"MODIFIED BIOPHYSICAL PROFILE IN ANTEPARTUM FETAL SURVEILLANCE OF HIGH RISK PREGNANCIES"

BY

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Dissertation submitted to the

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of the requirements for the degree of

MASTER OF SURGERY

In

OBSTETRICS AND GYNAECOLOGY

Under the guidance of

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LIST OF ABBREVIATIONS USED

AF	--	Amniotic Fluid
AFI	--	Amniotic Fluid Index
AFV	--	Amniotic Fluid Volume
ANS	--	Autonomic Nervous System
BPP	--	Biophysical Profile
CNS	--	Central Nervous System
CST	--	Contraction Stress Test
EFHR	--	Electronic Fetal Heart Rate
FHR	--	Fetal Heart Rate
IUGR	--	Intrauterine Growth Retardation
MBPP	--	Modified Biophysical Profile
MVP	--	Maximum Vertical Pocket
NICU	--	Neonatal Intensive Care Unit
NST	--	Non-stress Test
PIH	--	Pregnancy Induced Hypertension
PROM	--	Premature Rupture of Membranes
VAST	--	Vibro-acoustic Stimulation Test

ABSTRACT

Background:

Fetal biophysical profile is a well established method of antepartum surveillance in high risk pregnancy. Classical biophysical profile with all parameters (fetal breathing movements, fetal tone, fetal gross body movements, amniotic fluid volume and non-stress test) needs two phase testing by ultrasound and external Doppler monitor to record fetal heart rate, is more cumbersome, time consuming and expensive. The modified biophysical profile (MBPP) suggested by Nageotte et al combines Non stress test (NST) as a short term marker of fetal status and the amniotic fluid index (AFI) as marker of long term placental function is easier to perform and less time consuming than classical biophysical profile.

Objectives:-

1) To study the effectiveness of using modified biophysical profile as a primary antepartum fetal surveillance test in predicting perinatal outcome.

2) To compare the morbidity and mortality with respect to each of the parameters of modified biophysical profile, that is NST and AFI individually.

Methods:-

This study was a prospective clinical study which consisted of 70 patients having pregnancy with high risk factors. The patients were evaluated with the modified biophysical profile consisting of NST recording for 20mins, followed ultrasound assessment of amniotic fluid volume, using four quadrant technique.

Results :-

- When the Modified biophysical profile is normal, it gives reassurance that the foetal status is good with good perinatal outcome.
- When the MBPP is abnormal there is increased incidence of perinatal morbidity as well as mortality.

When considered individually, abnormal AFI was associated with increased incidence of perinatal morbidity and abnormal NST was associated with increased incidence of perinatal morbidity as well as perinatal mortality.

Interpretation and conclusion:-

Modified biophysical profile is an effective primary antepartum fetal surveillance test in high risk pregnancies in predicting perinatal outcome.

Key words:-

Modified biophysical profile (MBPP), biophysical profile (BPP), non stress test (NST), amniotic fluid index (AFI), fetal heart rate (FHR), amniotic fluid volume(AFV).

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INTRODUCTION

It has been a known fact that no health problem can be of greater consequence to a nation, than maternal health and perinatal mortality.

From hospital records it is observed that the average perinatal mortality in a year is about 45 per 1000 live births. Various maternal complications such as pre – eclampsia, eclampsia, anemia, oligohydramnios etc. are the major causes for perinatal loss. Such high risk pregnancies need to be identified so that appropriate surveillance and timely interventions can be employed and thus bring down the rate of perinatal morbidity and mortality.

Antenatal fetal surveillance is directed at identifying fetuses of the high risk pregnancy group which are at risk of suffering intrauterine hypoxia with resultant damage including death.

Since the 19th century, fetal assessment consisted of auscultation of fetal heart sounds and subjective recording of fetal movements .In the 20th century, these techniques have been augmented by electronic fetal heart rate monitoring and sonographic evaluation of fetal activity and amniotic fluid volume.

The fetal biophysical profile is one of the most widely accepted test for the evaluation of fetal well being in such high risk cases. The original biophysical profile was described by Manning et al, which includes study of five variables i.e. breathing movement, fetal tone, fetal body movement, amniotic fluid index and non-stress test. It needs two phase testing by ultrasound and external Doppler monitor to record fetal heart rate. The complete biophysical is more cumbersome, time consuming and is more expensive.

The modified biophysical profile (MBPP) suggested by Nageotte et al combines Non stress test (NST) as a short term marker of fetal status and the amniotic fluid index (AFI) as marker of long term placental function is easier to perform and less time Consuming than complete biophysical profile or contraction stress test. Also MBPP is considered to be as effective as complete biophysical profile.

Hence in this study, Modified biophysical profile is used as primary surveillance test in high risk pregnancy to study its effectiveness in predicting perinatal outcome.

AIMS AND OBJECTIVES

1) To study the effectiveness of using modified biophysical profile as a primary antepartum fetal surveillance test in predicting perinatal outcome.

2) To compare the morbidity and mortality with respect to each of the parameters of modified biophysical profile, that is NST and AFI individually.

REVIEW OF LITERATURE

1. Miller et al[1]conducted a study to determine the false negative and false-positive rates of ante partum testing by use of the modified biophysical profile and concluded that the false negative rate of modified biophysical profile is lower than that of non stress test and compares favourably with the false negative rates of the contraction stress test and the complete biophysical profile.
2. Morris JM [2]et al conducted a prospective double blinded observational study to determine the usefulness of ultrasound assessment of amniotic fluid in predicting adverse outcome in prolonged pregnancy and concluded that AFI is superior to a measure of single deepest pool but routine use is likely to lead to increased obstetric intervention without improvement in perinatal outcomes.
3. Compitak K et al[3] studied the diagnostic performance of NST, AFI and modified biophysical profile for screening fetal acidemia in high risk pregnancies and concluded that modified biophysical profile had a significantly higher sensitivity than NST or AFI alone in screening for fetal acidemia. So a modified biophysical profile should be used to screen for fetal acidemia in high-risk pregnancies.
4. Chauhan SP et al[4] conducted a randomized clinical trial to determine the superior technique of either of the amniotic fluid index (AFI) versus the Single deepest pocket technique in predicting an adverse pregnancy outcome among high risk patients, and concluded that during antepartum fetal surveillance, use of single deepest pocket compared with AFI is associated with significantly lower rate of suspected oligohydramnios.

5. In a study by Magann EF et al[5] on biophysical profile with Amniotic fluid volume assessments, a conclusion was drawn that AFI offers no advantage in detecting adverse outcomes compared with single deepest pocket, when performed with biophysical profile.
6. In a study by Jamal A et al[6] on fetal biophysical profile versus modified biophysical profile in the management of high risk pregnancies, it was concluded that, there was no significant difference with comparison of the sensitivity, specificity and negative predictive value of two tests for all measures of outcome except the positive. Original biophysical profile is more costly and time consuming than modified biophysical profile.
7. In a study by Dayal AK et al[7], it was found that , fetomaternal hemorrhage was the single most identifiable cause of false negetive results in cases of subsequent fetal death following a normal biophysical profile.
8. Marks et al[8], studied the amniotic fluid index in postdated pregnancies in 511 cases ,and concluded that ,oligohydramnios was detected in 11.5% of the study population.
9. Nageotte MP et al[9] ,evaluated the perinatal outcomes in high risk pregnancies monitored with a modified biophysical profile and concluded that modified biophysical profile is an excellent means of fetal surveillance and identifies a group of patients at increased risk for adverse perinatal outcome and small for gestational age infants. There does not appear to be a significant benefit with contraction stress test compared with the modified biophysical profile as a back up test. Further, the contraction stress test is associated with a higher rate of intervention for an abnormal test than is the modified biophysical profile.

10. Hill LM et al[10], studied the ultrasonographically detected prevalence of polyhydramnios and neonatal outcome in 102 cases of mild to severe polyhydramnios ,and found that the etiology for polyhydramnios was apparent in 16.5% of the cases with mild polyhydramnios. When polyhydramnios was characterized as moderate or severe, a definable cause was determined in 21 of 23 cases(91.3%).
11. Rutherford et al[11], evaluated the amniotic fluid assessment using a semiquantitative four quadrant technique, the amniotic fluid index as an adjunct to antepartum fetal heart rate testing and found an inverse relationship between amniotic fluid index and non-reactive non-stress tests, fetal heart rate decelarations, meconium staining, caesarean section for fetal distress, and low APGAR scores. Adverse perinatal outcome was significantly more frequent with diminished compared with normal amniotic fluid volume, even if the NST was reactive.
12. **Barret and associates[12]** in 1981 conducted the twice weekly testing with non stress test and felt it was necessary in certain high-risk pregnancies to avoid fetal death within 7 days following a normal reactive test results.
13. In 1983, **Vintzileous[13]** used modification of biophysical profile by combining two variables non-stress test and amniotic fluid index.
14. In 1984, **Chamberlain[14]** in his retrospective chart review has concluded that gross and corrected perinatal mortality in association with normal amniotic fluid volume ranged from 4.65/1000 and 1.97/1000 respectively, to 187.5/1000 and 109.4/1000 in association with amniotic fluid volume.

15. **Phelan et al**[15] in 1987 used a semiquantitative assessment of amniotic fluid called amniotic fluid index, which involved summing up the largest vertical pocket of amniotic fluid in each of the four quadrants of the uterus.
16. **Clark and co-workers**[16] (1989) used an abbreviated biophysical profile as their first line antepartum test. Specifically, a vibroacoustic non-stress test and amniotic fluid index were performed twice weekly in 2628 singleton pregnancies. Amniotic fluid index < 5 cm was considered abnormal. The typical test required only 10 minutes to perform.
17. The **American College of Obstetrics and Gynaecology**[17] **in 1999** has concluded that modified biophysical profile test described using non-stress test and amniotic fluid index is an acceptable means of antepartum fetal surveillance.

NON-STRESS TEST

DEFINITION:

The definition currently recommended by American college of obstetrics and gynaecology (ACOG 1999) is, two or more accelerations that peak at 15 beats per minute or more, each lasting 15 seconds or more and all occurring within 20 minutes of beginning the test[18].

HISTORY:

Freeman and colleagues (1975) and Lee and colleagues (1975) introduced the non stress test to describe the fetal heart rate acceleration in response to fetal movement as a sign of fetal health. This test involved the use of Doppler detected fetal heart rate acceleration coincident with fetal movements perceived by the mother.

By the end of 1970's , the non- stress test had become the primary method of testing fetal health .Currently non-stress test is the most widely used primary testing method for assessment of fetal well being and also has been incorporated into the biophysical profile testing system.

Principle:

Non-stress test is based on the principle that, a well oxygenated fetus responds to spontaneous or induced movements with fetal heart accelerations.

This indirectly indicates a normally functioning autonomic nervous system and excludes cellular hypoxia[19].

Fetal heart rate acceleration:

Fetal heart rate is normally increased or decreased on a beat to beat basis mediated by autonomic influences from brain stem centres. Thus, fetal heart rate acceleration is an indication of autonomic function. Beat to beat variability is under the control of autonomic nervous system. (Matsurra & collegues 1996)[20].

The fetal heart rate has its own intrinsic activity and a rate determined by the spontaneous activity of the pacemaker SA node; this structure has the fastest rate and determines the rate of a normal heart. The next pacemaker is in the atrium followed by AV node, which has the slowest rate of activity and generates the idioventricular rhythm.

The fetal heart rate is modulated by a number of stimuli. Central nervous system influence is important with cortical and subcortical influences which are not under voluntary control. The cardioregulatory centre in the brain stem also plays a part. Other physiological factors that regulate the heart rate are circulatory catecholamines, chemoreceptors, baroreceptors and their interplay with the ANS.

The efferent component of ANS is composed of the sympathetic and parasympathetic systems. There is a constant input from these systems, wherein, the sympathetic impulses drive the heart rate to increase and parasympathetic impulses which drive the heart rate to decrease.

Gestational age influences on fetal heart rate:

Gestational age influences acceleration or reactivity of fetal heart rate. Pillai & James (1990) studied the development of fetal heart rate acceleration patterns during

normal pregnancy& noticed that the percentage of body movements accompanied by acceleration and amplitude of these increased with gestational age

The National Institute of Child Health and Human Development fetal monitoring workshop (1997) has defined acceleration based on gestational age. The acme of acceleration is 15beats per minute or more above the baseline rate, and the acceleration lasts 15 seconds or longer but less than 2 minutes in a fetus at or beyond 32 weeks. Before 32 weeks, accelerations are defined as having an acme 10 beats per minute or more above the baseline for 10 seconds or longer.

FIGO CLASSIFICATION OF NST IN ANTEPARTUM PERIOD:

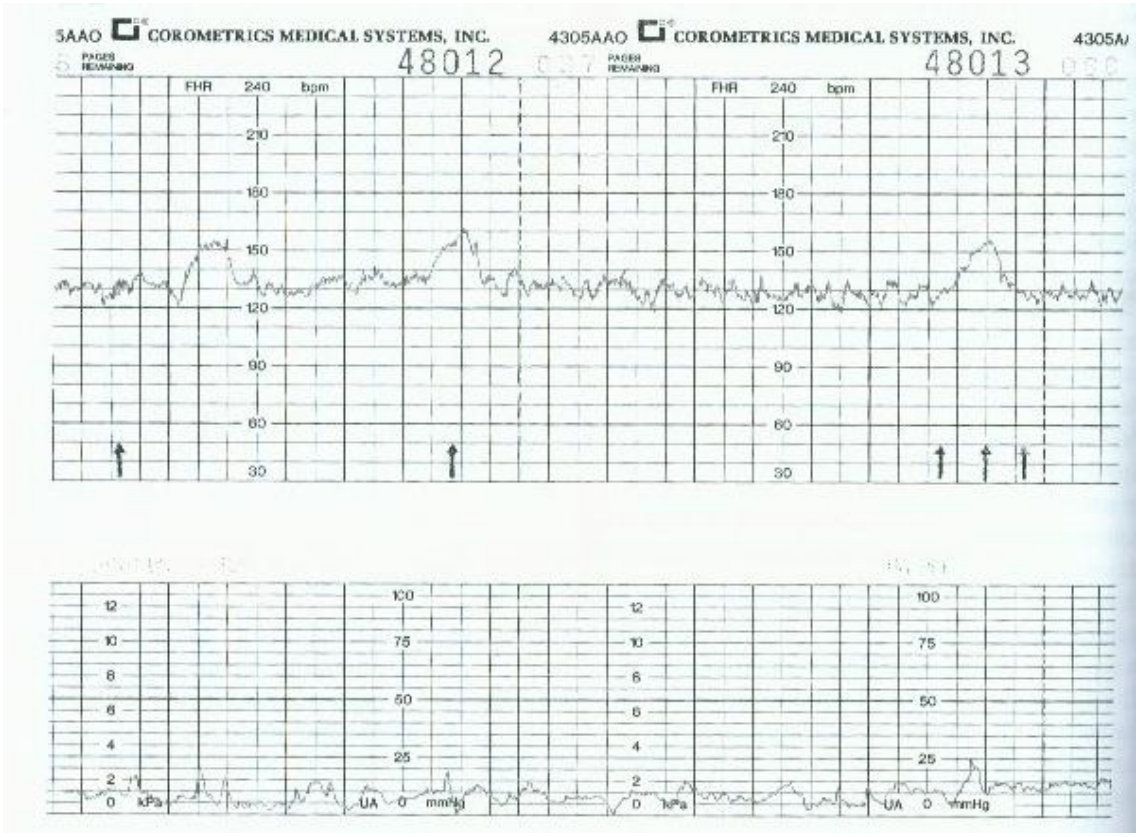
1) Normal pattern /Reactive NST/Reassuring:

- Baseline FHR 110 to 150 bpm
- Amplitude of baseline variability 5 to 25 bpm
- Absence of decelerations except for sporadic, mild decelerations of very short duration.
- Presence of two or more accelerations during a 10 minute period.
- When there is moderate tachycardia (150 to 170 bpm) or moderate bradycardia (100 to 110 bpm) , a reactive trace without decelerations is reassuring of good health.

INTERPRETATION:

Repeat according to clinical situation and the degree of fetal risk.

Figure – 1: Reactive NST trace



2) Suspicious pattern/ Equivocal:

- Baseline FHR 150 to 170 bpm or 100 to 110 bpm.
- Amplitude of variability between 5 to 10 bpm for more than 40 minutes.
- Increased variability above 25 bpm in the absence of accelerations.
- Absence of acceleration for more than 40 minutes (non reactive trace)
- Sporadic deceleration of any type unless severe.

INTERPRETATION:

Continue for 90 minutes until trace becomes reactive or repeat NST within 24 hours or vibroacoustic stimulation.

3) Pathological pattern / abnormal:

Any of the following:

- Baseline FHR below 100 or above 170 bpm,
- Silent pattern of less than 5 bpm for more than 40 minutes.
- Sinusoidal pattern: frequency less than 6 cycles per minute.
- Repeated late, prolonged and severe variable decelerations (more than 40 bpm)
- Periodically recurring and repeated decelerations of any type.
- Amplitude more than 10 bpm for more than 20 min.

INTERPRETATION:

Warrants some action in the form of additional test or delivery depending on the clinical picture.

INSTRUMENTS FOR NON STRESS TEST

The instrument used for recording NST is called cardiotocogram. Depending upon where the sensors are placed, these monitors are of two kinds:

1. External monitors: sensors are placed on the maternal abdomen.

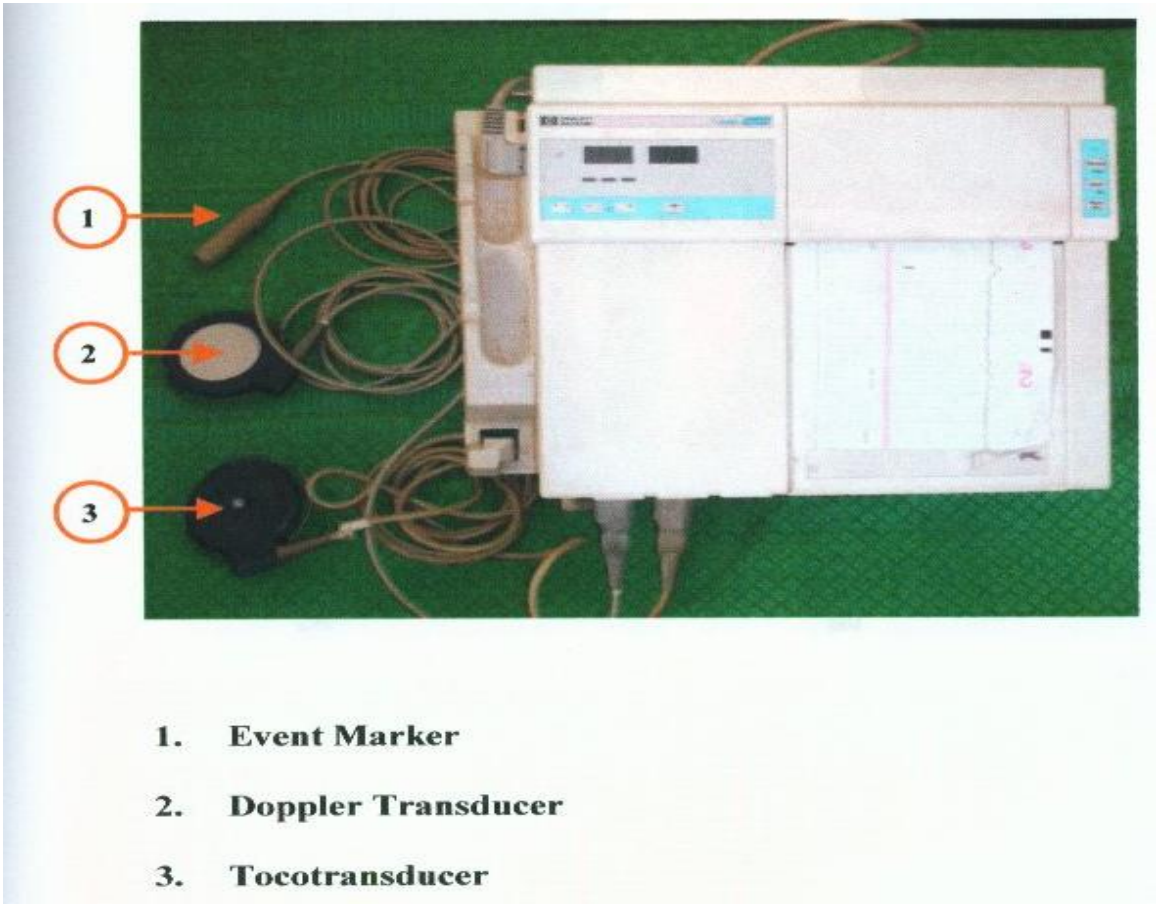
2. Internal monitors: are placed in the fetal scalp by the vaginal route.

