | NIFEDIPINE GROUP | | | |
|-----------------------------------|------------------|----------|-----------|----------|-------------------------|----------|-----------|----------|
| | A | | NA | | A | | NA | |
| | NO | % | NO | % | NO | % | NO | % |
| <2 KG | 4 | 4.12% | 9 | 9.27% | 4 | 4.12% | 3 | 3.09% |
| 2 - 2.5KG | 28 | 28.86% | 1 | 1.03% | 17 | 17.52% | 2 | 2.06% |
| 2.5 - 3 KG | 45 | 46.39% | - | - | 63 | 64.94% | 1 | 1.03% |
| >3kg | 9 | 9.27% | - | - | 5 | 5.15% | - | - |

Among the achieved cases 46.39% and 64.94% found in NTG group and in nifedipine group respectively in 2.5 – 3 kg group . >3kg was found in 9.27% in NTG group compared to nifedipine group 5.15%.

WEIGHT OF BABY AT BIRTH



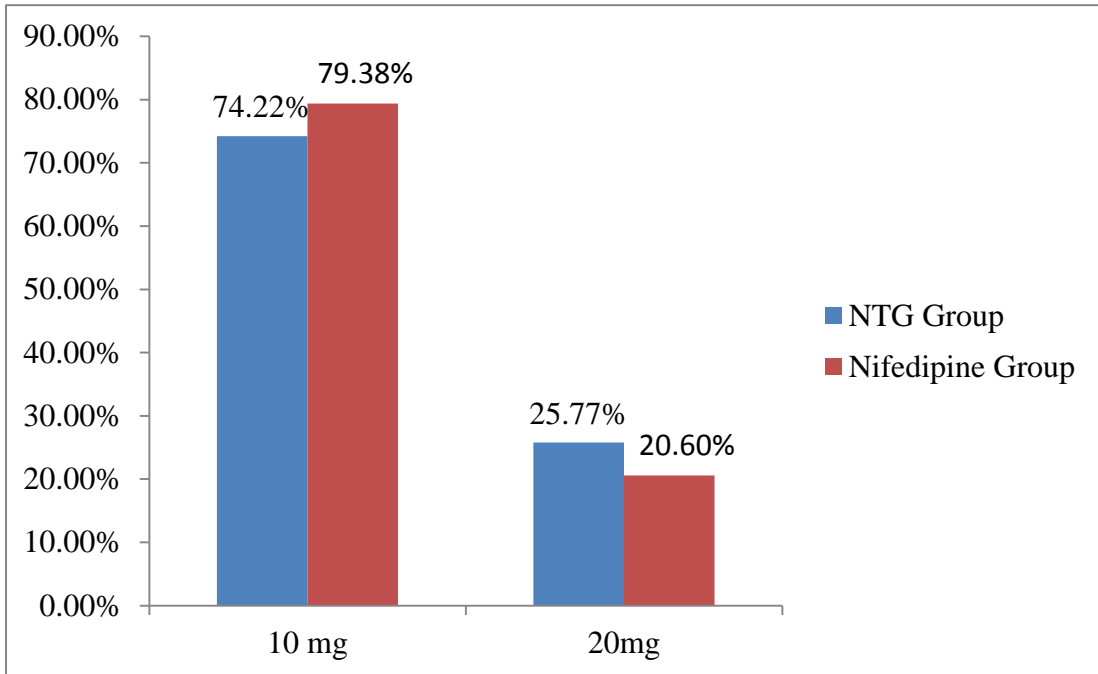
DOSAGE REQUIRED

TABLE - 17

| NTG GROUP | | | NIFEDIPINE GROUP | | |
|-----------|----|--------|------------------|----|--------|
| mg | NO | % | mg | NO | % |
| 10 mg | 72 | 74.22% | 20 mg | 77 | 79.38% |
| 20 mg | 25 | 25.77% | 40 mg | 20 | 20.6% |

Among the nitroglycerine group 74.22% required 10 mg and 25.77% required 20 mg . 79.38% and 20.6% required 20 mg and 40 mg in the nifedipine group Respectively.

DOSAGE REQUIRED



DISCUSSION

DISCUSSION

In our study the range of gestational age was 28 to 37 weeks in other studies it was 24 to 32 weeks (Nikolov et al) and 26 to 34 weeks (Bekkari et al). Gestational Age was from 20 to 26 weeks up to a maximum of 33.5 weeks to 36 weeks in Cochrane metaanalysis by King JF et al⁴⁶ in 2003.

In our study the dosage of nifedipine used is 40 mg of oral nifedipine in the first hour followed by 20 mg of maintenance dose (Papatonis et al)⁶³. Bekkari et al¹⁴ used nifedipine of 30 mg of loading dose given as 10 mg tablets every 20 min 3 hours later followed by maintenance dose of 10 mg of oral nifedipine 6th hourly for 3 days.

Wani et al⁷⁰ found the prolongation beyond 2 days to be 91% with NTG versus 88% in ritodrine group but in the RNOTT multicentric trial NTG showed lower 63% efficacy in prolonging labour beyond 48 hours against 71% with ritodrine.

Nifedipine prolonged pregnancy two days in 80.9% women compared to 69.5% in ritodrine in the study by Papatonis et al.⁶³ In our study nifedipine is significantly better in prolonging pregnancy beyond 48 hours.

In the trial by papatsonis et al nifedipine was found to delay the childbirth beyond 7 and 14 days in 72.1% and 64.7% patients respectively compare to ritodrine group. The mean prolongation of days in this study was 27.66 days in NTG group and 34.653 in the nifedipine group which was similar to the results in paptsonis et al.⁶³

A number of studies have quoted that nifedipine decreases the incidence of RDS similarly smith et al reported the same effect which is similarly present in our study.

The side effects of NTG and ritodrine compared by Lees et al found that the only side effect with NTG was headache which is similar with our studies papatsonias et al found the incidence of side effects with nifedipine to be significantly less than ritodrine. Similarly in our study the incidence of side effects are less with nifedipine when compared to nitroglycerine group.