External monitors are used for antepartum assessment and during early labor.

Internal monitors are used during labor after the rupture of membranes.

Cardiotocogram: It essentially consists of a central unit with attachments. A central unit processes the signals from the sensors and prints them in the form of a trace.

Figure – 2: Cardiotocogram



Apart from the central unit, the other parts of the instruments are :

Ultrasound transducer

This contains a transmitter as a signal source and a receiver. The signals are continuously transmitted through the maternal abdominal wall and make contact with the fetal heart through a coupling gel media; the reflected signal undergoes a frequency change (Doppler shift) as the reflecting interface i.e. when the fetal heart moves. The electronic sensors in the monitorsense this frequency change and converts it into an electronic signal. The electronic signal can then be used as a marker of the fetal heart beat, as well as the source of the development of an audible signal that provides the sound that is heard clinically. Transducers are made up of seven elements of Piezo-electric crystals so that it can emit and receive ultrasound over a wide angle covering some degree of change in fetal heart positions. Generally, operate frequency of 1.5 Mhz. Ultrasound power output density is 4 mm/cm2.

The tocotransducer

This is a process gauge that picks up the uterine activity and is fixed on the maternal abdomen at the level of fundus of the uterus. The change in the shape and hardness of the uterus with contraction depresses a plunger on the tocotransducer, which moves a slight distance and causes a change in voltage of small electric current that is passing through. These voltage changes are proportional to the uterine activity and are represented quantitatively by the fetal monitor as contractions.

Aquasonic gel

Ultrasound waves travel very poorly through air and extremely easily through liquids. Gel is applied to eliminate air between transducer and mother’s abdomen .

Abdominal belt

Two types of belt: Disposable belt and reusable belt (good).

Fetal vibroacoustic stimulation test (VAST)

It is a fetal surveillance test which aims to assess the functional state of fetal CNS and its reflex cardiovascular response and through these its blood oxygen status[21]. Because of its high accuracy, ease of administration &a shorter testing time, vibroacoustic stimulated modified biophysical profile is a reliable diagnostic approach[22.]

Basis of VAST

The finding that fetal cochlear apparatus gets mature enough to appreciate acoustic stimulation from 28 weeks of gestation (Smith, 1994)[23] and the observation and assumption that, the auditory sensation is one of the first to get affected by hypoxia[24] is the basis of vibroacoustic stimulation test.

Procedure:

The fetus is given a VAST by placing vibroaoustic stimulator anywhere over the baby's vertex i.e. near its ear for a period of maximum 3 seconds. In healthy fetus acceleration occurs almost instantly on giving the stimulus. If acceleration fails to occur with one stimulus, it may be repeated at one minute intervals for a maximum of 3 times.Response to VAST is either reactive or non-reactive.

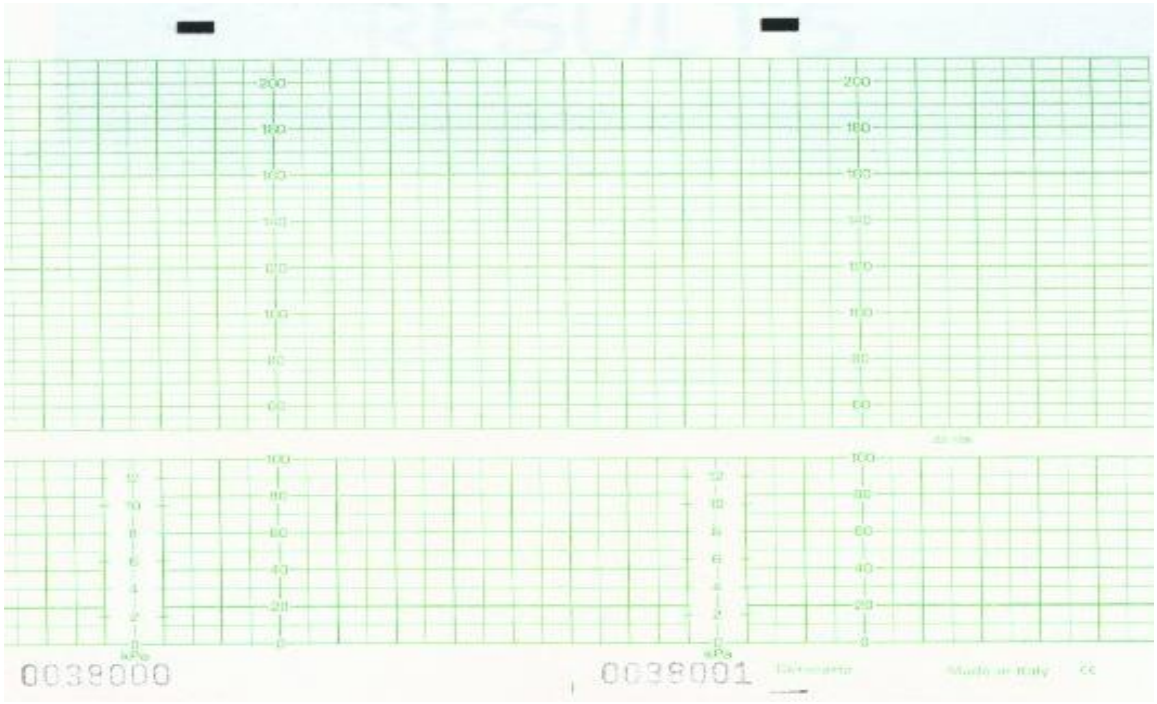
Reactive:

If there occurs two or more fetal heart rate accelerations of atleast15 bpm lasting for atleast 15 secs in a 10 minute period (Smith et al, 1986).

The trace and the paper

The paper that is used for recording the trace is heat sensitive and consists of two panels. The upper panel is the fetal heart rate where the fetal heart rate is recorded and the lower panel records the uterine activity. Chart recording speed is 1 to 3cm per min.

Figure – 3 : Sample Graph Paper

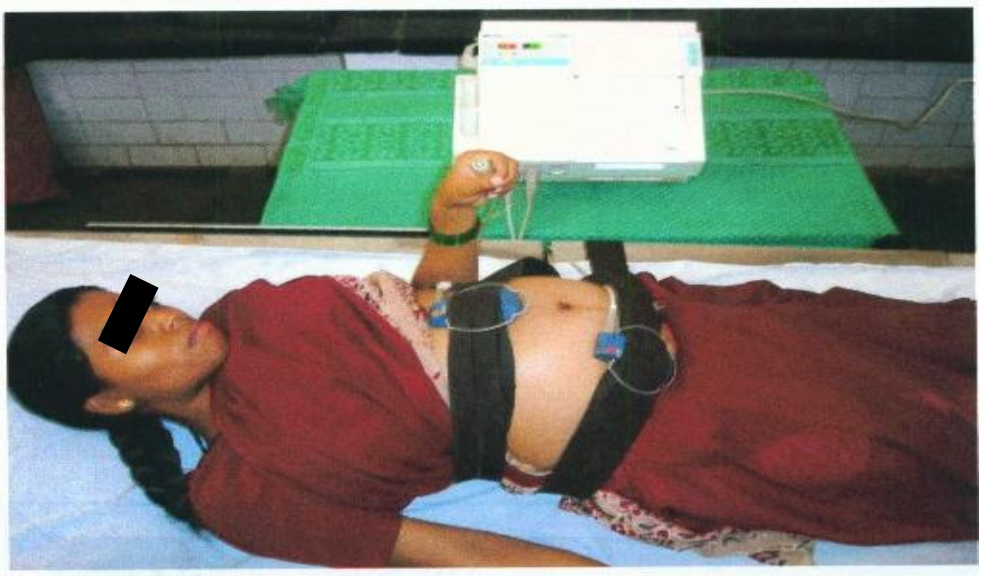


Non-stress test and maternal position

It has been reported that compression of the abdominal aorta by the pregnant uterus results in decrease uterine blood flow. This reduction may or may not be compensated by collateral circulation from the ovarian or other arteries.

Supine position leads to decrease in femoral artery pulse pressure, especially during uterine contractions. Therefore during abdominal aortic compression by the pregnant uterus, the degree of resulting aortic blood flow reduction may be evaluated using measurements of blood pressure or pelvic pressure reduction in the femoral artery. They reported 19% of late decelerations. This effect is seen more easily in primiparas than multiparas[25]. It is difficult to understand why minority of pregnant women demonstrates compression of the abdominal aorta in the supine position, while the majority do not.A number of anatomic variations may be responsible, such as the degree of lumbar curvature, position of the abdominal aorta over the lumbar vertebrae, level of aortic bifurcation and level of origin of the ovarian arteries that may produce collateral circulation during aortic compression. The NST is a simple and convenient tool, but a major drawback is the high percentage of false positive non-reactive NST results, which even in the lateral position, are still unaccounted for. In some reports a semilateral position is mentioned during the NST (a difficult position to maintain for any length of time as compared with the full lateral decubitus position). However, by performing the NST in the full lateral decubitus position, patient comfort may be increased while simultaneously reducing the number of false positive results.

Figure – 4 : Method of performing NST



Method of performing NST:

NST is non-invasive, easily performed and interpreted. It is readily accepted by the patient.

- Place the patient in semi-Fowler's position. Use pillows under one of her hips to displace the weight of the gravid uterus away from the inferior venacava.
- Apply the tococardiographic equipment to the maternal abdomen, and observe the uterine activity and FHR for 10 minutes.
- Instruct the patient to press the calibration button of the uterine contraction tracing each time she feels fetal movements.
- A reactive trace is present when two or more accelerations of FHR are clearly recorded over a 20 minute period with each acceleration of 15 or more beats/minute and lasting for 15 seconds or more, usually occurring

  simultaneously with episodes of fetal movement recorded by the patient.
- If no spontaneous movement occurs during the initial 20 minute of observation, the test is continued for another 20 minutes and during this period fetal movement is provoked by external manipulation (VAST). If there is no acceleration with spontaneous/repeated external stimulus during a 40 minute period, the test is considered non-reactive.

Reliability of NST

The false negative rate of test is 3.2/1000 (i.e. a reactive NST in a fetus who is actually in distress) indicating that the likelihood of fetal death or serious morbidity following a reactive NST is extremely low and generally due to acute conditions like placental abruption, cord complications etc.

False positive rate

Non-reactive results in normal fetuses is very high i.e. 50% for morbidity and 80% for mortality, indicating that the probability of serious fetal problems is low, when the test is non-reactive.

ASSESSMENT OF FETAL WELL BEING

Non-stress test

Freeman R. K. and colleagues (1975)[26] introduced the NST to describe FHR acceleration in response to fetal movement as a sign of fetal health. By the end of 1970s, the CST was replaced by the NST as the primary method of testing fetal health. Simplistically the NST is primarily a test of fetal condition and it differs from the CST, which is a test of uteroplacental function. The evaluation of fetus by EFHR monitoring is a complete process and many factors have to be taken into consideration like baseline FHR, bradycardia, tachycardia, beat-to-beat variability, accelerations, decelerations etc.

Baseline FHR

The baseline FHR is the mean level of FHR when it is stable. It should not include acceleration and decelerations. It is determined over a period of 5-10 minute and expressed in beats/minute. The normal range of the baseline FHR at term is 110-150 beats/minute.

BRADYCARDIA

It is the baseline heart rate < 110 beats/minute. It is further classified into:

Mild: 100-110 beats/minute

Moderate: 80-100 beats/minute

Severe: < 80 beats/minute

Causes:

Cord compression, prolapse of cord, abruptio placenta, scar dehiscence, uterine hyperstimulation, digoxin. In healthy fetus cord compression is the main cause of bradycardia.

Action:

Adjusting maternal position, IV fluids, oxygen, stopping oxytocin may correct the condition. Most cases of prolonged bradycardia will show signs of recovery towards the baseline rate within 6 minutes. The recovery towards the normal baseline within the 6 minutes and good baseline variability at the time of bradycardia and during recovery are reassuring signs.

TACHYCARDIA

It is the baseline fetal heart rate > 150 beats/minute. It is further classified into:

- Mild/suspicious tachycardia – 150 to 180 beats/minute.
- Severe/pathological tachycardia – 180 beats/minute. Before 34 weeks gestation the baseline is normally higher and upto 160 beats/minute is acceptable.

Causes

Hypoxia, fetal anaemia, fetal cardiac failure, fetal arrhythmia, prematurity, maternal fever, maternal anxiety, maternal or fetal hyperthyroidism, chorioamnionitis, parasympatholytic drugs like Atropine, betamimetic drugs for e.g. Salbutamol, Ritodrine, Isoxysuprine.

BEAT-TO-BEAT VARIABILITY

It is the degree to which the baseline varies within a particular bandwidth excluding accelerations and decelerations. It reflects the interaction of parasympathetic and sympathetic systems. The change in the baseline rate and change in baseline variability are the key signs of developing hypoxia and acidosis.

Normal beat-to-beat variability ranges from 10-25 beats/minute.

- Beat-to-beat variability of < 5 beats/minute is described as absent beat-to-beat variability.
- Short-term variability – 5-10 beats/minute is reduced beat-to-beat variability.
- Long-term variability – 25 beats/minute as increased beat-to-beat variability.

The baseline variability (normal – 10 to 25 beats/minute) is determined by drawing horizontal lines at the level of the highest point of the peak and lowest point of the troughs of the heightness of the trace in a 3 cm segment (for paper speed of 3 cm/min).

BANDWIDTHS

They are classified as:

Silent pattern(0-5) – severely compromised fetus with depression of CNS.

- Reduced (6-10) – Narrow undulatory Normal fetus

- Normal (11-25) – undulatory
- Salutatory (> 25) seen with fetal hypoxia, cord compression and occipitoposterior presentation.

The baseline variability indicates the integrity of ANS. Baseline variability is a good predictor of fetal well being and when it is observed during the last 20 minute before delivery, babies were in good condition regardless of the other features of the trace/FHR pattern. Research indicates that the likelihood of fetal acidosis when normal baseline variability exists is zero. Quiet sleep is associated with episodes of decreased variability, which generally lasts for upto 40 minute. Active movements are associated with good variability and accelerations. The presence of two accelerations in a 20 minute period of time is termed as a reactive trace and is suggestive of fetus in good health.

However, in order to be described as non-reactive it should run for a period of atleast 40 minute during which two accelerations are not identified in any 20 minute period.

Reduced baseline variability:

Commonest reasons are: Fetal sleep or quiet phase of FHR cycle (lasting upto 40 minute, longer if the mother is medicated). Other reasons could be hypoxia, prematurity, tachycardia, drugs (Sedative, anti-hypertensive, anaesthetics), local anaesthetic reaction, congenital malformation (especially if CNS more than CVS) and Cardiac arrhythmias.

Accelerations

It is defined as a transient increase in heart rate of 15 beats/minute or more and lasting 15 seconds or more above the baseline. The recording of atleast two accelerations in a 20 minute period is considered a reactive trace. Accelerations are considered a good sign of fetal health, the fetus is responding to stimuli and displaying biological integrity of its mechanisms controlling the fetal heart.

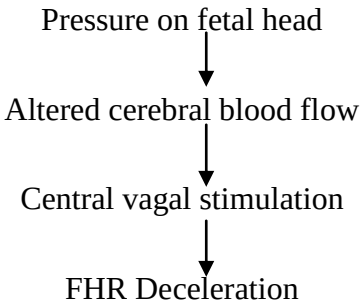
Decelerations

Transient slowing of FHR with uterine contraction is known as decelerations. It is a transient episode of slowing of FHR by > 15 beats/minute from the baseline and lasting 15 seconds or more. The absence of decelerations is reassuring.

Decelerations are classified as: Early, late, variable decelerations.

Early decelerations (Type I)

Definition: Early decelerations are synchronous with contraction, in late first stage/II stage of labour with descent of head.



- Caused by head compression.
- Benign and does not cause hypoxia or acidosis.
- U-shaped and proportional to magnitude of contraction.
- No treatment is necessary.

LATE DECELERATIONS (Type II)

A transient but repetitive deceleration of FHR occurs late in the contraction phase. The nadir of deceleration occurring after the apex of contraction and FHR returns to baseline after the contractions is over. It is likely to be the result of hypoxia and associated with metabolic acidosis from uteroplacental insufficiency.

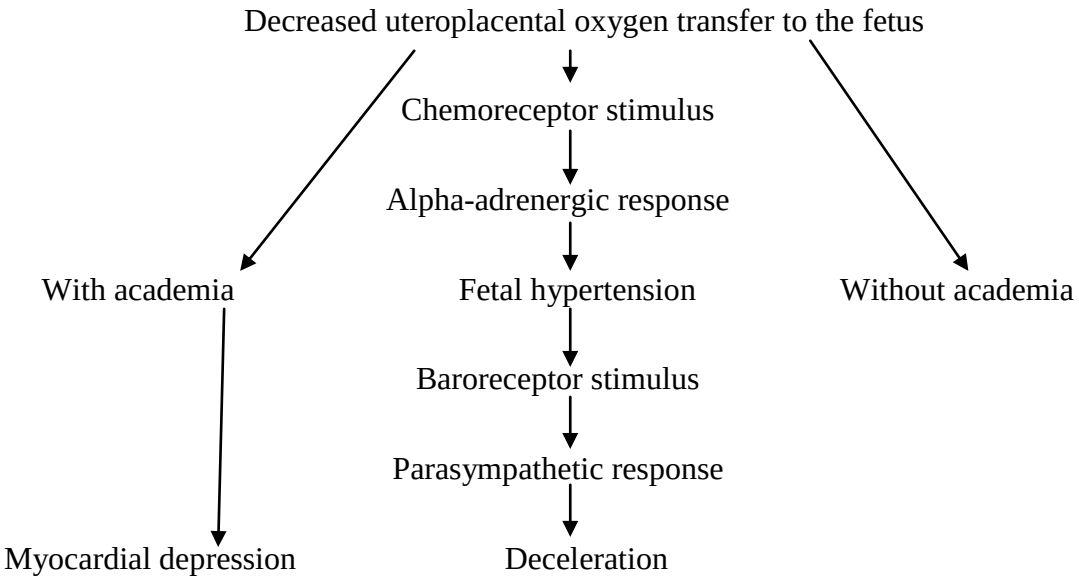
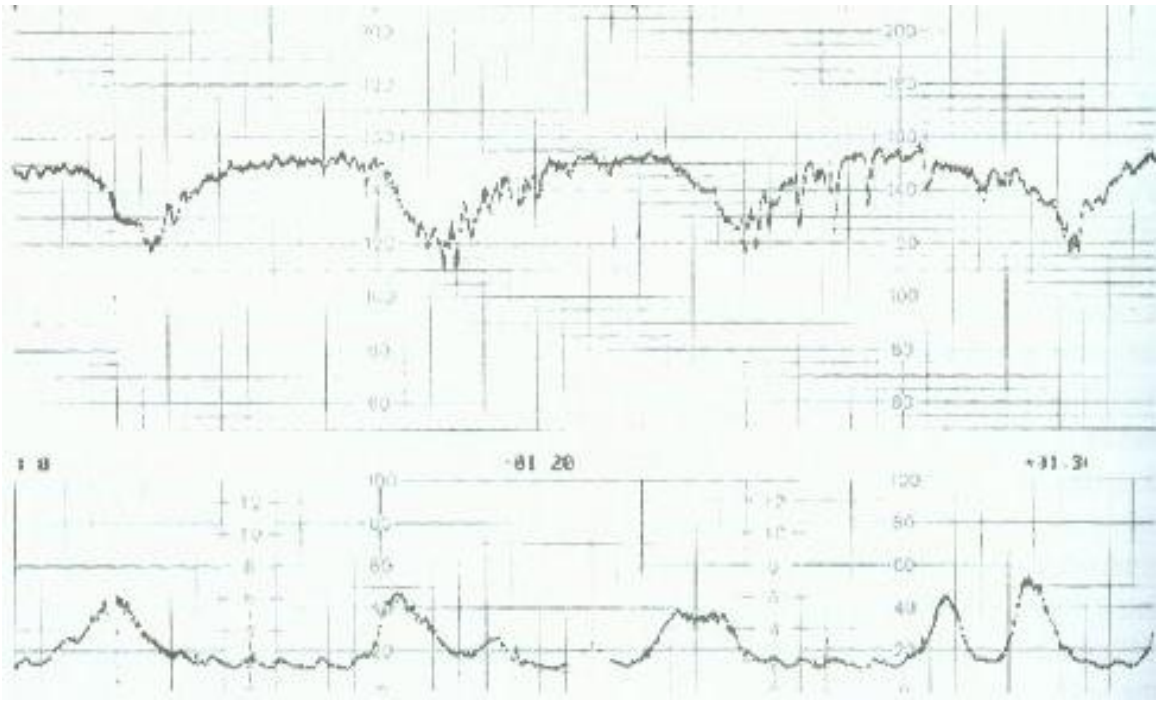
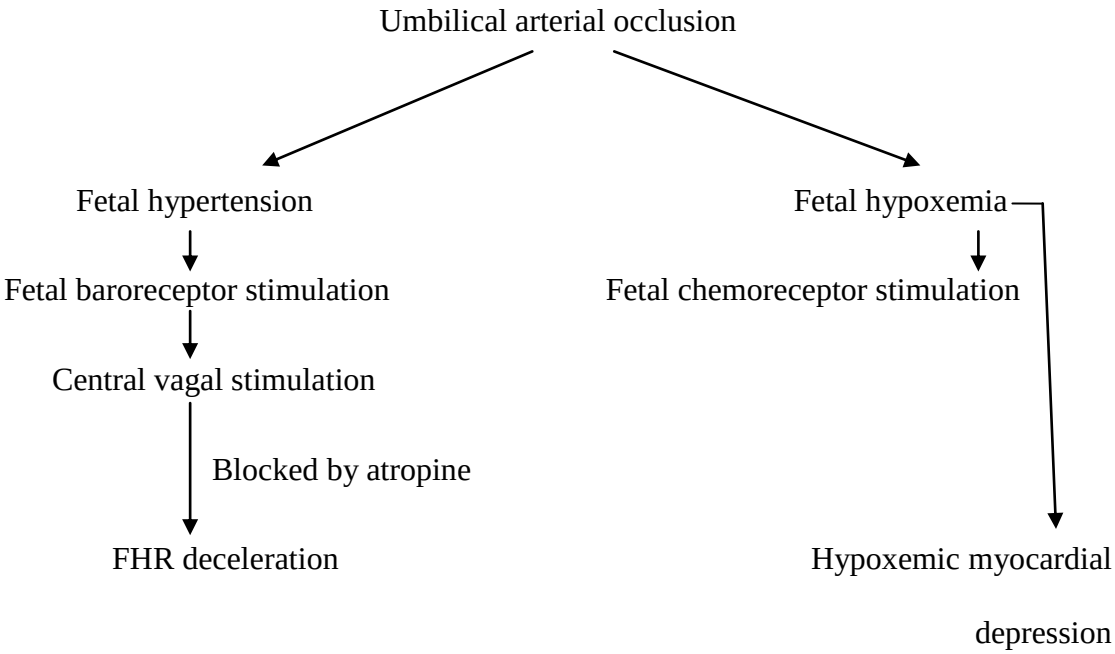


Figure – 5 : Trace showing variable decelarations



VARIABLE DECELERATION OF CORD COMPRESSION

Includes all other patterns of temporary slowing of FHR, which are not necessarily related to uterine contractions. It is thought to indicate cord compression and may disappear with the change in position of the patient.



Other patterns and variations

Pseudo distress pattern

Describes a circumstances caused by a very active fetus with so many confluent accelerations that it is misinterpreted as tachycardia with decelerations. The clinical picture should provide clues to correct identification.It is easy to identify these patterns as non-pathological if the fetus is well grown, has a normal amniotic fluid level and is moving actively during the recording of the heart rate. Such traces should have good baseline variability at the true rate and at the higher (i.e. acceleration) rate.

It is to be remembered that, a hypoxic fetus with a tachycardia with or without decelerations does not move actively. Sinusoidal pattern is one FHR pattern, which cannot be distinguished by intermittent auscultation. The trace looks like a seismograph during a sustained but moderate earthquake. A regular up and down pattern going 3 to 5 beats/minute above and then below the imaginary "middle" of a baseline at a rate of 2 to 5 times/minute. It is associated with severe anemia or hypoxic fetuses it is looked upon with anxiety. Sinusoidal pattern in healthy fetuses can be exhibited during – fetal sucking (physiological sinusoidal pattern).

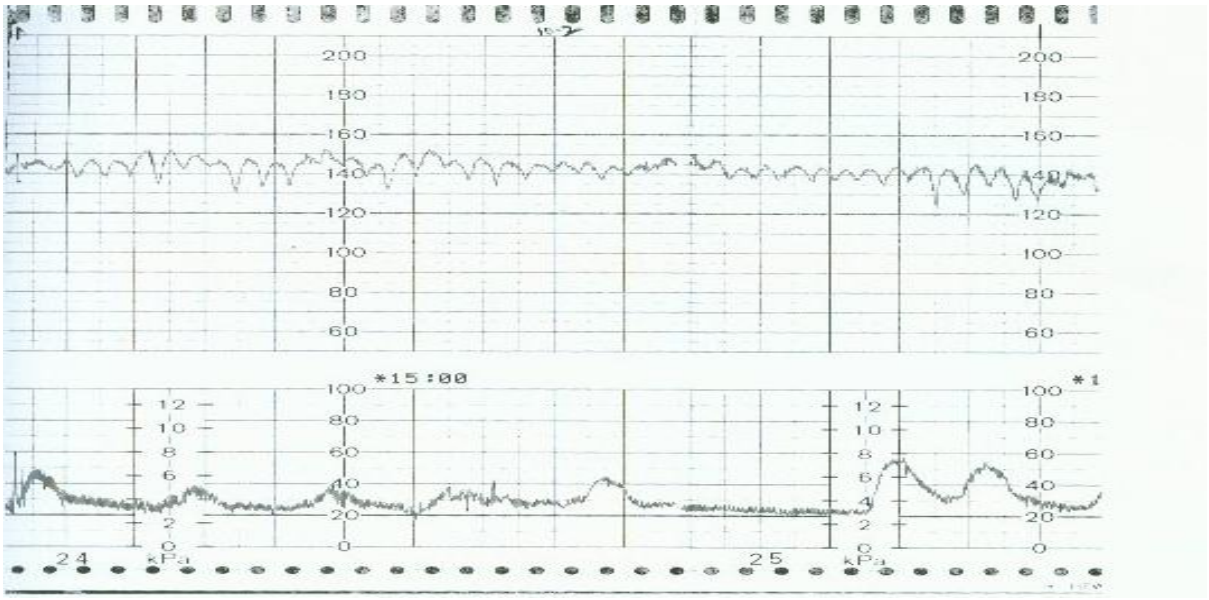
Typical pathological sinusoidal FHR pattern

- Stable baseline rate of 110 to 150 beats/minute.
- Regular acceleration having an amplitude of 5 to 15 beats/minute.
- Frequency of 2 to 5 cycles/minute and afixed or flat baseline variability.
- The oscillation of waveform above and below the baseline is equal.
- Most important feature is that there are no areas of normal FHR variability and there are no accelerations.
- Reactivity/Normal baseline variability in the FHR tracing prior to or just after the episode of a period of sinusoidal FHR pattern is suggestive of an uncompromised fetus.

Pseudo-sinusoidal pattern

It is not pathological. It has a sharp saw tooth appearance of baseline variability, which is very frequent (more than five ups and down/minute) whereas sinister sinusoidal patterns have smooth slow curves.

Figure – 6 : Trace showing sinusoidal pattern



Causes of pathological sinusoidal pattern:

Rhesus disease, Anemia– Due to infection, haemoglobinopathies (Bart's thalassemia) and feto maternal transfusion, bleeding from the fetus (vasa previa).

Table – 1 : AMERICAN COLLEGE OF OBSTETRICS AND GYNAECOLOGY guidelines for antepartum surveillance using EFHRM (Electronic Fetal Heart Rate Monitoring).

Indication	Initiation	Frequency
Post-term pregnancy	41 week	Twice a week
PROM	At onset	Daily
Bleeding	26 weeks/ onset	Twice a week
Oligoamnios	26 weeks/ onset	Twice a week
Polyhydramnios	32 weeks	Weekly
Diabetes Mellitus (well controlled)	36 weeks	Weekly
Diabetes Mellitus (Poor controlled)	32 weeks	Twice a week
Chronic hypertension or PIH	28 week	Weekly

AMNIOTIC FLUID INDEX

Amniotic fluid provides a protected milieu for the growing fetus, cushioning the fetus against mechanical and biological injury, supplying nutrients & facilitating growth & movement.

Both an abnormal increase & decrease in amniotic fluid volume is associated with increase in maternal morbidity & perinatal morbidity & mortality.

Factors influencing amniotic fluid volume:

The factors influencing amniotic fluid volume are:

- Fetal Urine
- Fetal respiratory tract
- Fetal skin
- Fetal swallowing

Fetal Urine :

Fetal urination is thought to be the major source of AF after fetal kidney function begins at 10-12 weeks. Urine production per kg body weight increases from 110ml/kg/24hours at 25weeks to 190 ml/kg/24hours at 39 weeks.

Term output of urine is 1000 to 1200ml/day

Estimated near term urine flow probably averages 700 to 900ml/day.

Urine flow rate decreases after 40 weeks of gestation. Any condition that prevents the formation of urine or the entry of urine into amniotic sac almost invariably results in oligoamnios in second half of gestation. More recent reports fully support the concept that anuria or oliguria is a frequent cause of oligoamnios.

Ultrasound estimation using serial bladder measurements suggests that near term urine production rate of 1200 ml/day. This concept is supported by the almost complete absence of amniotic fluid with fetal renal agenesis or urinary outflow obstruction. Thus changes in fetal urinary flow rate have an important effect on AFV and clinical evaluation of oligohydramnios or polyhydramnios must focus on fetal renal function.

Fetal respiratory tract :

Fetal lung fluid is an additional contributor to AFV at a rate approximately to one-half that of urine flow. Amniotic fluid enters the fetal lungs by way of the trachea and is absorbed by the capillaries lining the alveoli.

Studies in near term fetal sheep have shown that there is an outflow from the lungs of 200-400 ml/day and that this flow of 10% of body weight/day is mediated by an active transport of chloride across the epithelial lining of the developing lung.

Average of 50% of the fluid secreted by fetal lungs enteres the amniotic sac and the remainder is swallowed as it exits the trachea[27]. In humans, the phospholipid measured in amniotic fluid when lecithin/Sphingomyelin (L/S) ratios are determined are of pulmonary origin and are not passed in significant quantities through the urine. Presence of pulmonary surfactants strongly supports the above concept.

Fetal skin :

Amniotic fluid may be derived from water transport across the highly permeable skin of the fetus during the first half gestation. At 22-25 weeks, keratinization of the skin occurs, it is generally accepted that significant amounts of

water and solute are not transferred across this membrane after keratinization except for small lipid-soluble molecules, such as carbon dioxide.

Fetal swallowing:

Fetus begins swallowing at 8 to 11 weeks of gestation

Estimated fetal swallowing rate is 500ml/day [28]

Swallowing decreases to near zero prior to delivery or fetal demise. Studies have shown that fetal hypoxia suppresses fetal swallowing activity, whereas fetal hypertoxicity and angiotensin II may enhance swallowing.

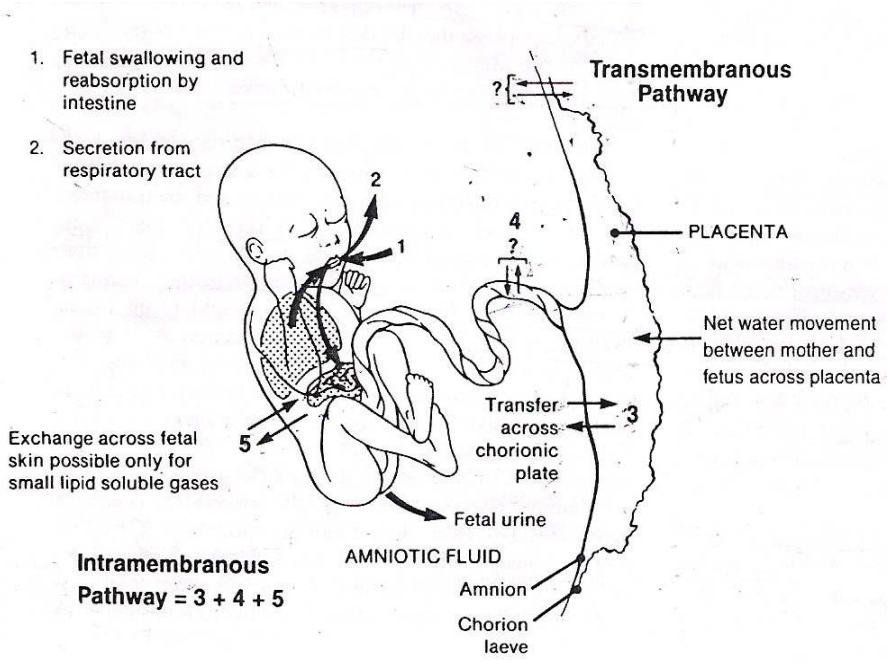
The excretion of fetal urine and the swallowing of amniotic fluid by fetus are the two major pathways for the formation and clearance. The secretion of large volumes of fluid each day by fetal lungs, is a major source of amniotic fluid during the second half of gestation.

Regulation of amniotic fluid volume:

There are two pathways for fluid to enter and leave amniotic space.

1. Intramembranous pathway: Rapid movements of both water and solutes occur between amniotic fluid and fetal blood within placenta and membranes.
2. Transmembranous pathway: Movement of water and solutes between amniotic fluid and maternal blood within the wall of uterus. Fluid may be secreted by fetal oral nasal cavities, which contribute to AFV.

Figure – 7: Regulation of amniotic fluid volume

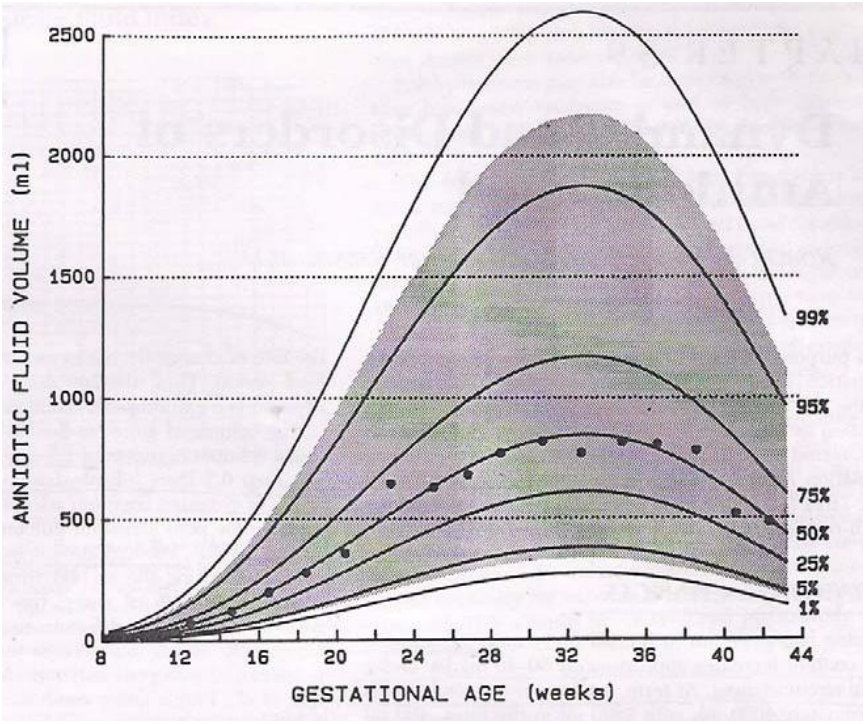


Amniotic fluid changes with gestational age:

AFV increases progressively during gestation and its volume decreases as labour approaches i.e near full term and even becomes severely reduced in the post term period. Volumes of amniotic fluid at various gestational ages have been studied by the use of direct volumetric methods, indicator dilution techniques and more recently, quantitative amniotic fluid by ultrasonographic methods.