SUMMARY

SUMMARY

In the study with NTG and NIFEDIPINE n= 97 it was observed that Preterm labour is common in primigravida in the age group of 20 to 29 years.

1. There were 43 to 45 % of cases between 32 to 34 weeks.
2. Previous preterm delivery was found in 10.3 %, previous abortions was found in 8.24% in NTG GROUP and 8.24% in NIFEDIPINE group.
3. Failure of tocolysis was more in NTG group when compare to nifedipine group. But statistically it was insignificant but when the cervical dilatation was greater than 3 cm, nifedipine was significantly more effective in prolonging pregnancy compare to NTG.
4. The prolongation of pregnancy more than 48 hours was found to be more in 32 to 34 weeks in NTG and nifedipine group.
5. Among the nitroglycerine group 74.22% required 10 mg and 25.77% required 20 mg . 79.38% and 20.6% required 20 mg and 40 mg in the nifedipine group respectively.
6. The cervix was 1 cm dilated in 28.86% both in NTG and nifedipine group, 2cm dilated in 43.29% and 39.17% in NTG group and

nifedipine group respectively and 27.83% and 31.95 % in 3 cm dilated in NTG and nifedipine group respectively.

7. The patients who delivered after 48 hours in NTG and nifedipine group with cervical dilatation 2cm is 41.2% and 39.17% respectively and 28.86% and 27.83% in patients with 1 cm dilatation respectively. p value is 0.03.
8. The cervix was 25% effaced in 53.60% of cases and 50.51% of cases in NTG group and nifedipine group respectively, 50% effaced in 25.77% of cases and 27.83% of cases in NTG group and nifedipine group respectively , 20.16% and 21.64% of cases in NTG group and nifedipine group respectively.
9. Among the patients who delivered successfully in the NTG group and nifedipine group the cervix was 25 % effaced in 51.54 % and 48.45% and 50 % effaced in 23.71% and 26.80% and 75% effaced in 14.31% and 18.55% respectively. P value is 0.9.
10. Headache and maternal tachycardia were the most common side effect.
11. No maternal mortality.

12. The neonatal mortality was 5.15% in NTG group and 3.09% in nifedipine. Not achieved group in vaginal delivery. No neonatal mortality in caesarian Group. 85.56% and 83.50% of cases delivered vaginally in nifedipine group and nitroglycerine group respectively.
13. Among the achieved cases 46.39% and 64.94% found in NTG group and in nifedipine group respectively in 2.5 – 3 kg group . >3kg was found in 9.27% in NTG group compared to nifedipine group 5.15%.

CONCLUSION

CONCLUSION

It is concluded from the study that oral Nifedipine is better in safety and efficacy than transdermal patch of nitroglycerine in prolonging the pregnancy.

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ANNEXURES

ABBREVIATION

ABBREVIATIONS

| | | |
|-----------|---|---------------------------------|
| I.P NO | - | In patients number |
| OBS.CODE | - | Obstetric code |
| GA | - | Gestational age |
| CD | - | Cervical dilatation |
| MOD | - | Mode of delivery |
| B.Wt | - | Birth weight |
| TOCOLYSIS | - | |
| A | - | Achieved |
| NA | - | Not achieved |
| NICU | - | Neonatal intensive care unit |
| A/SB/ND | - | |
| A | - | Alive |
| SB | - | Still birth |
| ND | - | Neonatal death |
| V | - | Vaginal birth |
| LSCS | - | Lower segment caesarean section |
| N | - | Nausea |
| V | - | Vomiting |
| Ff | - | Facial flushing |
| I | - | Irritation |

| | |
|-----|---------------------------------|
| H | - Headache |
| R | - Rash |
| RDS | - Respiratory distress syndrome |
| NTG | - Nitroglycerine |
| GOA | - Gestation on Admission |
| GOD | - Gestation on Delivery |
| LMP | - Last Menstrual Period |
| EDD | - Expected Date of Delivery |

PROFORMA

PROFORMA

| | |
|-------|-----|
| Name | LMP |
| Age | EDD |
| IP No | POG |
| DOA | DOD |

Presenting Complaints

Obstetrical History

O/E

General Condition

| | | | |
|-------|----|--------|--------|
| Pulse | BP | Weight | Height |
|-------|----|--------|--------|

Pallor

Pedal Edema

Temperature

CVS

RS

P/A

P/S (Date & Time)

P/V (Date & Time)

Tocolytic therapy received

Outcome after 48 hours

Side Effects reported

Subsequent course of pregnancy

1) Any further of preterm pain Yes/No

If “Yes”, managed by

2) Any significant antenatal complication

PIH/APH/PROM

3) Mode of Delivery

Perinatal Outcome Chart

Time of Birth

Date of Birth

Birth Weight

Live Born/Still Born

APGAR score (1, 5, 10 minutes)

Any Congenital Anomaly

Length of Stay in NICU (If Applicable)

History of Respiratory Distress Syndrome

Outcome

CONSENT FORM

PATIENT CONSENT FORM

Study Details : **Study of tocolytic effects of oral nifedipine Vs transdermal nitroglycerine patch in preterm labour.**

Study Centre : **Department of Obstetrics and Gynecology
R.S.R.M Hospital
Stanley Medical College
Chennai - 600 001.**

Patient may check (✓) these boxes:

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected.

I understand that the investigator of the clinical study, others working on his behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study.

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms.

I hereby give permission to undergo complete clinical examination and questionnaire.

I hereby consent to participate in this study.