- AFV increases progressively during gestation until approximately 32 weeks.
- From 32 to 39 weeks, the mean AFV is relatively constant in the range of 700 to 800ml.
- From 40 to 44 week, there is a progressive decrease in AFV at a rate of 8% per week averaging in only 400ml at 42 weeks[29].

Figure – 8: Amniotic fluid volume changes with gestational age



Abnormalities of amniotic fluid volume:

- Oligohydramnios
- Polyhydramnios

Oligohydramnios:

Definition: Oligohydromnios is defined as the absence of an amniotic fluid pocket, measuring 1centimeter in vertical diameter or an AFI less than 5.

Causes :

- Pregnancy induced hypertension
- Post term pregnancy
- Premature rupture of membranes
- Intrauterine growth restriction (IUGR)
- Fetal renal anomalies: Renal agencies, urethral obstruction prune belly syndrome bilateral multicystic dysplastic kidneys.
- Non renal fetal abnormalities: Triploidy, thanatophoric dwarfism, thyroid gland agencies, skeletal dysplasias, congenital heart block, multiple anomalies.
- Chronic abruption
- Leaking fluid following amniocentesis or chorionic villus sampling.
- Drugs like prostaglandin inhibitors, angiotensin converting enzyme inhibitors & non steroidal anti-inflammatory drugs.

Figure – 9 : Oligohydramnios

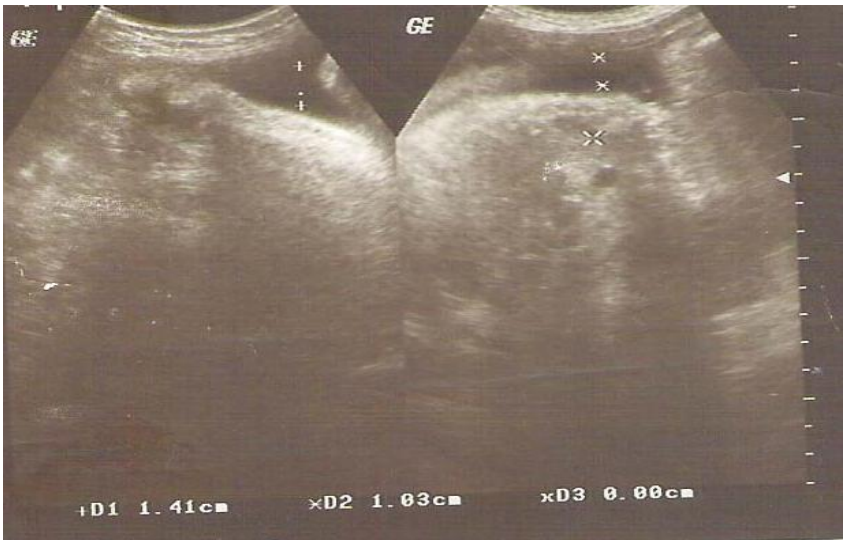
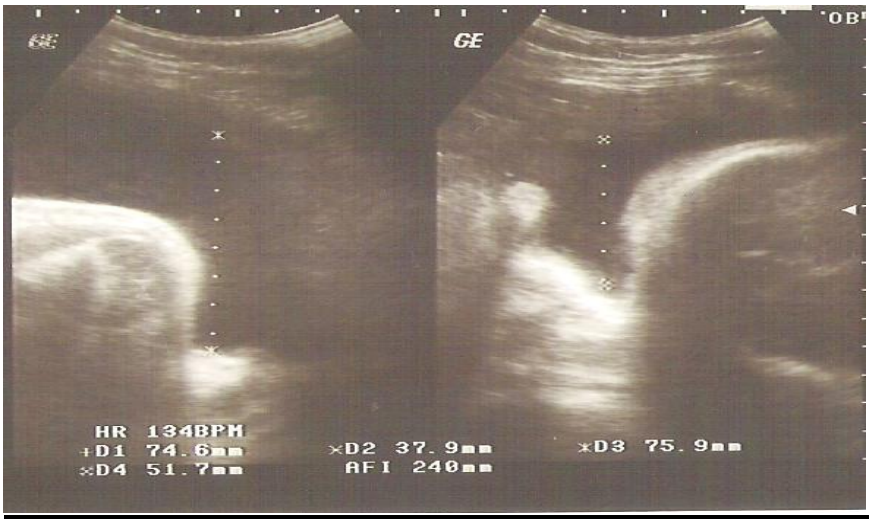


Figure – 10: Polyhydramnios



Polyhydramnios :

Definition : It is defined as amniotic fluid volume in excess of 1.5 to 2 litres or AFV above 95th percentile or AFI measuring >18cms (MVP> 8cms).

Causes:

- Maternal
- Fetal
- Placental
- Idiopathic

MATERNAL -15%

- Rh isoimmunization
- Diabetes mellitus

FETAL-18%

- Multiple pregnancy
- Fetal anomalies (central nervous system anomalies,gastrointestinal anomalies, genitourinary anomalies, skeletal malformations, fetal tumours, cardiac anomalies, chromosomal defects , genetic syndromes , hematologic disorders , fetal infections , miscellaneous)

PLACENTAL-<1%

- Placental chorioangioma
- Circumvallate placenta syndrome

Idiopathic – 66%

Value of amniotic fluid volume assessment in pregnancy evaluation

The importance of AFV as an indicator of fetal status was appreciated relatively recently. Ultrasound assessment of amniotic fluid is used frequently to identify fetuses at risk of having adverse outcomes as suggested by the finding of abnormal fluid volumes. Today, assessing AFV subjectively or semiquantitatively during ultrasound and during antepartum examination is common. Since 1987, when Phelan et al described the AFI as a method of semiquantitatively estimating AFV, this index has been increasingly incorporated into reports of routine obstetric ultrasonography.

Amniotic fluid volume assessment in pregnancy evaluation is helpful in:

1. **Prediction of poor perinatal outcome in perinatal mortality**

   Chamberlain and associates[30] reviewed charts of 7562 high-risk obstetrical patients referred for BPP. The corrected perinatal mortality rate for patients with qualitatively normal AF was 1.97 in 1000 compared with 412 in 1000 when AFV was increased. These investigations also reported a 13 fold increase in perinatal mortality rate (56-5/1000) when AFV was marginal by sonographic assessment and a 47 fold increase (187.5/1000) when severe oligoamnios was present.

2. **Perinatal morbidity and mortality :**

   Pregnancies complicated by extremes of AFV are subject to increased rates of perinatal morbidity and mortality.

During labour, excessive AF is associated with abnormal fetal presentation, operative delivery, abruption placenta and post partum haemorrhage. Verma and colleagues compared outcomes of 135 patients with sonographically diagnosed polyhydramnios to healthy pregnant women and found that preterm delivery occurred in 11.1% in the study group compared with 6.7% in the control group. The incidence of fetal distress, low Apgar scores, macrosomic infants and admission to NICU was substantially greater in the study group.

With oligohydramnios, IUGR, meconium passage, FHR abnormalities and depressed Apgar scores are a common.

Chouhan and associates assessed the outcomes of patients with oligohydramnios on admission in labour. Fetuses with oligohydramnios were more likely than controls to have fetal acidosis (25% vs 10.5% respectively) and neonatal asphyxia (31.2% vs 17.6% respectively).

3. **Prediction of IUGR and placental insufficiency.**

Oligohydramnios is often a sign of poor placental function. Because fetal urinary flow is determined in part by the state of fetal hydration, which in turn is determined by placental function. Oligohydramnios is frequently associated with IUGR, intrapartum asphyxia and fetal death[31].

- AFI>5cms with reactive NST – incidence of fetal death is <1 in 1000 in a week.
- Patients with mild oligohydramnios (AFI 5-8cms) may develop severe oligohydramnios within 4 days.

- Patients with borderline AFI are associated with higher incidence of IUGR and thus need more intensive antenatal monitoring.
- AFI – 5 to 10cm (borderline AFI) should be an indication of twice weekly antepartum testing and need more intensive antenatal monitoring.

Methods of estimating AFV:

Before the availability of ultrasound, assessment of AFV depended on palpation of the abdomen, measurement of the symphysio fundal height and abdominal girth. As the ability to visualize the fetus and its environment with ultrasound, several sonographic methods of amniotic fluid assessment have been proposed, each with distinct advantages and disadvantages. Methods of estimating AFV are as follows:

- Subjective assessment
- Maximum vertical pocket method
- Amniotic fluid index

a) Subjective assessment :

In this method, the relative amount of echo-free areas is compared to the space occupied by the fetus itself. Although this method is simple and rapid. It requires a highly trained observer and lack of a numerical result for comparision and trending are important disadvantages.

b) Maximum vertical pocket (MVP):

This technique involves selecting the single deepest uninterrupted pocket of AF and measuring its depth. Although easy to perform and reasonably reproducible, the criteria for normal have not been rigorously established.

Manning and associates proposed that oligohydramnios be defined as the absence of any AFV pocket of atleast 1cm deep (1cm rule) and polyhydramnios as any pocket larger than 8cm.

But other investigations have found that 1cm rule poorly predictive, through it was highly predictive of (89% senisitivity) IUGR in the study by Manning and associates.

Bottoms and associates[32] noted that the absence of a fluid pocket of atleast 1cm deep was exceedingly rare and may be too restrictive a criterion for oligohydramnios.

Table - 2 : Study of AFV by MVP method by Bottoms & associates

AFV	% of patients	MVP Depth (in cm)
Increased	3	≥ 8
Normal	94	>2 to <8
Marginal	2	>1 to <2
Decreased	1	<1

This scale was derived from at risk pregnancies in 3rd trimester rather than from healthy women and at various gestational ages. Inter and intraobserver variation was not evaluated. Relationship of MVP to actual AFV was not determined.

c) Amniotic Fluid Index :

This method was described by Phelan and co-workers (1987)[15] involves adding the vertical depths of largest pocket in each of four equal uterine quadrants. The mean AFI increased from 7 to 30cm from 12 until 26 weeks and then plateaued for rest of gestation at approximately 16cm.

Phelan et al studied AFI in 330 patients of at risk pregnancies.

Table – 3: Study of AFI by Phelan et al

AFV	AFI value (cm)	No of patients (%)
Very low	<5	8%
Low	5.1 to 8.0	20%
Normal	8.1 to 18	66%
High	>18	6%

Patients with AFI <5cm had considerably high rates abnormal fetal heart rate testing meconium passage, caesarean delivery for fetal distress, low Apgar scores.

Patients with hydramnios (>18cms) did not have substantially different pregnancy outcomes than the women without this complication. The investigators recommend that labour be induced in patients with oligoamnios (AFI <5cm) to reduce the increased risk of fetal death and morbidity.

Inter and Intra observer variability of AFI

In another study by Moore and cayle[33], where they measured AFI cross sectionally in 791 patients with uncomplicated, pregnancies from 16 to 44 weeks, they described polyhydramnios ie. 95th percentile as corresponding to AFI to 20 cm and near term the mean of AFI as 12 cm. Reproducibility is a desirable characteristic of an AFV estimation method. When intra observer and inter observer variations were assessed by Moore and Cayle, mean errors of 5 mm and 10 mm were noted respectively, equivalent to 3% and 7% of the AFI. The percentage error was 10% to 15% with AFI's < 10 cm.

Brunner et al, reported the coefficients of variation in AFI measurements to be 10.8% (within examiners) and 15.4% (between examiners). Rutherford et al, reported intra observer error of 4 cm and interobserver error of 2 cm.

To minimize these errors, the authors recommend that AFI be performed in triplicate and averaged when evaluating AFV in patients with suspected oligohydramnios.

Other factors influencing AFI

Transducer pressure, Ambient temperature, Diabetic glucose control, altitude, Status of material hydration, Gestational age influences the normal distribution of AFI, resulting in significant differences for term, pre-term and post-term pregnancy.

Amniotic Fluid Index vs. Maximum Vertical Pocket:

The relative efficiency of AFI and MVP has been assessed in multiple studies. Moore compared amniotic fluid index and maximum vertical pocket in 1168 patients, noted a correlation co-efficient of 0.51. He noted that sensitivity of maximum vertical pocket technique in identifying oligohydramnios was poor, 58% of cases with oligohydrmnios by amniotic fluid index had “normal values” according to single pocket technique. Chauhan SP et al conducted a randomized clinical trial to determine the superior technique of either of the amniotic fluid index (AFI) versus the Single deepest pocket technique in predicting an adverse preagnancy outcome among high risk patients, and concluded that during antepartum fetal surveillance, use of single deepest pocket compared with AFI is associated with significantly lower rate of suspected oligohydramnios.

Hence, amniotic fluid index technique of amniotic fluid volume assessment was found superior by various other investigators compared to maximum vertical pocket method.

Correlation of sonographic estimates with actual AFV:

Strong et al[34] correlated an intrauterine infusion of 250 ml of saline with a rise in AFV of 4 cm. Chauhan[35] recorded a mean increase in AFV of 5.8 ± 2.6 cm after 250 ml saline were infused into patients with ruptured membranes.

These infusion studies indicate that a near-term mean AFI of 14 cm is equivalent to 700 ml, a value notably similar to the 717 ml reported by Brace and Wolf[36].

Didly and associates[37] performed a study using PAH (Para amino hippurate) indicator- dilution method in 50 women in 3rd trimester of pregnancy that was having amniocentesis. The AFI was highly predictive of actual volume, with a correlation co efficient of 0.84 and a mean error of 7%.

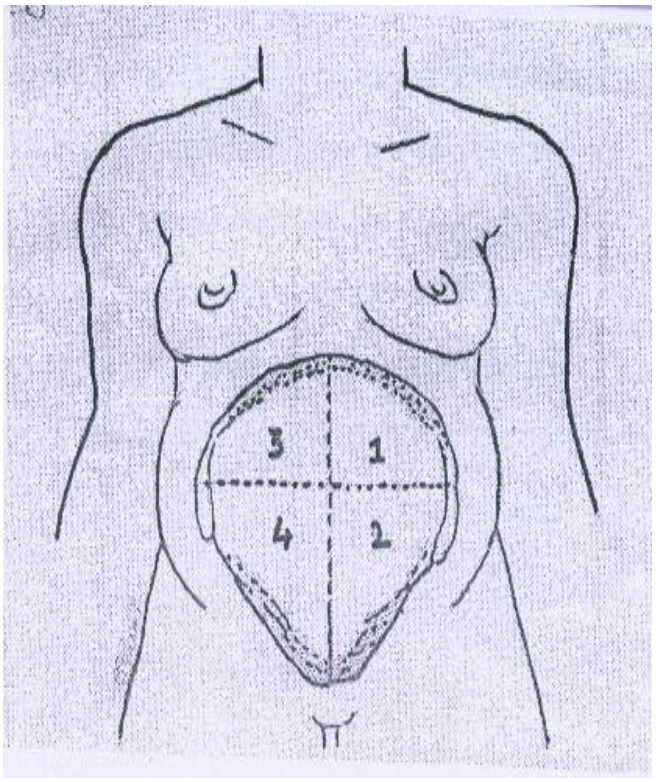
In summary, these studies found that the AFI is a reproducible and proportional index of actual AFV. It is more reliable in identifying extremes of AFV than the MVP.

Procedure for measuring AFI

- Position of the patient: Supine as for ultrasound examination. Slight left, tilt and bent knees will improve the patient comfort.

- A linear/curvilinear/sector transducer can be used (Convex 3.5 MHz). This definitive study was performed using 3.5MHz linear transducer. Although curvilinear probe probably provides similar results, the sector probe comparability is not established.
- Some authors recommend using umbilicus as the dividing point. But it is inappropriate if <28 week gestation. Divide the uterus into four quadrants using the maternal sagittal midline vertically and an arbitrary transverse line approximately halfway between the symphysis pubis and upper edge of the uterine fundus.
- Transducer must be kept parallel to the maternal sagittal plane and perpendicular to the maternal coronal plane. Tilting the transducer medially may result in inadvertent measurement of adjacent quadrant.
- The vertical depths of unobstructed and clear pocket of AF is visualized. The ultrasound calipers are manipulated to measure this pocket in a strictly vertical direction. Measuring pockets with umbilical cord may over estimate the AFV.
- The process is repeated in each of the four quadrant and the pocket measurements summed up to obtain AFI.
- If AFI<8cm, perform the four quadrant evaluation 3 times and average the values. Performing triplicate measurements, in oligoamnios reduces intraobserver error.

Figure – 11 : Division of the uterus into four quadrants to measure AFI



Frequency of AF evaluation

AFI measuring >8 cm and gestational weeks<41 weeks were associated with a less than 0.5% chance of developing oligomnios within next 4 days (Lagrew et al)[38]. Heing et al found similar results, with a 1.7% chance in the same gestational age group with an AFI>8 cm.

In case of borderline AFI (5 to 8 cm), Lagrew et al and Heing et al, reported oligohydramnios risks of 5 and 18% respectively.

At > 41 weeks of gestation, Marks and Divon[39] reported a potential decline in the AFI of 25% per week. Based on the above, fluid evaluation can be done weekly in pregnancies <41 weeks of gestation. If the AFI <8cm, twice-weekly evaluation is recommended.

MATERIALS AND METHODS

Source of data:

Pregnant women with high risk factors attending the antenatal out patient clinic or admitted to the wards in the Obstetrics and Gynaecology department of Shri.B.M. Patil Medical College Hospital & Research Centre from October 2007 to May 2009 , for their high risk factors were recruited into the study.

Selection criteria:

Inclusion Criteria

- Gestational age of 30 weeks or more
- Pre – eclampsia
- Anaemia
- Pregnancies beyond 40wks
- Oligohydramnios and polyhydramnios
- History of previous still births
- Clinically suspected IUGR
- Heart diseases complicating pregnancy
- Diabetes mellitus / Gestational diabetes
- Decreased fetal movements

Exclusion criteria

- Fetuses with congenital anamolies
- Multi-fetal pregnancies

Method of collection of data:

After taking written and informed consent and fulfilling the inclusion criteria, patients were included into the study.

Methods of study:

A detailed history of the pregnant women included in the study was taken and thorough clinical examination including recording of vital parameters, Systemic and obstetric examination was carried out at booking or admission All preliminary investigations including ultrasound were done. The risk factor for which the patient was included in the study was noted.

The patients were evaluated with the modified biophysical profile consisting of NST recording for 20mins, followed by amniotic fluid index measurement using four quadrant technique. The test was initiated at 30 wks of gestation or at the gestational age at which risk factors was identified.

The test was repeated weekly or bi-weekly depending on the findings of the previous tests and the risk factors.

Test results were documented as follows:

The NST was performed with cardiotocogram (FM model – Viridia 50A, Hawlett Packard) in Semi-Fowlers position. Recording of FHR, fetal movements, uterine contractions was done. The trace was considered as reactive, if more than 2 fetal movements with acceleration of more than or equal to 15 beats/minute lasting for more than or equal to 15 seconds, with good beat-to-beat variability and no decelerations. If the reactive pattern was not recorded within 20 minutes period, the fetus was stimulated with VAST (fetal acoustic stimulator), or administration of a

glucose containing beverage and the test continued for another 20 minutes period. If there is no reactivity in this extended period, the trace was deemed non-reactive.