Signature / Thumb impression:

Place:

Date:

Patient Name and Address:

Signature of Investigator:
(Investigator's Name):

Place:

Date Study

ஆராய்ச்சி தகவல் தாள்

சென்னை அரசு ஸ்டான்லி மருத்துவமனைக்கு வரும் மகப்பேறு அடைந்த பெண்களிடம் குறைமாத பிரசவத்தை தடுப்பதில் கீழ்கண்ட இரண்டு மருந்துகளில் எது சிறந்தது என்பதை கண்டறியும் ஒரு ஆய்வு

1..நிபிடிபின் மாத்திரை

2.நைட்ரோ கிளிசரின்(தோல் வழியாக)

நீங்கள் இந்த ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம். இந்த ஆராய்ச்சியில் பங்கேற்பதால் தங்களது நோயின் ஆய்வறிக்கையோ அல்லது சிகிச்சையோ பாதிக்கப்படாது என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியின் முடிவுகளை அல்லது கருத்துகளை வெளியிடும் போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியில் இருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

இந்த சிறப்புப் பரிசோதனைகளின் முடிவுகளை ஆராய்ச்சியின் போதோ அல்லது ஆராய்ச்சியின் முடிவின் போதோ தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் பங்கேற்பாளர் கையொப்பம்

தேதி:

ETHICAL COMMITTEE

INSTITUTIONAL ETHICAL COMMITTEE,
STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work : Comparison of Oral nifedipine and transdermal nitroglycerine as a tocolytic for preterm labour.

Principal Investigator : Dr. Badmini

Designation : PG in MD (O&G)

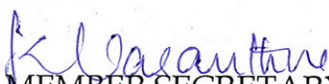
Department : Department of Obstetrics & Gynaecology
Government Stanley Medical College,
Chennai-01

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 05.08.2014 at the Council Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.


MEMBER SECRETARY,
IEC, SMC, CHENNAI

MASTER CHART

| S.NO | NAME | AGE | IP.NO | OBS.CODE | GOA | CONTRACTIONS/10 | CD IN CMS | EFFACEMENT | GOD | NO OF DAYS | MOD | B.WT | SIDE EFFECT | TOCOLYSIS | NICU | A/SB/ND |
|------|----------------|-----|-------|----------|------|-----------------|-----------|------------|------|------------|------|------|-------------|-----------|------|---------|
| 27 | KALAIYARASI | 27 | 3833 | PRIMI | 32.4 | 2 | 1 | 25% | 35.6 | 23 | V | 2.4 | H | A | - | A |
| 28 | VENNILLA | 20 | 1648 | PRIMI | 33.1 | 3 | 2 | 50% | 37.2 | 29 | V | 2.5 | I | A | - | A |
| 29 | PREMAKUMARI | 21 | 1481 | PRIMI | 34 | 2 | 3 | 25% | 36.4 | 18 | V | 2.35 | - | A | - | A |
| 30 | SUMATHY | 23 | 3896 | G3P2L2 | 28.2 | 3 | 3 | 75% | 28.3 | 24 HRS | V | 1.1 | H | NA | - | SB |
| 31 | LAKSHMI | 28 | 554 | PRIMI | 32.1 | 2 | 1 | 50% | 35.1 | 21 | V | 2.5 | - | A | - | A |
| 32 | SINDHUMATHI | 20 | 3920 | PRIMI | 31.6 | 2 | 2 | 25% | 34.6 | 21 | LSCS | 2.1 | - | A | - | A |
| 33 | KALPANADEV | 24 | 3866 | PRIMI | 34.5 | 3 | 1 | 50% | 38.2 | 25 | V | 3.2 | I | A | - | A |
| 34 | CHITRA | 24 | 3866 | G2AI | 28.2 | 3 | 3 | 75% | 36.2 | 56 | V | 2.75 | H | A | - | A |
| 35 | SANGEETHA | 23 | 4665 | PRIMI | 29.6 | 3 | 1 | 25% | 32.1 | 16 | V | 1.9 | - | A | 5 | A |
| 36 | VAIDESHWARI | 24 | 3823 | PRIMI | 32.5 | 2 | 2 | 25% | 33 | 1 | V | 1.8 | - | A | 6 | ND |
| 37 | NASREEN | 27 | 8471 | PRIMI | 31.6 | 2 | 3 | 75% | 37.6 | 42 | V | 2.5 | - | A | - | A |
| 38 | SUGANYA | 22 | 3935 | PRIMI | 33.5 | 3 | 2 | 25% | 36.2 | 18 | V | 2.45 | - | A | - | A |
| 39 | VIJAYALAKSHMI | 20 | 3938 | PRIMI | 34.6 | 2 | 2 | 25% | 37.2 | 17 | V | 2.5 | - | A | - | A |
| 40 | GEETHA | 23 | 3782 | PRIMI | 32.3 | 3 | 3 | 75% | 36.3 | 28 | V | 2.8 | - | A | - | A |
| 41 | SAMUNDEESHWARI | 26 | 3556 | PRIMI | 31.4 | 2 | 2 | 25% | 37.4 | 42 | LSCS | 2.9 | - | A | 1 | A |
| 42 | INDHUMATHI | 24 | 4006 | G2P1L1 | 30.6 | 3 | 2 | 50% | 36.6 | 42 | V | 2.6 | - | A | - | A |
| 43 | PREMAKUMARI | 24 | 3733 | PRIMI | 28.4 | 2 | 3 | 25% | 28.5 | 1 | V | 1.06 | H | NA | - | SB |
| 44 | SIVARANJANI | 21 | 4489 | G2P1L1 | 31.2 | 2 | 2 | 25% | 37.6 | 47 | V | 2.7 | - | A | - | A |
| 45 | RATHNA | 20 | 3868 | G2P1L1 | 30.5 | 2 | 2 | 50% | 34.2 | 25 | V | 2.3 | I | A | 6HRS | A |
| 46 | KANITAMIL | 23 | 8624 | PRIMI | 33.2 | 2 | 2 | 25% | 38.2 | 35 | V | 2.8 | H | A | - | A |
| 47 | AMUL | 28 | 4013 | G3P1L1A1 | 32.2 | 3 | 3 | 50% | 35.2 | 21 | V | 2.4 | - | A | - | A |
| 48 | JANNAT | 21 | 3928 | PRIMI | 33.2 | 3 | 2 | 25% | 34.4 | 9 | V | 2 | H | A | 4 | A |
| 49 | AYESHA | 19 | 4170 | PRIMI | 33.5 | 2 | 1 | 25% | 35.6 | 15 | V | 1.8 | - | A | 7 | A |
| 50 | RENUGA | 26 | 3856 | G3P2L2 | 31.5 | 2 | 1 | 25% | 36.5 | 35 | V | 2.7 | - | A | - | A |
| 51 | HAMEEDHA | 18 | 3986 | PRIMI | 28.6 | 3 | 1 | 75% | 38.6 | 66 | V | 2.9 | - | A | 7 | A |
| 52 | MANOJA | 21 | 8413 | PRIMI | 29.6 | 3 | 2 | 25% | 36.6 | 49 | V | 2.8 | - | A | - | A |
| 53 | MEENA | 24 | 8509 | PRIMI | 32.2 | 3 | 2 | 50% | 36.2 | 28 | V | 2.5 | - | A | - | A |
| 54 | JANAKI | 24 | 4726 | G2A1 | 31.6 | 3 | 3 | 75% | 32 | 22HRS | V | 2 | - | NA | - | A |

| S.NO | NAME | AGE | IP.NO | OBS.CODE | GOA | CONTRACTIONS/10 | CD IN CMS | EFFACEMENT | GOD | NO OF DAYS | MOD | B.WT | SIDE EFFECT | TOCOLYSIS | NICU | A/SB/ND |
|------|--------------|-----|-------|----------|------|-----------------|-----------|------------|------|------------|-----|------|-------------|-----------|------|---------|
| 55 | RAMADEVI | 21 | 4276 | PRIMI | 33.3 | 2 | 2 | 25% | 36.3 | 21 | V | 2.4 | - | A | - | A |
| 56 | ASWINI | 20 | 4048 | G2A1 | 30.3 | 2 | 1 | 50% | 36.2 | 43 | V | 2.6 | - | A | - | A |
| 57 | KAVITHA | 20 | 8443 | PRIMI | 34.2 | 3 | 2 | 75% | 37.2 | 21 | V | 2.8 | - | A | - | A |
| 58 | JEYASHREE | 22 | 3263 | PRIMI | 28.2 | 3 | 2 | 50%* | * | * | * | * | * | * | * | * |
| 59 | JAMUNA | 26 | 8276 | G2P1L1 | 31.4 | 3 | 1 | 75% | 31.5 | 24HRS | V | 1.9 | - | NA | 6 | A |
| 60 | USHA | 19 | 3791 | G2P1L1 | 33.1 | 3 | 2 | 50% | 35.2 | 15 | V | 2.49 | | A | - | A |
| 61 | SATHYA | 26 | 4280 | G3P2L1 | 28.2 | 3 | 2 | 25% | 37.2 | 63 | V | 3.06 | H | A | - | A |
| 62 | KANAGA | 22 | 4299 | G2P1L1 | 30.2 | 2 | 1 | 50% | 35.6 | 39 | V | 3.1 | I | A | - | A |
| 63 | MALATHI | 25 | 8639 | G3P1L1A1 | 32.5 | 3 | 3 | 25% | 37.2 | 32 | V | 2.8 | - | A | - | A |
| 64 | SHANTHI | 39 | 5076 | G3P2L1 | 33.1 | 3 | 1 | 75% | 37.2 | 29 | V | 2.8 | - | A | - | A |
| 65 | BHAVANI | 22 | 7271 | PRIMI | 29.2 | 2 | 3 | 25% | 36.2 | 49 | V | 2.9 | - | A | - | A |
| 66 | RENUGA | 21 | 4255 | PRIMI | 28.6 | 3 | 3 | 25% | 36.6 | 56 | V | 2.5 | H | A | | A |
| 67 | YAMUNA | 21 | 4653 | G2P1L1 | 32.6 | 3 | 1 | 25% | 37.2 | 31 | V | 3.2 | I | A | -- | A |
| 68 | UMA | 22 | 7705 | PRIMI | 28.6 | 2 | 2 | 50% | 34.2 | 38 | V | 2.4 | - | A | - | A |
| 69 | RANJINI | 23 | 5609 | G2P1L1 | 31.2 | 3 | 1 | 25% | 35.2 | 28 | V | 2.3 | - | A | - | A |
| 70 | SONIYA | 21 | 4752 | G2A1 | 32.3 | 3 | 1 | 25% | 36.2 | 27 | V | 2.7 | - | A | - | A |
| 71 | TAMILVANI | 23 | 13046 | G2A1 | 34.5 | 3 | 2 | 50% | 38.2 | 24 | V | 2.45 | - | A | - | A |
| 72 | MARIVALLI | 22 | 11207 | PRIMI | 30.6 | 3 | 3 | 75% | 36.2 | 38 | V | 2.8 | - | A | - | A |
| 73 | RENUGA | 25 | 4369 | G2P1L1 | 28.5 | 3 | 2 | 25% | 35.4 | 30 | V | 2.05 | - | A | - | A |
| 74 | MADHAVI | 23 | 7269 | PRIMI | 32.1 | 2 | 3 | 75% | 36.1 | 28 | V | 2.6 | I | A | - | A |
| 75 | GOWTHAMI | 22 | 7419 | PRIMI | 30.5 | 2 | 3 | 50% | 36.4 | 40 | V | 2.7 | H | A | - | A |
| 76 | KRISHNAPRIYA | 20 | 13168 | PRIMI | 34.6 | 3 | 2 | 50% | 36.6 | 14 | V | 2.8 | H | A | - | A |
| 77 | MANJU | 20 | 7826 | PRIMI | 31.2 | 3 | 3 | 75% | 31.3 | 18HRS | V | 1.9 | I | NA | - | A |
| 78 | RAGINI | 20 | 8879 | G2A1 | 31.3 | 2 | 3 | 25% | 36.2 | 34 | V | 2.2 | - | A | 2 | A |
| 79 | RAMEE | 22 | 8160 | PRIMI | 32.3 | 3 | 2 | 50%* | * | * | * | * | * | * | * | * |
| 80 | JEEVA | 20 | 13083 | PRIMI | 34.3 | 2 | 3 | 25% | 38.2 | 27 | V | 2.7 | I | A | | A |
| 81 | SAFIYA | 20 | 8113 | PRIMI | 30.2 | 3 | 3 | 75% | 30.3 | 18HRS | V | 1.2 | H | NA | | A |
| 82 | FARIDHA | 22 | 4836 | PRIMI | 32.6 | 3 | 3 | 25% | 36.4 | 26 | V | 2.8 | - | A | | A |