Real-time ultrasound scanning was performed using a 3.5 MHz sector probe(Logic α200) and general survey of fetus was done and presentation noted. The volume of amniotic fluid was measured according to the four quadrant technique described by Phelan et al. With the patient in supine position, uterus was divided into four equal quadrants by two imaginary lines. The vertical line corresponding to linea alba and a transverse line equidistant from pubic symphysis to the top of the fundus. The transducer was held vertically along the maternal longitudinal axis. An AFI was obtained by summing up the depths of largest vertical pockets, which is cord free in all the four quadrants. An AFI of >5 was considered normal and less than or equal to five or >18 was considered as abnormal. Patient's management was decided on gestational age, other risk factors and MBPP results. The last observation of MBPP before 1week of delivery was compared with outcome of pregnancy.

End points to assess outcome of pregnancy

- Thick meconium staining of liquor
- 5 minute Apgar score < 7 was considered as abnormal.
- Admission to NICU
- Perinatal morbidity
- Perinatal mortality

Interpretation of MBPP and action

- If both tests were normal – weekly fetal surveillance with MBPP.
- If both tests were abnormal – management depends on gestational age.

  If gestational age > 36 weeks – Delivery

  If gestational age < 36 weeks – Management is individualized.
- If NST is reactive, but AFI is decreased – evaluate for chronic fetal conditions particularly congenital abnormalities and perform MBPP twice weekly.
- If AFI is normal and NST is non-reactive, further testing with a full BPP is indicated.

Statistical analysis:

A descriptive statistics i.e. percentages and frequencies were calculated. Chi-square test was used to test the association between the variables. Binary logistic regression was applied to measure the risk associated with modified biophysical profile results. Z test (proportion) was applied to find the significant difference.

RESULTS AND OBSERVATIONS

The study group consisted of 70 patients having pregnancy with high risk factors attending the antenatal outpatient clinic or admitted to the wards in the Obstetrics and Gynaecology department of Shri.B.M. Patil Medical College Hospital & Research Centre from October 2007 to May 2009.

A detailed history was taken and thorough systemic and obstetric examination was done. The patients were evaluated with the modified biophysical profile consisting of NST recording for 20mins, followed by amniotic fluid index measurement using four quadrant technique. The test was initiated at 30 wks of gestation or at the gestational age at which risk factors was identified.

The test was repeated weekly or bi-weekly depending on the severity of the risk factor.

The results and observations recorded in the study are evaluated under the following parameters.

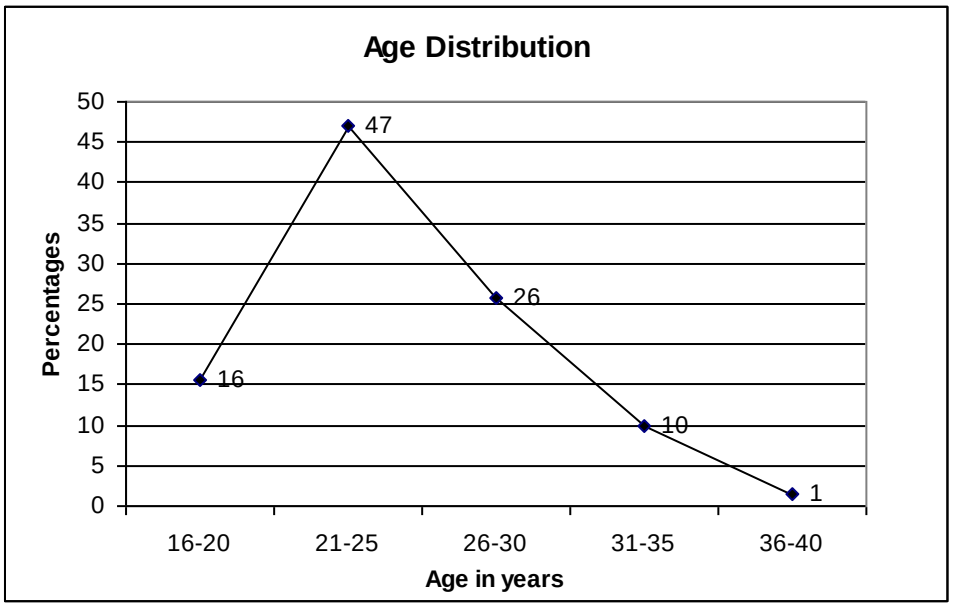
Age distribution:

It was observed that, out of 70 patients 11 of them (16%) belonged to the age group between 16-20 years. Majority of the cases (47%) belonged to an age group of 21-25years.18 patients (26%) belonged to age group of 26-30 years of age.10% of the patients were aged between 31-35 years and only one patient among the study group was aged >35 years

Table – 4 : Age Distribution

Age in years	Number	%
16-20	11	16
21-25	33	47
26-30	18	26
31-35	7	10
36-40	1	1
Total	70	100
Mean ± S.D.	25 ± 4	

Graph – 1 : Age Distribution



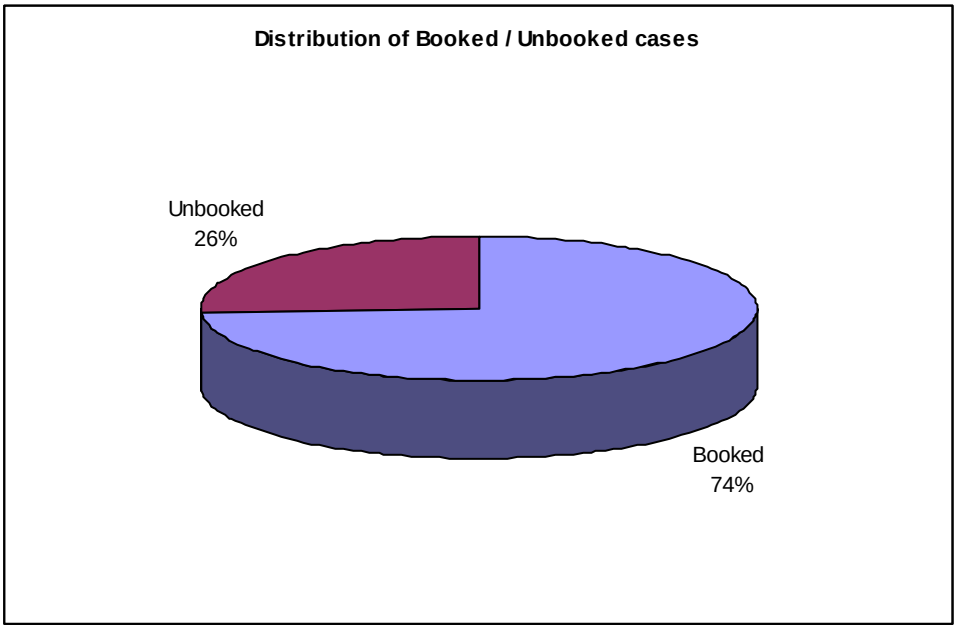
Distribution of booked and unbooked cases:

In the present study, majority of the cases (74%) were booked and 26% were unbooked.

Table – 5 : Distribution of Booked/ Unbooked cases

Cases	Number	%
Booked	52	74
Unbooked	18	26

Graph – 2 : Distribution of booked/ unbooked cases



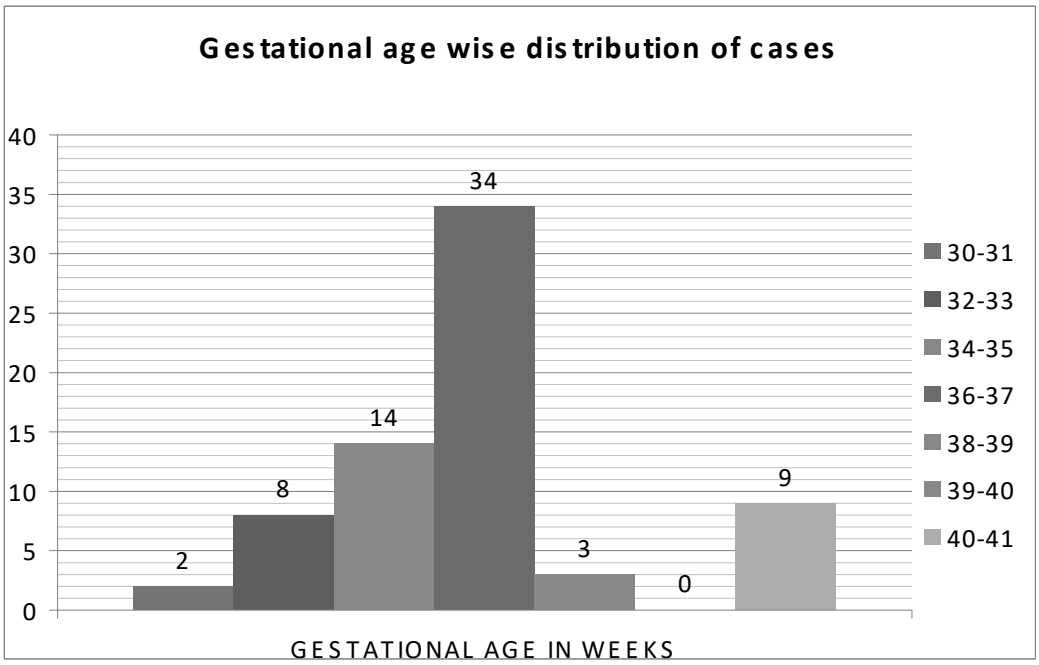
Gestational age wise distribution of cases:

When the patients were categorized according to the gestational age in weeks, it was found that majority of the patients belonged to the gestational age between 36-37 weeks (48.5%). 20% of the cases were between the gestational age of 34-35 weeks. 12.8% of the cases belonged to 40-41 weeks of gestational age and 11.4% of them to 32-33 weeks of gestation. Those whose gestational age was between 38-39 weeks constituted 7.5%of the patients and only 2.85% of the cases were between 30-31 weeks of gestation.

Table – 6 : Gestational age wise distribution of cases

Gestational age in weeks	Number	%
30-31	2	2.85%
32-33	8	11.4%
34-35	14	20%
36-37	34	48.5%
38-39	3	7.5%
39-40	0	-
40-41	9	12.8%
Total	70	

Graph -3 : Gestational age wise distribution of cases



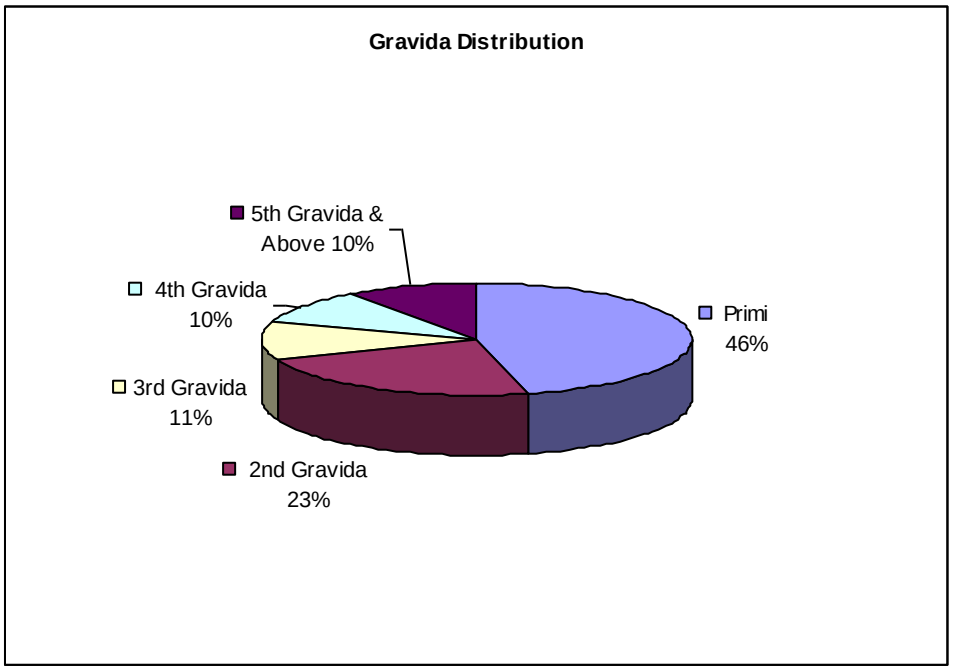
Gravida distribution:

Majority of the cases were primigravidae (46%), followed by 2nd gravidae who constituted 23% of the total number of cases. 11% 0f the cases were 3rd gravidae. 4th gravidae and patients who were gravida 5 and above constituted 10% each.

Table – 7 : Gravida Distribution

Gravida	Number	%
Primigravida	32	46
2nd Gravida	16	23
3rd Gravida	8	11
4th Gravida	7	10
5th Gravida & Above	7	10

Graph – 4 : Gravida Distribution



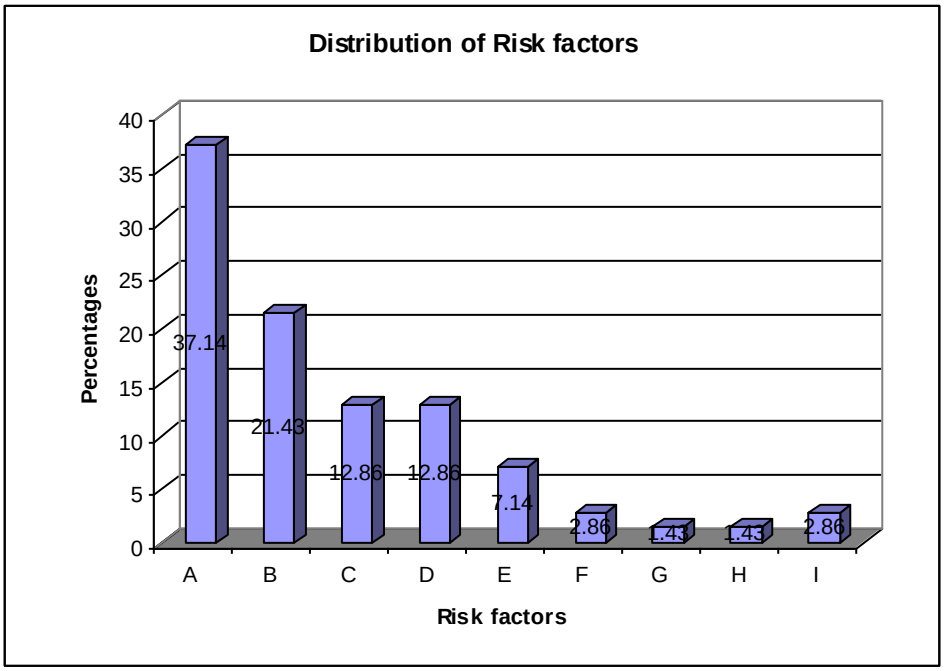
Distribution of risk factors:

The risk factors with which the patients presented were; hypertensive disorders in pregnancy which included mild and severe pre-eclampsia and gestational hypertension (37.14%), which formed the majority of cases. patients with bad obstetric history formed 21.43% of the cases and those with postdatism formed 12.86%. patients who presented with decreased fetal movements were 12.6%.those with oligohydramnios were 7.13% and polyhydramnios were 2.86%. Diabetes mellitus and hypothyroidism formed 1.43% of the cases each and patients with rheumatic heart disease constituted 2.86%.

Table – 8 : Distribution of Risk factors

Risk factors	Number	%
Hypertensive disorders in pregnancy	26	37.14
BOH	15	21.43
Post datism	9	12.86
↓Fetal movements	9	12.86
Oligoamnios	5	7.13
Polyhydramnios	2	2.86
Diabetes Mellitus	1	1.43
Hypothyroidism	1	1.43
RHD	2	2.86

Graph – 5 : Distribution of Risk factors



A-Hy. Disorders; **B-**BOH **; C-**Post date **D-**↓Fetal mov**. E-**Oligoamnios**; F-** Polyhy**. G-**Diabetic me**. H-**Hypothyriodism**;I-** RHD

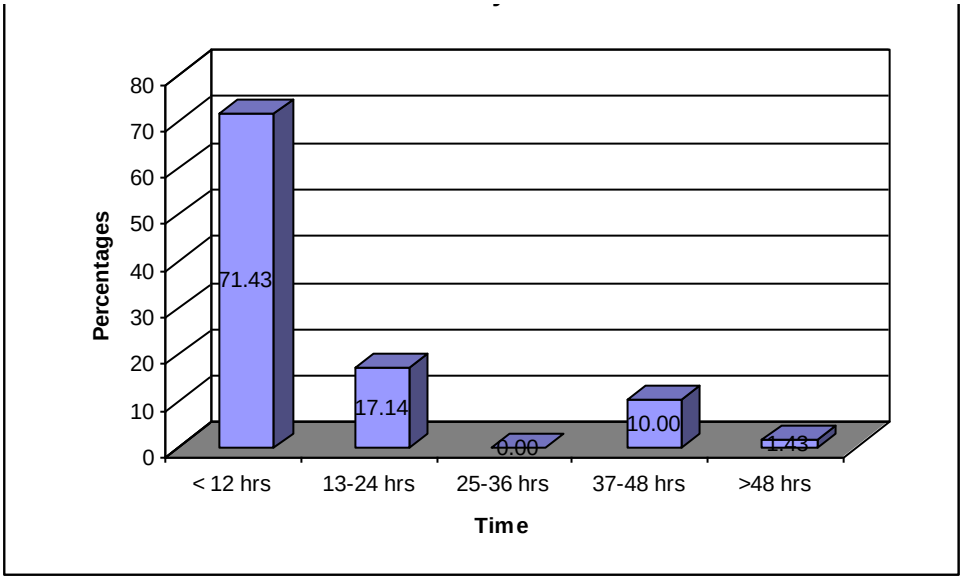
Last test and delivery interval:

Majority of the patients (71.43%) delivered within 12 hours of conducting the last test.17.14% of the cases delivered within 13 to 24 hours and those who delivered after 48 hours of test constituted only 1.43%.