| S.NO | NAME | AGE | IP.NO | OBS.CODE | GOA | CONTRACTIONS/10 | CD IN CMS | EFFACEMENT | GOD | NO OF DAYS | MOD | B.WT | SIDEFFECT | TOCOLYSIS | NICU | A/SB/ND |
|------|---------------|-----|-------|----------|------|-----------------|-----------|------------|------|------------|------|------|-----------|-----------|------|---------|
| 83 | AISWARYA | 18 | 4529 | PRIMI | 31.2 | 3 | 2 | 50% | 34.4 | 23 | V | 2.11 | H | A | | A |
| 84 | PRIYA | 21 | 8766 | PRIMI | 30.6 | 3 | 1 | 25% | 36.4 | 40 | V | 2.8 | - | A | | A |
| 85 | MABHUNI | 32 | 12946 | G2P1L0 | 31.2 | 3 | 1 | 25% | 35.6 | 28 | V | 2.2 | - | A | | A |
| 86 | RAJINI | 20 | 10766 | PRIMI | 32.1 | 3 | 1 | 50% | 37.2 | 36 | LSCS | 3.1 | H | A | | A |
| 87 | SANDHYA | 22 | 9866 | PRIMI | 33.4 | 3 | 2 | 25% | 36.2 | 19 | V | 2.5 | - | A | | A |
| 88 | KUDIYARASI | 22 | 2296 | PRIMI | 34.2 | 2 | 3 | 25% | 37.3 | 22 | V | 2.8 | I | A | | A |
| 89 | MADHAVI | 22 | 10762 | PRIMI | 30.6 | 3 | 1 | 50% | # | # | # | # | # | A | # | # |
| 90 | UMA | 22 | 7806 | G2A1 | 32.6 | 3 | 2 | 25% | 37.2 | 31 | V | 2.9 | - | A | | A |
| 91 | ROOPAVATHY | 29 | 12737 | G2P1L1 | 35.2 | 2 | 1 | 25% | 38.6 | 25 | V | 2.6 | H | A | | A |
| 92 | GAJALAKSHMI | 28 | 10733 | PRIMI | 34.3 | 3 | 2 | 75% | 37.3 | 28 | V | 2.7 | - | A | | A |
| 93 | VIJAYALAKSHMI | 23 | 12759 | PRIMI | 33.5 | 3 | 3 | 25% | 34.2 | 3 | V | 2.3 | H | A | | A |
| 94 | JAMUNA | 22 | 4756 | PRIMI | 29.6 | 2 | 3 | 50% | 29.6 | 20HRS | V | 1.2 | - | NA | 1 | ND |
| 95 | JASMINE | 23 | 4858 | G2P1L1 | 30.1 | 3 | 2 | 75% | 37.2 | 50 | LSCS | 2.8 | I | A | | A |
| 96 | DEVI | 29 | 12555 | PRIMI | 29.2 | 2 | 2 | 25% | 36.2 | 42 | V | 2.8 | - | A | | A |
| 97 | MENAGA | 23 | 4649 | G2P1L1 | 31.2 | 3 | 3 | 50% | 35.3 | 29 | V | 2.18 | H | A | | A |
| 98 | JANAKI | 23 | 8472 | PRIMI | 28.5 | 2 | 1 | 75% | 37.5 | 61 | V | 2.8 | - | A | | A |
| 99 | RITA | 24 | 9650 | PRIMI | 29.2 | 3 | 2 | 25% | 37.5 | 59 | V | 2.9 | - | A | | A |
| 100 | VIJAYALAKSHMI | 22 | 13192 | PRIMI | 32 | 2 | 2 | 25% | 32.4 | 12HRS | V | 1.8 | | NA | 6 | A |

ORAL NIFEDIPINE

| S.NO | NAME | AGE | IP.NO | OBS.CODE | GOA | CONTRACT | CD IN CMS | EFFACEMENT | GOD | NO OF DAYS | MOD | B.WT | SIDE EFFECT | TOCOLYSIS A/NA | NICU | A/SB/ND |
|------|---------------|-----|-------|----------|------|----------|-----------|------------|------|------------|------|------|-------------|----------------|------|---------|
| 1 | SATHYA | 18 | 349 | PRIMI | 28.2 | 2 | 1 | 25% | 34.2 | 42 | V | 1.5 | | A | 20 | A |
| 2 | PRIYA | 20 | 114 | PRIMI | 32.2 | 2 | 2 | 25% | 36.5 | 31 | V | 2.75 | | A | - | A |
| 3 | DEEPA | 25 | 484 | PRIMI | 33.1 | 3 | 2 | 50% | 36.4 | 24 | LSCS | 2.2 | HYPO | A | - | A |
| 4 | ARUNASANDHYA | 22 | 725 | PRIMI | 34 | 2 | 3 | 75% | 37.4 | 23 | V | 3 | | A | - | A |
| 5 | VENILA | 20 | 1648 | PRIMI | 32.1 | 3 | 1 | 25% | 35.6 | 26 | V | 2.59 | TACY | A | - | A |
| 6 | GAYATHRI | 20 | 1789 | PRIMI | 28.2 | 2 | 3 | 75% | 36.6 | 74 | V | 2.3 | | A | - | A |
| 7 | RUKASAR | 20 | 2015 | PRIMI | 33.2 | 3 | 2 | 50% | 37.2 | 28 | V | 2.6 | Ff | A | - | A |
| 8 | LAKSHMI | 19 | 288 | PRIMI | 30.1 | 2 | 2 | 25% | 36.3 | 44 | LSCS | 2.2 | | A | 2 | A |
| 9 | SAKTHIDEVI | 19 | 450 | PRIMI | 31.4 | 3 | 2 | 25% | 36.6 | 37 | V | 2.7 | TACY | A | - | A |
| 10 | LAKSHMI | 28 | 554 | PRIMI | 32.5 | 2 | 2 | 50% | 37.3 | 32 | V | 2.5 | | A | - | A |
| 11 | RATHAN | 20 | 3868 | G2PIL1 | 33.4 | 3 | 1 | 50% | 37.4 | 28 | V | 2.3 | TACHY,HYPO | A | - | A |
| 12 | MEHATAJ | 20 | 3788 | G3A2 | 33.5 | 3 | 2 | 25% | 37.5 | 28 | V | 2.5 | | A | - | A |
| 13 | DEVI | 26 | 3951 | G2P1L1 | 32.6 | 3 | 1 | 75% | 37.2 | 31 | V | 3 | | A | - | A |
| 14 | SAGAYAMARY | 21 | 4280 | PRIMI | 39.5 | 3 | 2 | 75% | 6HRS | 6HRS | V | 1.02 | | NA | - | SB |
| 15 | PREETHA | 20 | 3864 | PRIMI | 31.6 | 3 | 1 | 25% | 36.6 | 35 | V | 2.8 | | A | - | A |
| 16 | VALARMATHI | 21 | 4296 | PRIMI | 30.6 | 2 | 2 | 25% | 37.2 | 45 | V | 2.4 | Ff | A | - | A |
| 17 | LAKSHMI | 21 | 4399 | G2P1L1 | 32.5 | 2 | 3 | 50% | 38.2 | 38 | V | 2.8 | | A | - | A |
| 18 | YOGESHWARI | 22 | 4388 | PRIMI | 32.6 | 3 | 1 | 75% | 38.3 | 39 | V | 2.9 | | A | - | A |
| 19 | PRIYA | 21 | 4323 | G2A1 | 33.4 | 2 | 2 | 25% | 37.4 | 28 | V | 2.7 | TACY | A | - | A |
| 20 | KANAGA | 25 | 4122 | PRIMI | 34.2 | 3 | 3 | 75% | 36.6 | 16 | V | 2.5 | | A | - | A |
| 21 | NADHIYA | 21 | 4325 | G2P1L1 | 28.2 | 2 | 1 | 25%* | * | * | * | * | * | * | * | * |
| 22 | JEYALAKSHMI | 27 | 5039 | PRIMI | 28 | 3 | 2 | 50% | 37.1 | 72 | V | 2.8 | | A | - | A |
| 23 | SHANMUGAPRIYA | 18 | 4681 | PRIMI | 30.1 | 2 | 3 | 25% | 36.6 | 47 | V | 2.45 | | A | - | A |
| 24 | SONIYA | 21 | 4752 | G2A1 | 31.2 | 3 | 1 | 50% | 36.4 | 37 | V | 2.7 | HYPO,TACY | A | - | A |
| 25 | VISALI | 19 | 4750 | G2P1L1 | 32.3 | 2 | 2 | 50% | 37.2 | 34 | V | 2.9 | | A | - | A |
| 26 | RANJANI | 25 | 4960 | G2P1L1 | 33.4 | 3 | 3 | 75% | 38.2 | 33 | V | 2.8 | | A | - | A |
| 27 | GEETHA | 28 | 5002 | G3P1L1A1 | 30.2 | 2 | 1 | 25% | 37 | 47 | V | 2.7 | | A | - | A |
| 28 | ASWINI | 20 | 4048 | PRIMI | 31.3 | 2 | 2 | 50% | 36.6 | 38 | V | 2.6 | TACY | A | - | A |
| 29 | MUMTAJ | 22 | 4607 | PRIMI | 33.5 | 2 | 3 | 50% | 38 | 30 | V | 2.79 | Ff | A | - | A |
| 30 | RAHEMUNISHA | 19 | 5147 | PRIMI | 28.2 | 3 | 3 | 25% | 37.2 | 63 | V | 2.9 | | A | - | A |
| 31 | MOHANA | 23 | 4649 | PRIMI | 30.2 | 2 | 1 | 25% | 36.6 | 46 | V | 2.7 | TACY,HYPO | A | - | A |
| 32 | DILMAYA | 19 | 4888 | PRIMI | 33.2 | 3 | 1 | 25% | 38.2 | 35 | V | 2.9 | | A | - | A |
| 33 | SIVARANJANI | 22 | 7338 | PRIMI | 30.2 | 3 | 2 | 50% | 37.2 | 42 | V | 2.5 | | A | - | A |
| 34 | JEYANTHI | 23 | 7375 | G2P1L0 | 31.3 | 3 | 3 | 25% | 36.6 | 38 | V | 2.7 | TACY | A | - | A |
| 35 | SUGANTHI | 23 | 4381 | G2P1L1 | 32.4 | 3 | 1 | 25% | 37.3 | 34 | V | 2.6 | | A | - | A |