Table – 9 : Last test and delivery interval

Last test & delivery interval	Number	%
< 12 hrs	50	71.43
13-24 hrs	12	17.14
25-36 hrs	0	0
37-48 hrs	7	10.00
>48 hrs	1	1.43

Graph – 6 : Last test and delivery interval



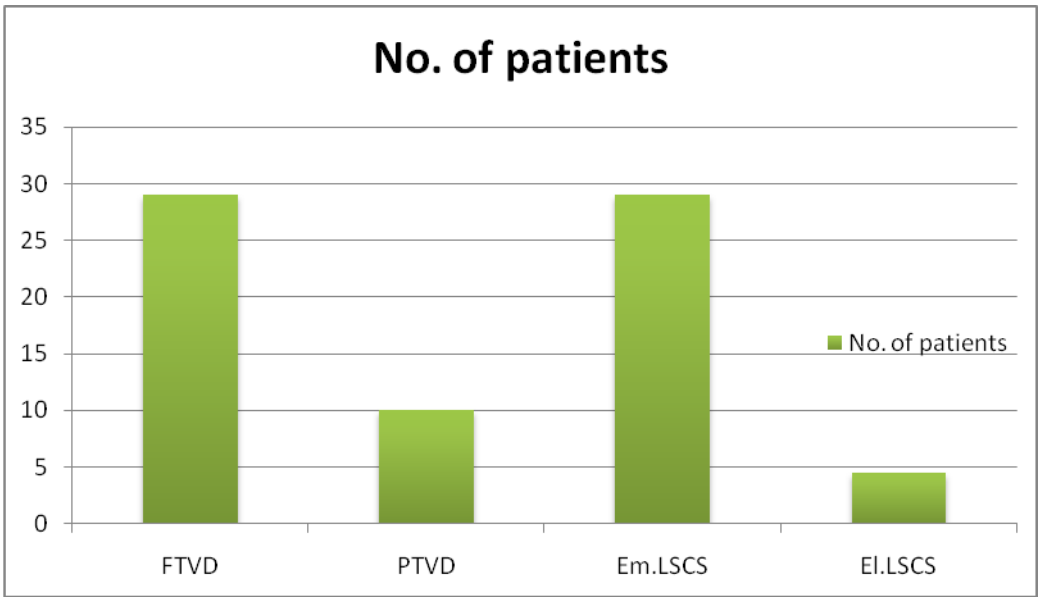
Mode of delivery:

Out of 70 patients 39 of them had vaginal delivery and 31 of them had caesarean section .out of the 39 patients who had vaginal delivery 29 of them (41.23%) had full term vaginal delivery and 10 of them (14.29%) had preterm vaginal delivery. Out of the 31 patients who had caesarean section 29 of them (41.42%) had emergency LSCS and 2 of them (2.86%) had elective LSCS.

Table – 10 : Mode of Delivery

Test Delivery interval	Number	%
FTVD	29	41.23
PTVD	10	14.29
LSCS-Emergency	29	41.42
LSCS-Elective	2	2.86

Graph – 7 : Mode of Delivery



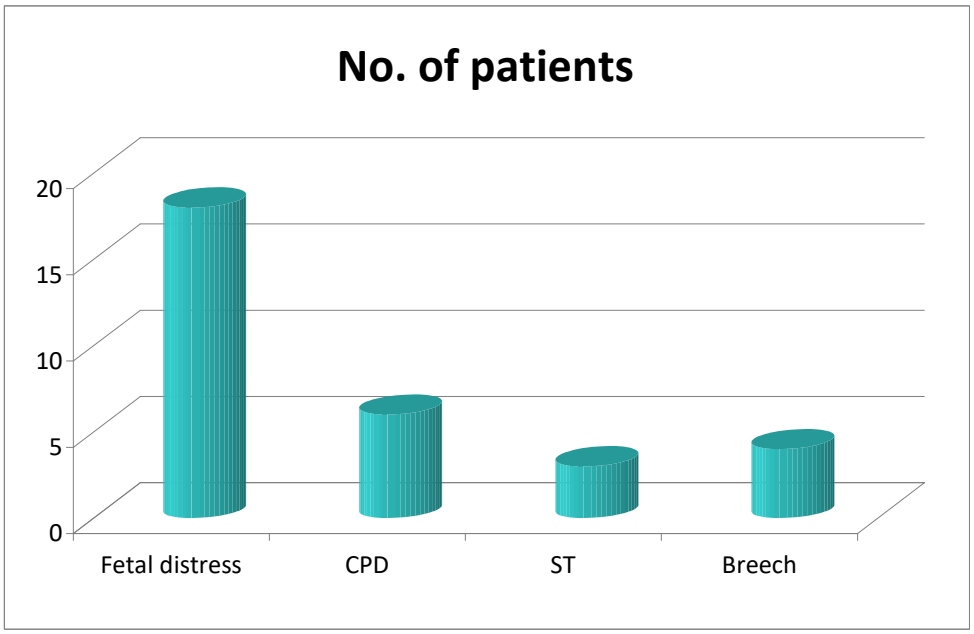
Indications for LSCS:

Out of the 31cases who underwent caesarean section majority of them (75%) had fetal distress as the indication for LSCS. Other indications were cephalo pelvic disproportion (19.35%), scar tenderness in 9.6%, and breech presentation in 12.9% of the cases.

Table – 11 Indicatons for LSCS

Indications	Number	%
Fetal distress	18	75
CPD	6	19.35
Scar Tenderness	3	9.6
Breech	4	12.9

Graph – 8 : Indicatons for LSCS



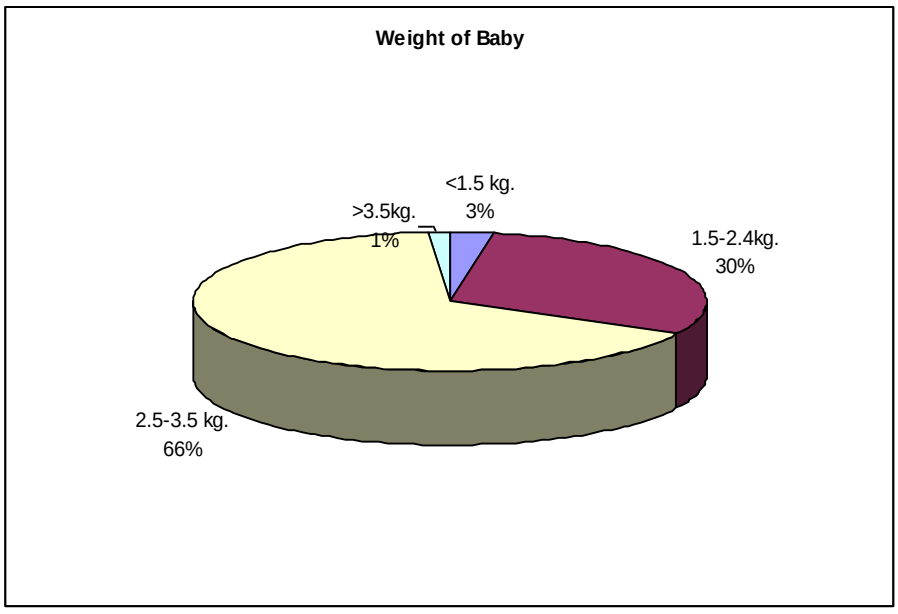
Distribution of weight of the baby:

Majority of the babies had birth weight between 2.5-3.5 kgs (65.71%) , followed by 30%of the babies whose birth weight was between 1.5-2.4 kgs . Those with <1.5 kg birth weight constituted 2.86% and those with >3.5 kgs constituted only 1.43%.

Table – 12 : Weight of baby

Birth weight in Kg.	Number	%
<1.5	2	2.86
1.5-2.4	21	30
2.5-3.5	46	65.71
>3.5	1	1.43

Graph – 9 : Weight of baby



Last test results:

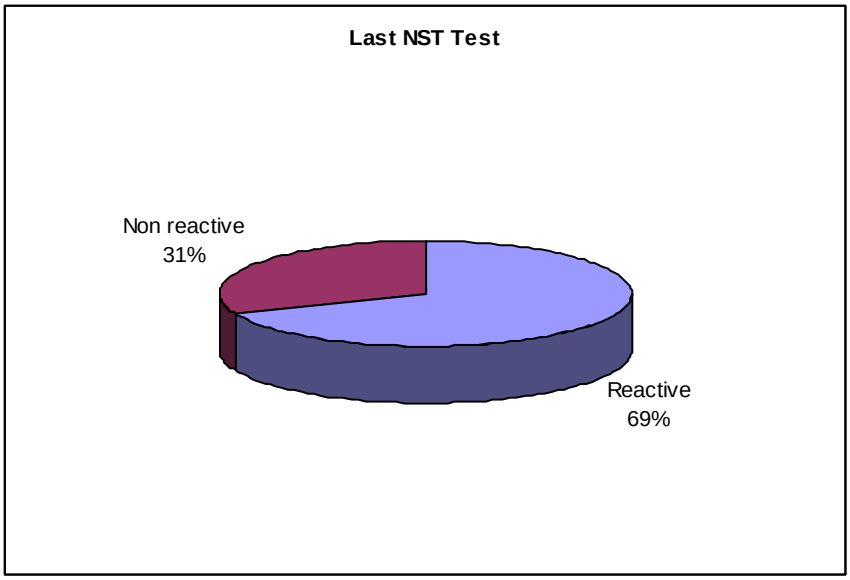
Last NST results:

The last NST test results were reactive in 48patients (68.57%) it was non reactive in 22(31.43%) patients.

Table – 13 : Last NST Test result

State	Number	%
Reactive	48	68.57
Non reactive	22	31.43

Graph – 10 (A) : Last NST Test result



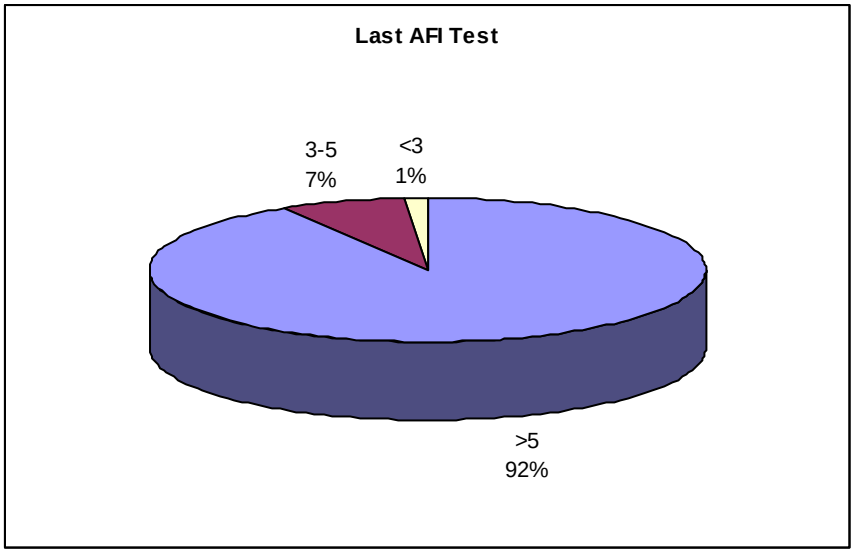
Last AFI result:

The amniotic fluid index was >5 in 64 patients (91.43%) and was in between 3&5 in 5 patients (7.14%) and was <3 in 1 patient (1.43%).

Table – 14 : Last AFI Test result

AFI Test	Number	%
>5	64	91.43
3-5	5	7.14
<3	1	1.43

Graph 10 (B) : Last AFI Test result



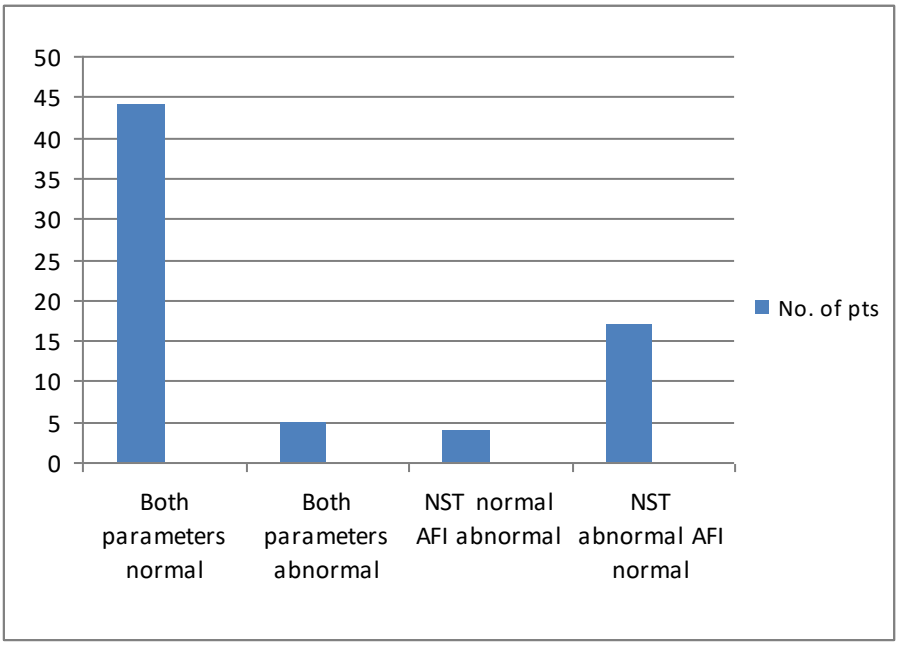
Last MBPP result:

Among the modified biophysical profiles done in 70 patients both parameters (NST and AFI) were normal in 44 patients (62.85%), both parameters were abnormal in 5 patients (7.14%) , NST was normal and AFI was abnormal in 4 patients (5.71%), AFI was normal and NST was abnormal in 17 patients(24.29%).

Table – 15 : MBPP Profile

	Number	%
Both parameters normal	44	62.85
Both parameters abnormal	5	7.14
NST normal AFI abnormal	4	5.71
NST abnormal AFI normal	17	24.29

Graph – 10 (C) : MBPP Profile



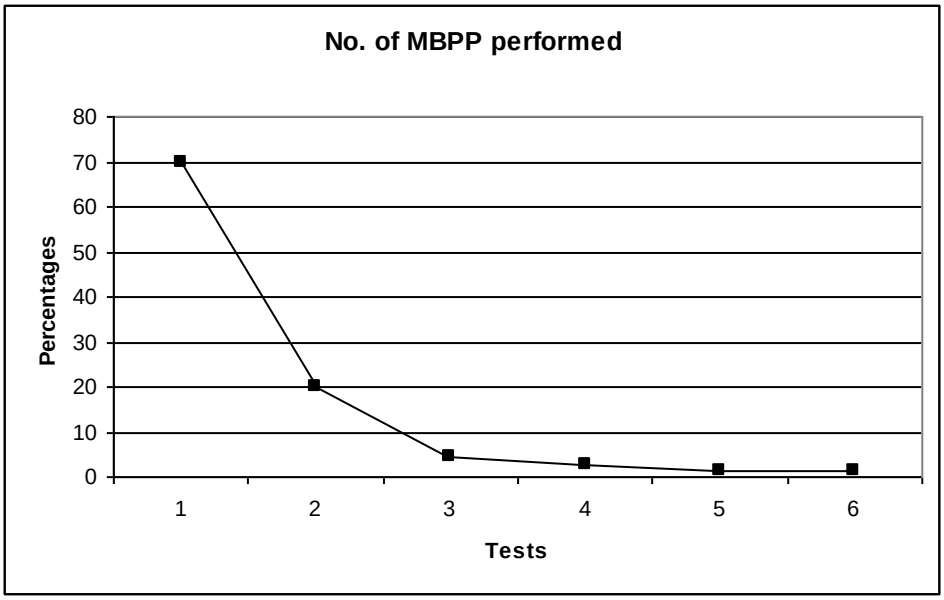
Number of MBPP'S performed:

70% of the patients in the study group had one MBPP test performed, 20% had two MBPP tests performed, 4.29% of them had three MBPP tests performed and 2.86% of them had four MBPP tests performed. Five and six MBPPS were performed in 1.43% of the patients each.

Table – 16 : Number of MBPP's performed

Number of tests performed	Number	%
1	49	70
2	14	20
3	3	4.29
4	2	2.86
5	1	1.43
6	1	1.43

Graph – 11 : Number of MBPP's performed



Last test results versus mode of delivery:

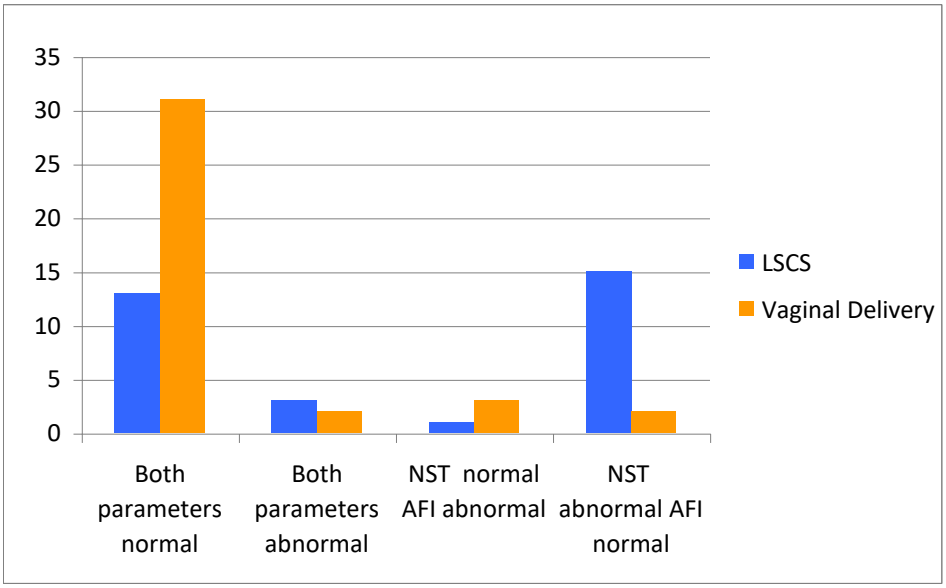
Among the modified biophysical profiles done in 70 patients when both parameters (NST and AFI) were normal (44 patients) 13(29.5%) patients underwent LSCS and 31(70.45%) patients had vaginal delivery , when both parameters were abnormal (5 patients) 3 (60%) patients underwent LSCS and 2 (40%) patients had vaginal delivery ,when NST was normal and only AFI was abnormal (4patients) 3 (75%) patients had vaginal delivery & 1(25%) of them underwent LSCS, when AFI was normal and NST was abnormal(17 patients) 15 patients (88.23%) underwent LSCS and 2(11.7%) patients had vaginal delivery .

This suggests that the rate of caesarean section is high when either both parameters are abnormal or when NST is abnormal.

Table – 17 : Last test results Vs Mode of delivery

Last MBPP results (No. of cases)	**LSCS**	**Vaginal Delivery**	**P- value**
Both parameters normal (44)	13	31	0.06 NS
Both parameters abnormal (5)	3	2	0.026 S
NST normal AFI abnormal(4)	1	3	0.999 NS
NST abnormal AFI normal(17)	15	2	0.000 S

Graph – 12 (A) : Last test results Vs Mode of delivery



Last NST result versus mode of delivery:

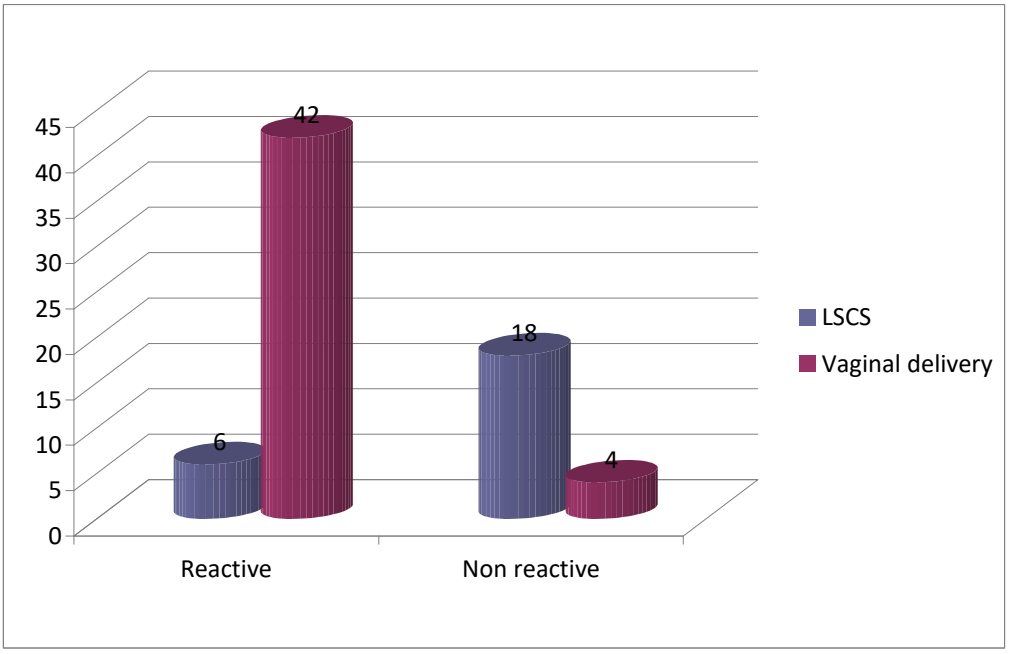
Of the 70 patients, when NST was considered individually with the mode of delivery, the observations were as follows; when NST was reactive 6 patients had LSCS and 42 patients had vaginal delivery. When NST was non-reactive 18 patients had LSCS and 4 patients had vaginal delivery.