| S.NO | NAME | AGE | IP.NO | OBS.CODE | GOA | CONTRACT | CD IN CMS | EFFACEMENT | GOD | NO OF DAYS | MOD | B.WT | SIDEFFECT | TOCOLYSIS A/NA | NICU | A/SB/ND |
|------|---------------|-----|-------|----------|------|----------|-----------|------------|-------|------------|------|------|-----------|----------------|------|---------|
| 36 | KAYALVIZHI | 25 | 7384 | G3P1L1A1 | 33.6 | 3 | 1 | 50% | 36.6 | 21 | V | 2.9 | | A | - | A |
| 37 | SASIKALA | 28 | 8111 | PRIMI | 30.3 | 3 | 2 | 75% | 35.2 | 36 | V | 2.5 | Ff | A | - | A |
| 38 | SARALA | 30 | 3663 | PRIMI | 29.2 | 3 | 3 | 25% | 6HRS | 6HRS | V | 1.2 | | NA | - | SB |
| 39 | LEELA | 21 | 4856 | PRIMI | 28.5 | 2 | 3 | 50% | 37.3 | 61 | V | 2.6 | TACY | A | - | A |
| 40 | VAIDHEKI | 21 | 4242 | PRIMI | 30.5 | 3 | 2 | 75% | 36.5 | 42 | V | 2.8 | | A | - | A |
| 41 | RADHIKA | 20 | 2962 | PRIMI | 32.5 | 2 | 1 | 25%* | * | * | * | * | * | * | * | * |
| 42 | SANDHYA | 22 | 7418 | PRIMI | 33.2 | 3 | 1 | 25% | 36.3 | 22 | V | 2.3 | | A | 2 | A |
| 43 | DATCHAYINI | 26 | 4160 | G2P1L0 | 34.3 | 2 | 2 | 25% | 37.2 | 20 | V | 2.8 | TACY,HYPO | A | - | A |
| 44 | SANGEETJA | 18 | 5164 | PRIMI | 30.2 | 3 | 3 | 75% | 18HRS | 18HRS | V | 1.6 | TACY | NA | - | D |
| 45 | SABARKANYAS | 22 | 4851 | G2P1L1 | 31.5 | 3 | 1 | 50% | 34.3 | 19 | V | 1.9 | | A | 10 | A |
| 46 | VARALAKSHMI | 20 | 4345 | PRIMI | 32.6 | 3 | 2 | 25% | 37.2 | 31 | V | 2.9 | | A | 7 | A |
| 47 | NANDHINI | 18 | 7450 | PRIMI | 33.3 | 3 | 3 | 25% | 36.4 | 22 | V | 2.7 | | A | - | A |
| 48 | NALINI | 21 | 7378 | G3A2 | 32.4 | 2 | 3 | 50% | 37.1 | 32 | V | 2.8 | N,V | A | - | A |
| 49 | SHOBANA | 25 | 4132 | PRIMI | 33.2 | 3 | 2 | 225% | 36.2 | 21 | V | 2.9 | | A | - | A |
| 50 | BANUPRIYA | 20 | 7322 | PRIMI | 28.5 | 3 | 1 | 50% | 37.2 | 60 | LSCS | 2.9 | | A | - | A |
| 51 | PADMAVATHY | 24 | 5035 | G3P1L1A1 | 30.3 | 2 | 1 | 25% | 36.2 | 41 | V | 2.6 | Ff | A | - | A |
| 52 | MAHALAKSHMI | 25 | 4126 | G2P1L1 | 28.2 | 3 | 2 | 25% | 36.1 | 55 | V | 2.8 | TACY | A | - | A |
| 53 | JEYANTHI | 24 | 7427 | G3P1L1A1 | 32.4 | 2 | 3 | 25% | 37.2 | 33 | V | 2.74 | | A | - | A |
| 54 | NARMADHA | 18 | 9650 | PRIMI | 33.1 | 3 | 2 | 25%# | # | # | # | # | | A | - | |
| 55 | DESARANI | 23 | 5007 | G2P1L1 | 32.3 | 3 | 3 | 25% | 37.5 | 37 | V | 3.1 | | A | - | A |
| 56 | DHANALAKSHMI | 21 | 4729 | PRIMI | 33.6 | 3 | 1 | 75% | 39.2 | 38 | LSCS | 2.8 | N,V | A | - | A |
| 57 | RAJALAKSHMI | 21 | 4718 | PRIMI | 31.2 | 3 | 1 | 25% | 37.1 | 41 | V | 2.75 | | A | 4 | A |
| 58 | BAGYAM | 23 | 4682 | G4P2L1A1 | 32.4 | 2 | 2 | 25% | 36.6 | 30 | V | 2.3 | | A | - | A |
| 59 | BEGUM | 21 | 3623 | PRIMI | 35.5 | 2 | 3 | 25% | 8HRS | 8HRS | V | 2.1 | TACY | NA | 3 | A |
| 60 | KARUNA | 29 | 3904 | G2A1 | 30.6 | 3 | 2 | 75% | 36.3 | 39 | V | 2.6 | HYPO | A | - | A |
| 61 | NAGASUDHA | 22 | 3120 | G3P2L1 | 28.2 | 2 | 2 | 25%* | * | * | * | * | * | * | * | * |
| 62 | TAMILARASI | 20 | 4680 | PRIMI | 30.2 | 3 | 1 | 25% | 36.2 | 42 | V | 2.6 | TACY | A | - | A |
| 63 | UMAMAHESHWARI | 21 | 3853 | G2P1L1 | 32.5 | 3 | 2 | 50% | 37.2 | 32 | V | 2.8 | | A | - | A |
| 64 | SAMUNDESHWARI | 18 | 4742 | PRIMI | 31.5 | 3 | 3 | 25% | 36.3 | 33 | V | 2.6 | HYPO | A | - | A |
| 65 | SUMATHI | 37 | 3805 | G2P1L1 | 33.4 | 3 | 3 | 75% | 37.2 | 26 | V | 2.8 | | A | - | A |
| 66 | JEYASUDHA | 24 | 8107 | G2P1L1 | 34.2 | 3 | 2 | 25% | 38 | 26 | V | 2.9 | HYPO | A | - | A |
| 67 | AMRITHA | 21 | 7507 | PRIMI | 33.5 | 2 | 1 | 50% | 37.6 | 29 | V | 3.1 | TACY | A | - | A |
| 68 | KALAIYARASI | 27 | 3833 | PRIMI | 31.6 | 2 | 2 | 25% | 36.5 | 34 | V | 2.5 | | A | 2 | A |
| 69 | RASEENA | 24 | 8520 | PRIMI | 32.6 | 3 | 3 | 50% | 37.2 | 31 | V | 2.5 | | A | - | A |
| 70 | SUMATHI | 25 | 8711 | PRIMI | 30.3 | 2 | 1 | 75% | 37.2 | 48 | LSCS | 2.6 | | A | - | A |
| 71 | JEGADEESHWARI | 24 | 7816 | G2A1 | 31.4 | 3 | 2 | 25% | 36.6 | 37 | V | 2.9 | TACY | A | - | A |
| 72 | INDHUMATHI | 20 | 4218 | PRIMI | 32.5 | 3 | 3 | 50% | 37.5 | 35 | V | 2.4 | Ff | A | - | A |