This indicates that when NST is abnormal the rate of caesarean sections are high.

Table – 18 : NST Vs Mode of delivery

No. of cases	LSCS	Vaginal Delivery	P- value
Reactive	6	42	0.000 S
Non reactive	18	4	

Graph – 12 (B) : NST Vs Mode of delivery



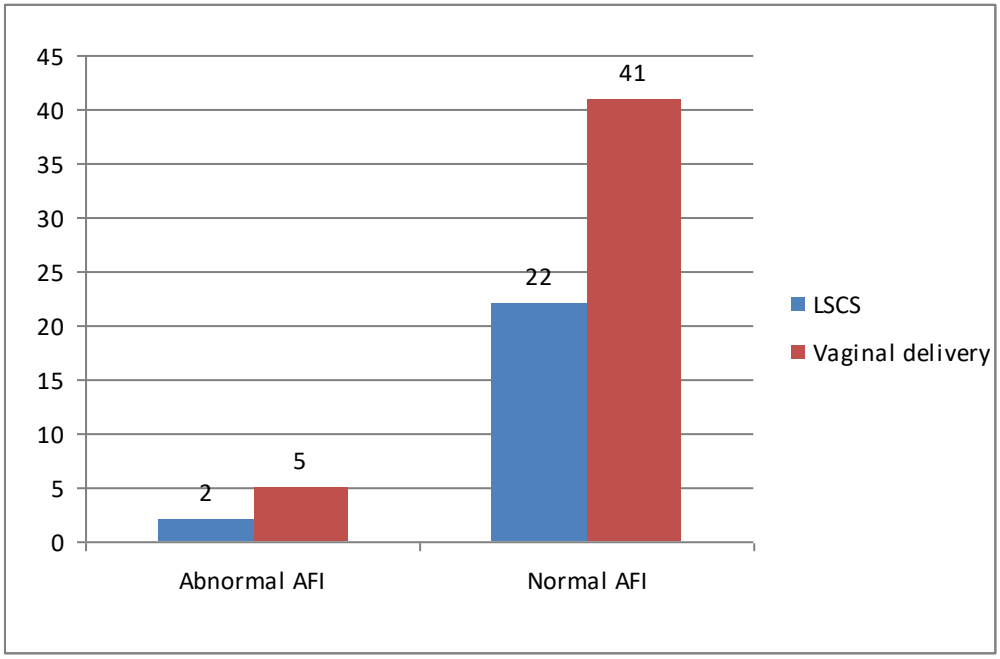
Last AFI result versus mode f delivery:

Of the 70 patients, when AFI was considered individually with the mode of delivery, the observations were as follows; when AFI was abnormal (<5 or >18), 2 patients had LSCS and 5 patients had vaginal delivery. When AFI was normal 22 patients had LSCS and 41 patients had vaginal delivery.

Table – 19 : AFI Vs Mode of delivery

No. of cases	LSCS	Vaginal Delivery	P- value
Abnormal AFI(<5 & >18)	2	5	0.949 NS
Normal AFI (>5 & <18)	22	41	

Graph – 12 (C) : AFI Vs Mode of delivery



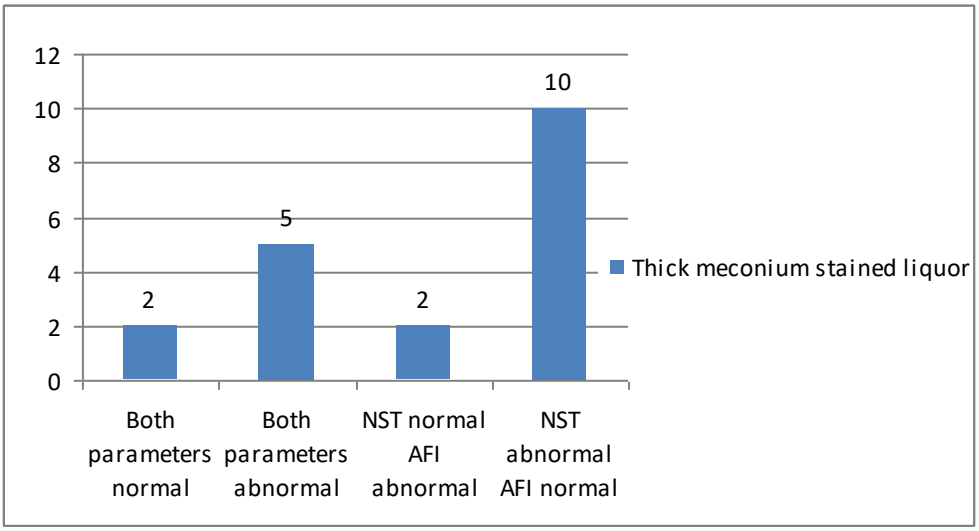
Last test results versus meconium staining of Liquor:

Out of 70 patients thick meconium staining of liquor was observed among 19 cases. When both parameters (NST and AFI) were normal out of 44 patients 2 patients had thick meconium stained liquor, when both parameters were abnormal all 5 out of 5 patients had thick meconium stained liquor ,when NST was normal and AFI was abnormal 2 patients of 4out had thick meconium stained liquor and when AFI was normal and NST was abnormal 10 patients had thick meconium stained liquor.

Table – 20 : Meconium staining of Liquor

Test results	Thick meconium stained liquor	p-value
Both parameters normal(44)	2	0.009 S
Both parameters abnormal(5)	5	HS
NST normal AFI abnormal(4)	2	0.4 NS
NST abnormal AFI normal(17)	10	0.001 S

Graph – 13 : Meconium staining of Liquor



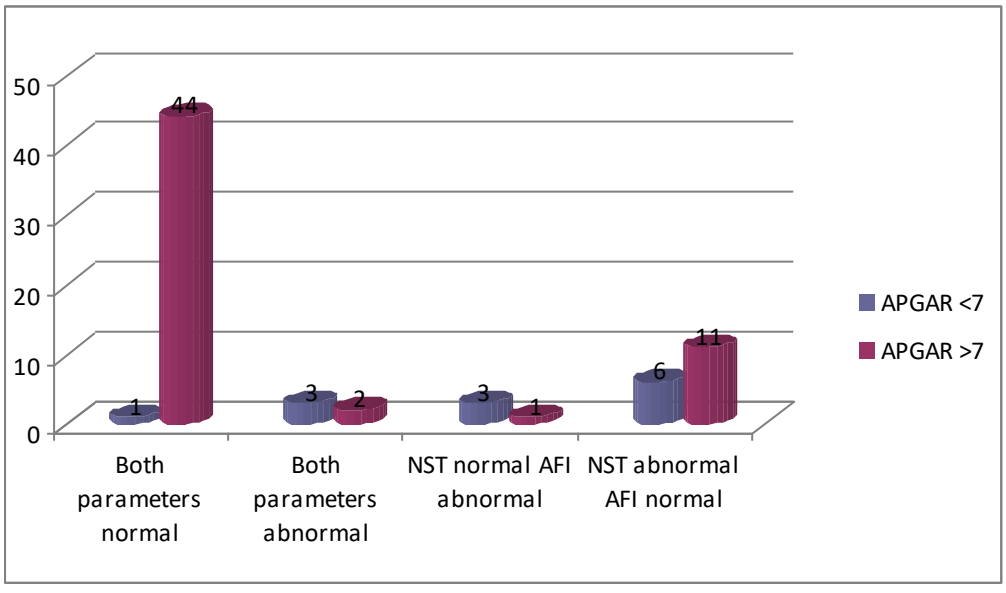
Last test result versus APGAR score at five minutes:

Among the 70 cases included in the study, APGAR score of <7was observed among 13 cases. when both parameters (NST and AFI) were normal 1 patient had APGAR score of <7, when both parameters were abnormal 3patients had APGAR score of <7 ,when NST was normal and AFI was abnormal 1 of the patients had APGAR score of <7 and when AFI was normal and NST was abnormal 6 patients had APGAR score of <7.

Table – 21 : Last test result Vs APGAR score

Test results	APGAR <7	APGAR >7	P- value
Both parameters normal (44)	1	43	0.009 S
Both parameters abnormal(5)	3	2	0.054 Near S
NST normal AFI abnormal(4)	3	1	0.739 NS
NST abnormal AFI normal(17)	6	11	0.001 S

Graph – 14 : Last test result Vs APGAR score



Perinatal morbidity associated with test results

When both parameters (NST and AFI) were normal perinatal morbidity was present in 13 cases (30%), when both parameters were abnormal 4(80%) of them had perinatal morbidity . when NST was normal and AFI was abnormal perinatal morbidity was present in 2(50%) cases and when AFI was normal and NST was abnormal 11(64.7%) of them had perinatal morbidity.

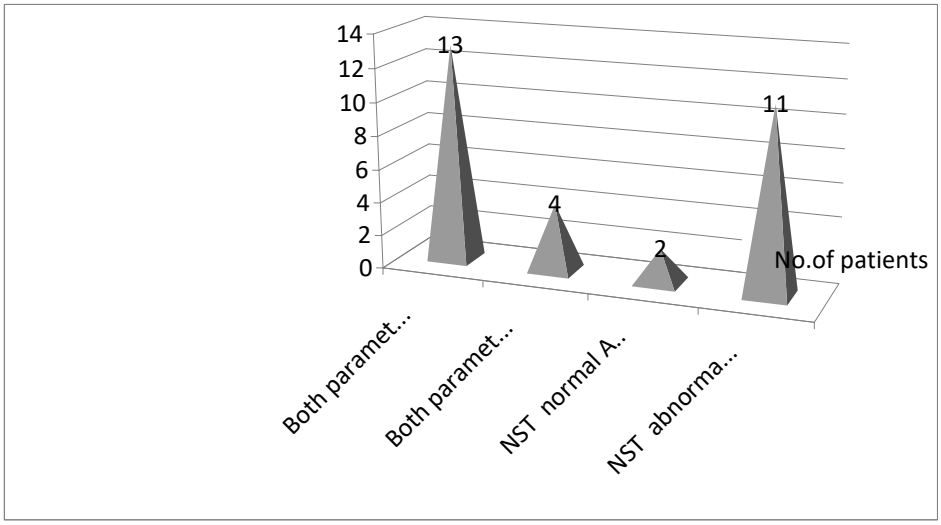
This suggests that whenever both parameters were abnormal or even one of the parameters were abnormal there was increased incidence of perinatal morbidity.

Table – 22 : Perinatal morbidity associated with test results

Test results	No. of patients	%	P-value
Both parameters normal(44)	13	30%	0.078 NS
Both parameters abnormal(5)	4	80%	0.053 Near S
NST normal AFI abnormal(4)	2	50%	0.1 NS
NST abnormal AFI normal(17)	11	64.7%	0.000 S

S- Significant; NS – Non Significant ; Near S – Near Significant

Graph – 16 : Perinatal morbidity associated with test results



Perinatal mortality associated with test results:

When both parameters (NST and AFI) were normal perinatal mortality was not present in any of the cases, when both parameters were abnormal 2(40%) of them had perinatal mortality . when NST was normal and AFI was abnormal perinatal motality was present in any of the cases and when AFI was normal and NST was abnormal 3(60%) of them had perinatal mortaliity.

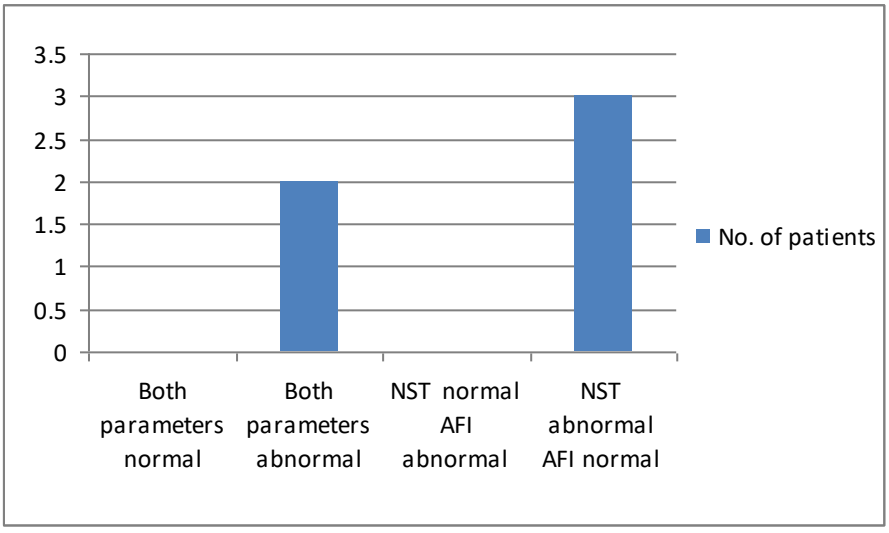
This suggests that abnormal MBPP and abnormal NST increased incidence of perinatal mortality.

Table – 23 : Perinatal mortality associated with test results

Test results	No. of patients	%	P-value
Both parameters normal	0	-	-
Both parameters abnormal	2	40%	0.003 S
NST normal AFI abnormal	0	-	-
NST abnormal AFI normal	3	60%	0.000 S

S- Significant; NS – Non Significant ; Near S – Near Significant

Graph – 17 : Perinatal mortality associated with test results



Details of mortality in the study group:

In our study there were 5 perinatal mortalities. Three cases had severe pre-eclampsia, one had mild pre- eclampsia and one had come with decreased fetal movements. MBPP was abnormal in 2 cases. The NST in all the 5 cases was non reactive and AFI was abnormal in two cases. One case was of 30 weeks of gestation, two cases were in between 34 to 35 weeks of gestation. One case was of 33 weeks of gestation and one belonged to 37 weeks of gestation. The birth weight of the babies were <1.5 in one case, between 1.5-2.4 kg in 3 cases and 3kg in one case.

Table – 24 : Details of mortality in the study group

Risk factor	**Last test results**		**Gestational age in weeks**	**Weight in kgs**
	NST	AFI		
Severe PE	NR	9cms	30 wks	1.1kg
Severe PE	NR	6cms	35 wks	2kg
Severe PE	NR	4cms	33 wks	1.5kg
Mild PE	NR	10cms	37 wks	3kg
Decreased fetal movements	NR	4cms	34 wks	1.8kg

The observations in the present study suggests that when the MBPP is abnormal there is increased incidence of perinatal morbidity as well as mortality. When considered individually, abnormal AFI was associated with increased incidence of perinatal morbidity and abnormal NST was associated with increased incidence of perinatal mortality.

DISCUSSION

One of the major goals of antepartum fetal surveillance is early identification of the compromised fetus and timely intervention. There are various methods of antepartum fetal surveillance. The best method is the one, which aims at identifying the fetus which is at risk, but still in an uncompromised state and requires immediate intervention. In the present study, the modified biophysical profile (MBPP), which is a combination of two parameters, is used as primary surveillance test for high risk patients. The two parameters are non stress test (NST), which is a short term marker of fetal status & amniotic fluid index (AFI), a long term marker of placental function.

The study group consisted of 70 pregnant patients with high risk factors in each of them. The major risk encountered in this study was hypertensive disorders in pregnancy.

Table – 25 : Comparison of incidence of risk factors with other study groups:

Risk factor	Nageotte etal (1994)	Eden et al (1988)[41]	Present study
PIH	11.8%	27.9%	37.14%

Majority of the patients were primigravidae (46%) and majority of them were in the age group of 21-25yrs (47%).

The surveillance of patients in study group was initiated at 30wks of gestation, as fetuses beyond this gestational age can be salvaged with good NICU facilities. But majority of the patients in our study had initiation of MBPP testing from 36 wks onwards. This was because of the late referral of patients or patients attending the

antenatal clinic, only after the development of complications. In the present study, there were 2 cases where testing was initiated at 30 wks of gestational age and 9 cases where testing was initiated after 41 wks of gestation.

There were 105 MBPP tests performed on 70 patients with an average test per patient being 1.5. The number of patients undergoing one test constituted 49%. The highest number of tests performed was 6 in one patient. The last test done showed that 64.29% of the MBPP test results as normal, 7.14 % as abnormal, NST was abnormal in 24.29% and AFI was abnormal (<5cms and >18cms) in 4.29% cases.

Of the 70 NST's in the last MBPP, 68.57% were reactive & 31.43% were non-reactive. The AFI values were >5 in 91.43% of the cases. Earlier works by Miller et al (1996) and Eden et al (1998) also showed similar results, evident from the following table.

Table – 26 : Comparison of last MBPP results with other study groups:

Test results	Miller et al	Eden et al	Present study
Reactive NST	90.8%	96.0%	68.57%
AFI >5	86.1%	88.4%	91.43%

The mode of delivery in the study group with respect to last MBPP result showed that when MBPP was normal with respect to both parameters (44), the incidence of LSCS and vaginal delivery among these were 18.8% and 44.28% respectively. When the MBPP was abnormal with respect to both parameters 60% of the cases had LSCS and 40%of them had vaginal delivery.

This shows that the mode of delivery in cases where MBPP was normal was vaginal in most of the cases and the incidence of LSCS in cases where MBPP was abnormal was increased.

The incidence for LSCS for fetal distress in various studies were as follows:-

Table – 27 : Comparison of incidence of LSCS for fetal distress with other study groups:

Studies	No. of patients (%)	P-value
Miller et al	15(8.8)	<0.0001 S
Eden et al	23(6.8)	<0.05 S
Nageotte et al	155(5.6)	<0.0001 S
Present study	18(25.7)	0.000 HS

In the study by Miller et al, caesarean section rate when test results were abnormal was high compared to those when MBPP was normal (36% v/s 13.2% ,p <0.0001). Similar results were seen in the study by Eden et al, who has 15.8% caesarean section rate when test results were abnormal, compared to 4.1% when the results were normal.