| S.NO | NAME | AGE | IP.NO | OBS.CODE | GOA | CONTRACT | CD IN CMS | EFFACEMENT | GOD | NO OF DAYS | MOD | B.WT | SIDEFFECT | TOCOLYSIS A/NA | NICU | A/SB/ND |
|------|-------------|-----|-------|----------|------|----------|-----------|------------|------|------------|------|------|-----------|----------------|------|---------|
| 73 | UDHAYAMATHI | 20 | 7855 | PRIMI | 33.4 | 2 | 1 | 50% | 8HRS | 8HRS | V | 1.9 | | NA | 3 | A |
| 74 | CHARUMATHI | 26 | 4203 | G2P1L1 | 28.6 | 3 | 2 | 25% | 35.6 | 35 | V | 2.3 | HYPO,TACY | A | - | A |
| 75 | NITHYA | 22 | 12061 | PRIMI | 30.2 | 2 | 3 | 25% | 36.2 | 42 | V | 2.6 | | A | - | A |
| 76 | AMUDHA | 21 | 5129 | G2P1L0 | 29.6 | 3 | 3 | 75% | 37.2 | 52 | V | 2.8 | | A | - | A |
| 77 | BHARATHI | 21 | 8793 | PRIMI | 30.4 | 3 | 2 | 25% | 36.6 | 44 | V | 2.7 | | A | - | A |
| 78 | NAGAMMA | 22 | 4991 | G3P2L2 | 32.6 | 2 | 1 | 50% | 38.2 | 38 | V | 3.1 | | A | - | A |
| 79 | THULASI | 20 | 12050 | PRIMI | 30.6 | 3 | 3 | 25% | 36.6 | 42 | V | 2.8 | Ff | A | - | A |
| 80 | GAYATHRI | 24 | 4832 | PRIMI | 32.5 | 2 | 2 | 25% | 36.2 | 24 | V | 2.9 | | A | - | A |
| 81 | LAVANYA | 22 | 8686 | G2P1L1 | 34.2 | 3 | 1 | 25% | 38.2 | 28 | V | 2.7 | | A | - | A |
| 82 | RAJASHRI | 20 | 9890 | PRIMI | 30.2 | 3 | 3 | 50% | # | # | # | # | | A | # | # |
| 83 | MAHESHWARI | 24 | 12176 | PRIMI | 28.2 | 3 | 2 | 75% | 36.3 | 57 | V | 2.7 | | A | - | A |
| 84 | PRABHAVATHI | 21 | 4829 | PRIMI | 33.2 | 3 | 2 | 25% | 37.2 | 28 | V | 2.5 | | A | 2 | A |
| 85 | SAROJINI | 22 | 8529 | PRIMI | 32.4 | 3 | 3 | 25% | 37.5 | 36 | V | 3.1 | | A | - | A |
| 86 | SWEDHA | 19 | 4491 | PRIMI | 30.2 | 2 | 1 | 25% | 36.6 | 46 | V | 2.8 | N,V | A | - | A |
| 87 | NISHANTHI | 21 | 8523 | PRIMI | 30.6 | 2 | 1 | 75% | 36.5 | 41 | V | 2.6 | | A | - | A |
| 88 | GOMATHI | 19 | 8650 | PRIMI | 34.3 | 2 | 3 | 25% | 6HRS | 6HRS | V | 2 | | NA | 3 | A |
| 89 | EZHIL | 22 | 6650 | PRIMI | 32.5 | 3 | 2 | 50% | 37.2 | 31 | LSCS | 2.8 | N,V | A | - | A |
| 90 | RAJINIDEVI | 20 | 7870 | PRIMI | 35.2 | 3 | 2 | 50% | 39.2 | 28 | V | 2.8 | | A | - | A |
| 91 | BHAVANI | 27 | 12350 | G2P1L1 | 30.3 | 3 | 3 | 25% | 37.5 | 51 | V | 2.9 | | A | - | A |
| 92 | SASIKALA | 28 | 9570 | PRIMI | 32.4 | 3 | 1 | 25% | 37.2 | 33 | V | 2.8 | | A | - | A |
| 93 | JEYA | 26 | 10721 | PRIMI | 31.2 | 2 | 2 | 75% | 38.2 | 49 | V | 3 | | A | - | A |
| 94 | SANDHYA | 20 | 12580 | PRIMI | 33.6 | 3 | 3 | 25% | 37.5 | 27 | V | 2.8 | | A | - | A |
| 95 | NADHIYA | 22 | 11750 | PRIMI | 32.5 | 2 | 3 | 25% | 37.4 | 36 | V | 2.9 | | A | - | A |
| 96 | VEMBAVALLI | 21 | 9592 | PRIMI | 30.2 | 3 | 1 | 50% | 37.2 | 49 | V | 2.8 | | A | - | A |
| 97 | REVATHI | 21 | 12965 | PRIMI | 29.6 | 2 | 2 | 75% | 37.3 | 53 | V | 2.7 | | A | - | A |
| 98 | KOKILLA | 22 | 9890 | G2P1L1 | 31.2 | 3 | 3 | 25% | 36.3 | 36 | V | 2.8 | | A | - | A |
| 99 | SANDHYA | 24 | 7856 | G2A1 | 32.3 | 2 | 3 | 25% | 37.2 | 34 | V | 2.9 | | A | - | A |
| 100 | MANJU | 28 | 12860 | PRIMI | 33.4 | 3 | 2 | 75% | 36.4 | 21 | V | 2.6 | | A | - | A |

TOCOLYSIS-A / NA
A-ACHIEVED
NA - NOT ACHIEVED

HRS - HOURS
G - GRAVIDA
P - PARA

A/SB/D
A-ALIVE
SB -STILL BIRTH
D -DEATH

L - LIVE

V- VAGINAL
LSCS - LOWER SEGMENT CAESERAN SECTION
***** - LOSS OF FOLLOW
- STILL CONTINUING
PREGNANCY

N - NAUSEA
V - VOMITTING
HYPO - HYPOTENSION
TACY - TACY CARDIA
Ff - FACIAL FLUSHING