In our study, the incidence of caesarean section for fetal distress was very high (30.1%) compared to other studies. Booked cases were more and majority of the cases were referred as our hospital is a tertiary referral centre.

Thick meconium staining of liquor is compared with other studies in the following table:-

Table – 28 : Comparison of thick meconium staining of liquor with other study groups:

Studies	No. of patients(%)	P-value
Eden et al (337)	52 (15.4)	<0.05 S
S.K. Patil et al (650)[40]	71 (11.5)	<0.05 S
Present study (70)	19 (27.14%)	0.000 HS

When studied with respect to the last MBPP, showed that whenever the test results were abnormal, we had 100% (all 5 out of 5 cases) showing thick meconium. When the test results were abnormal with respect NST only 52.6% (10 out of 19) had thick meconium. When the test results were abnormal with respect only AFI 10.5% (2out of 19) had thick meconium.

Hence from the above results, it is seen that the incidence of perinatal morbidity with respect to meconium is increased when both MBPP parameters were abnormal, and more so when NST abnormal compared to AFI abnormal when individual parameters were considered.

Compaison of 5minute APGAR score of <7 with other study groups:-

Table – 29 : Comparison of 5 minute APGAR score of <7 with other study groups:

Studies	No. of patients(%)	p-value
Nageotte et al	13(0.8%)	Not significant
Eden et al	5(1.5%)	<0.001,significant
Present study	13(18.57%)	0.000 HS

An APGAR score of <7 was seen in 18.57% of the cases in our study group. When both the parameters were abnormal 60% of the cases had APGAR <7 whereas when NST was normal and AFI was abnormal 3(4.28%) the cases had APGAR <7. When AFI was normal and NST was abnormal 8.57% of the cases had APGAR <7 .

In the present study 22 babies (31.42%) were admitted to NICU . This is comparable to earlier study by Compitak K et al on 185 patients with high risk pregnancies, which had 33.3% of the babies admitted to NICU in his study.

In our study, there were 5 (7.14%) perinatal mortalities wherein 4 cases were those with pre-eclampsia, one in a patient who came with decreased fetal movements.

A study by S.K.Patil et al showed a perinatal mortality of 8 out of 650 patients (1.2%) and Eden et al had 5.94% of perinatal mortalities in their study.

From the above discussion, we can conclude that MBPP can be used as a primary antepartum fetal surveillance test to predict the perinatal outcome in high risk cases.

CONCLUSION

Modified biophysical profile (MBPP) is easier, less time consuming, cost effective and patient compliant test.

- When the Modified biophysical profile is normal, it gives reassurance that the fetal status is good with good perinatal outcome. At the same time, when MBPP is abnormal, it indicates that the fetus may be compromised.

- When the MBPP is abnormal there is increased incidence of perinatal morbidity as well as mortality. Confirmation with complete biophysical profile can be done when MBPP results are abnormal.

- When considered individually, abnormal AFI was associated with increased incidence of perinatal morbidity and abnormal NST was associated with increased incidence of perinatal morbidity as well as perinatal mortality.
- MBPP can be used as a primary antepartum fetal surveillance test to predict perinatal outcome and provide timely intervention in high risk pregnancies.

The number of patients included in this study was 70. To formulate a definitive protocol, further multicentric studies with larger samples should be conducted.

SUMMARY

This study consisted of 70 patients having pregnancy with high risk factors attending the antenatal outpatient clinic or admitted to the wards in the obstetrics and gynaecology department of Shri.B.M. Patil Medical College Hospital & Research Centre from October 2007 to May 2009.

The patients were evaluated with the modified biophysical profile consisting of NST recording for 20mins, followed by amniotic fluid index measurement using four quadrant technique. The test was initiated at 30 wks of gestation or at the gestational age at which risk factors was identified.

The test was repeated weekly or bi-weekly depending on the risk factor and the test results.

The following results were noted :

- When the MBPP is normal Modified biophysical profile gives reassurance that the foetal status is good with good perinatal outcome.
- When the MBPP is abnormal there is increased incidence of perinatal morbidity as well as mortality.
- When considered individually, abnormal AFI was associated with increased incidence of perinatal morbidity and abnormal NST was associated with increased incidence of perinatal morbidity as well as perinatal mortality.

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CASE PROFORMA

Modified Bio-physical profile in antepartum fetal surveillance of high risk pregnancies.

Sl No. IP No. DOA: DOD:

Name: Age: Socio-economic Status:

Address: Occupation:

Registered / Unregistered

Presenting complaints:

Obstetric History :

Menstrual History:

Past History

Family History:

Personal History:

General Physical Examination:

Pulse: BP: Ht: Wt:

Pallor:

Icterus :

Edema:

Systemic Examination:

- Cardio vascular system:
- Respiratory System:
- Per abdominal Examination:

Obstetric Risk Factor:

Investigations:

- Hb%
- Urine examination → Albumin, Sugar, Microscopy
- Blood grouping & Rh typing
- Ultrasound examination:
    - Date
    - BPD (Biparietal diameter)
    - FL (Femoral length)
    - HC (Head circumference)
    - AC (Abdominal circumference)
    - AFI (Amniotic fluid index)
    - Presentation
    - EFW (Estimated fetal weight)

- Gestational age

- Non Stress test:
  - Date
  - Baseline fetal heart rate:
  - Beat to beat variability
  - Fetal movements
  - Acceleration
  - Deceleration
  - Impression

Management of Risk factors:

Mode of delivery:

Liquor:

Umbilical Cord/Placenta

Outcome:

Baby	Mother
- Weight	- Puerperium
- Apgar	

Conclusion:

MBPP – Normal

- Abnormal

Outcome: Normal

B.L.D.E.A'S

SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTER, BIJAPUR- 586103

SAMPLE INFORMED CONSENT FORM :

TITLE OF THE PROJECT : **MODIFIED BIOPHYSICAL PROFILE IN ANTEPARTUM FETAL SURVEILLANCE OF HIGH RISK PREGNANCY**

PRINCIPAL INVESTIGATOR : DR. K.P.Sowmya

GUIDE : Dr. S.R.Mudanur,
Professor,
Department of Obstetrics and Gynaecology

PURPOSE OF RESEARCH:

I have been informed that this is a study to evaluate the effectiveness of Modified biophysical profile as a primary antepartum fetal surveillance test in predicting perinatal outcome. I have also been given a free choice to participate in this study.

PROCEDURE:

I am aware that in addition to routine care received I will be asked series of questions by the investigator. I have been asked to undergo the necessary investigations and treatment, which will help the investigator in this study.

RISK AND DISCOMFORTS:

I understand that this procedure is not expected to aggravate any side effects or cause detrimental effect to me or my child.

BENEFITS:

I understand that my participation in this study will help to evaluate the effectiveness of Modified biophysical profile as a primary antepartum fetal surveillance test in predicting perinatal outcome.

CONFIDENTIALITY:

I understand that the medical information produced by this study will become a part of Hospital records and will be subject to the confidentiality and privacy regulation. Information of a sensitive personal nature will not be a part of the medical records, but will be stored in the investigator's research file and identified only by a code number. The code-key connecting name to numbers will be kept in a separate location.

If the data are used for publication in the medical literature or for teaching purpose, no name will be used and other identifiers such as photographs and audio or videotapes will be used only with my special written permission. I understand that I may see the photographs and videotapes and hear the audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at anytime. Dr. K.P.Sowmya is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of the study, which might influence my continued participation.

If during the study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me. A copy of this consent form will be given to me to keep for careful reading.

REFUSAL FOR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and that I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital. I also understand that Dr.K.P.Sowmya may terminate my participation in the study after she has explained the reasons for doing so and has helped arrange for my continued care by my own physician or physical therapist, if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me resulting directly from my participation in this study, if such injury were reported promptly, the appropriate treatment would be available to me, but no further compensation would be provided. I understand that by my agreement to participate in this study I am not waiving any of my legal rights.

I have explained to _____the purpose of the research, the procedures required and the possible risks and benefits to the best of my ability in patient's own language.

_____ _____

Dr.K.P.Sowmya Date

(Investigator)

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr.K.P.Sowmya has explained to me the purpose of research, the study procedures that I will undergo, and the possible risks and discomforts as well as benefits that I may experience in my own language. I have read and I understand this consent form. Therefore, I agree to give consent to participate as a subject in this research project.

_____	_____
Participant / Guardian	Date
_____	_____
Witness to signature	Date

KEY TO MASTER CHART

↓FM	-	Decreased Fetal Movement
AFI	-	Amniotic Fluid Index
BOH	-	Bad Obstetric History
CPD	-	Cephalopelvic Disproportion
DM	-	Diabetes Mellitus
Em.LSCS	-	Emergency Lower Segment Caesarean Section
El.LSCS	-	Elective Lower Segment Caesarean Section
Fet dist	-	Fetal distress
FTND	-	Full-term Normal Delivery
FTVD	-	Full-term Vaginal Delivery
G.Htn	-	Gestational hypertension
Hypothy	-	Hypothyroidism
MBPP	-	Modified Biophysical Profile
Mild PE	-	Mild pre-eclampsia
NR	-	Non-reactive NST
NST	-	Non-stress Test
Oligo	-	Oligohydramnios
Poly	-	Polyhydramnios
RHD	-	Rheumatic heart disease
S.PE	-	Severe pre- eclampsia
ST	-	Scar tenderness.

Sl. No	I.P. No.	Name	Age	Booked	Obstetric score					Risk factor	Gest Age at 1st MBPP	Total No.of MBPP	Last MBPP		Last Test Delivery Interval	Mode of Delivery	Indication	Liquor		Baby		APGAR 5'	PN Morb	PN Mort
					G	P	L	A	D				NST	AFI				Qty	Mec	Sex	Wt			
1	1E+05	savita	25	Y	1	0	0	0	0	↓FM	33wks	3	R	11cms	48hrs	FTVD		N	N	M	3	9	N	N
2	17246	Mallamma	29	Y	3	2	1	0	1	G.Htn	36wks	2	R	16cms	72hrs	FTVD		N	N	M	2.8	9	N	N
3	2E+05	Saira	34	Y	6	2	1	3	1	BOH	30wks	4	NR	6cms	2hrs	Em.LSCS	Fet.Dist	S	Y	F	1.6	8	Y	N
4	2683	Gourabai	34	Y	1	0	0	0	0	G.Htn	36wks	1	R	17cms	12hrs	FTVD		N	N	M	2.8	9	N	N
5	10541	Shanta	22	Y	0	0	0	0	0	oligo	33wks	2	NR	2cms	5hrs	PTVD		S	Y	M	1.7	8	Y	N
6	12803	Sulochana	35	Y	3	2	2	0	0	Oligo	32wks	1	R	4cms	24hrs	PTVD		S	Y	M	1.5	8	Y	N
7	12832	Kamala	25	Y	1	0	0	0	0	S.PE	33WKS	1	R	5cms	8hrs	PTVD		s	Y	M	1.6	8	Y	N
8	542	Gouri	24	Y	1	0	0	0	0	Oligo	35wks	1	NR	6cms	24hrs	El.LSCS	Breech	S	Y	F	2.7	9	N	N
9	2731	Rajashree	23	Y	2	1	1	0	0	↓FM	36wks	1	NR	8cms	2hrs	Em.LSCS	Fet.Dist	N	Y	M	2.2	8	Y	N
10	3646	Danamma	26	Y	3	2	2	0	0	Poly	34wks	2	R	19cms	5hrs	PTVD		E	N	F	2.3	9	N	N
11	4525	Suvarna	26	Y	2	1	1	0	0	Mild.PE	36wks	1	R	8cms	12hrs	FTVD		N	Y	M	1.7	9	Y	N
12	5865	Sneha	24	Y	1	0	0	0	0	Oligo	35wks	3	NR	4cms	3hrs	Em.LSCS	Fet.Dist	S	Y	M	1.7	5	Y	N
13	6911	Mangala	24	N	1	0	0	0	0	↓FM	36wks	1	R	11cms	2Days	Em.LSCS	Fet.Dist	N	Y	M	2.5	9	Y	N
14	7420	Neeta	22	Y	1	0	0	0	0	Mild.PE	37wks	1	NR	10cms	2hrs	Em.LSCS	Fet.Dist	N	Y	M	3.2	3		Y
15	9780	Saraswati	24	N	4	2	2	1	0	↓FM	34wks	1	NR	4cms	3hrs	Em.LSCS	Fet.Dist	S	Y	M	1.8			Y
16	12624	Neelamma	26	N	4	2	0	1	2	BOH	34wks	2	R	10cms	4dys	FTVD		N	N	M	2.7	9	N	N
17	14295	Nagamma	30	Y	5	4	2	0	2	BOH	36wks	2	R	12cms	24hrs	PTVD		N	N	M	2.5	9	N	N
18	13282	Sidawwa	26	Y	5	4	3	0	1	↓FM	37wks	1	R	13cms	48hrs	FTVD		N	N	M	2.7	9	N	N
19	14286	Susheela	26	N	1	0	0	0	0	↓FM	37wks	1	R	13cms	12hrs	Em.LSCS	ST	N	Y	F	2.7	9	N	N
20	13916	Mallamma	22	Y	3	2	0	0	2	BOH	32ks	5	NR	6cms	2hrs	Em.LSCS	Fet.Dist	S	Y	M	1.5	7	Y	N
21	14609	Gousiya	32	Y	2	1	1	0	0	S.PE	37wks	1	R	8cms	7hrs	FTVD		S	Y	M	2.4	8	N	N
22	1509	Namrata	22	Y	1	0	0	0	0	G.Htn	36wks	2	R	12cms	2days	FTVD		N	N	M	3.2	9	N	N
23	10692	vijayalaxmi	26	Y	2	1	1	0	0	Mild.PE	36wks	1	NR	4cms	2hrs	Em.LSCS	Fet.Dist	S	Y	M	1.9	8	Y	N
24	2E+05	Sunanda	22	Y	1	0	0	0	0	G.Htn	36wks	2	R	12cms	24hrs	Em.LSCS	Breech	N	N	F	2.5	9	N	N
25	15032	Nirmala	23	Y	2	1	1	0	0	poly	37wks	1	R	18cms	2Days	FTVD		E	N	F	2.7	9	N	N
26	17092	Nasreen	28	N	3	2	2	0	0	G.Htn	38wks	1	R	10cms	6hrs	FTVD		N	N	M	2.9	9	N	N
27	16236	Surayya	29	Y	1	0	0	0	0	S.PE	37wks	1	R	9cms	5hrs	Em.LSCS	CPD	S	Y	M	2.6	8	Y	N
28	16281	Smita	24	Y	2	0	0	1	0	G.Htn	37wks	1	R	12cms	24hrs	FTVD		N	N	F	2.6	9	N	N
29	16336	Geeta	32	Y	5	2	1	2	1	BOH	37wks	2	R	14cms	6hrs	Em.LSCS	CPD	N	N	F	2.4	9	N	N
30	16770	shilpa	26	Y	2	0	0	1	0	Mild.PE	37wks	1	R	11cms	12hrs	FTVD		N	N	F	3.2	9	N	N
31	16778	Mallawwa	20	Y	1	0	0	0	0	post.dt	41wks	1	R	8cms	24hrs	Em.LSCS	Breech	S	Y	F	3.3	9	N	N
32	16812	Shobha	24	Y	1	0	0	0	0	post.dt	42wks	1	R	10cms	8hrs	FTVD		S	N	F	2.6	9	N	N
33	18246	Roopa	24	Y	1	0	0	0	0	Mild.PE	37wks	1	R	12cms	18hrs	Em.LSCS	CPD	N	N	M	2.9	9	N	N
34	17343	Farida	18	Y	1	0	0	0	0	Typel DM	32wks	6	R	16cms	14hrs	FTVD		E	N	F	3.7	9	N	N

35	392	Meenakshi	25	Y	2	1	1	0	0	RHD	36wks	1	NR	9cms	3hrs	Em.LSCS	Fet.Dist	S	Y	F	2	5	Y	N

36	2640	Shaila	32	Y	2	1	1	0	0	Mild.PE	35wks	1	R	13cms	6hrs	PTVD		N	N	F	2.5	9	N	N
37	2765	Usha	27	Y	1	0	0	0	0	Hypothy	32wks	3	R	14cms	10hrs	El.LSCS	CPD	N	N	F	2.7	9	N	N
38	3356	Suma	28	Y	3	1	0	1	1	BOH	36wks	1	R	8cms	8hrs	FTVD		S	Y	M	2.7	9	N	N
39	3395	Sunita	22	Y	1	0	0	0	0	↓FM	37Wks	1	R	12cms	12hrs	Em.LSCS	ST	N	N	F	2.8	9	N	N
40	3380	Anasuya	38	Y	6	3	2	2	1	BOH	38wks	1	NR	10cms	2hrs	Em.LSCS	Fet.Dist	N	Y	M	3.4	7	Y	N
41	3463	Amruta	21	Y	1	0	0	0	0	Oligo	35wks	1	R	6cms	12hrs	PTVD		S	Y	M	2.6	8	Y	N
42	3529	Vijayalaxmi	28	Y	4	3	1	0	2	BOH	35wks	1	R	15cms	6hrs	FTVD		N	N	F	2.8	9	N	N
43	3699	Suvarna	26	Y	1	0	0	0	0	S.PE	30wks	2	NR	9cms	10hrs	PTVD		S	N	F	1.1	6		Y
44	3750	Farida	20	Y	2	1	1	0	0	↓FM	35wks	1	R	15cms	2Days	PTVD		N	N	F	1.8	7	Y	N
45	3759	Savitri	24	N	4	0	0	3	0	BOH	37wks	1	R	14cms	4hrs	Em.LSCS	CPD	N	N	F	2.9	9	N	N
46	3789	Bharati	22	Y	2	1	1	0	0	G.Htn	36wks	1	R	10cms	8hrs	FTVD		N	N	F	3	9	N	N
47	4299	Chandrika	20	Y	1	0	0	0	0	S.PE	35wks	2	NR	6cms	2hrs	Em.LSCS	Fet.Dist	S	Y	F	2	5		Y
48	4303	vijayalaxmi	24	N	2	1	1	0	0	G.Htn	37wks	1	R	10cms	8hrs	FTVD		N	N	M	2.7	9	N	N
49	4518	Renuka	28	N	5	4	1	0	3	BOH	36wks	2	R	14cms	4hrs	Em.LSCS	ST	N	N	F	3.5	9	N	N
50	4628	Mayawwa	19	N	1	0	0	0	0	post.dt	41wks	1	NR	13cms	2hrs	Em.LSCS	Fet.Dist	N	Y	F	3	9	Y	N
51	4643	Meenakshi	25	Y	1	0	0	0	0	G.Htn	36wks	2	R	4cms	3hrs	Em.LSCS	Breech	N	N	F	2.7	5	Y	N
52	4681	Basamma	32	Y	4	2	1	1	1	BOH	36wks	1	R	10cms	8hrs	FTVD		N	N	F	2.9	9	N	N
53	4924	Shobha	25	Y	1	0	0	0	0	post.dt	41wks	1	R	8cms	12hrs	FTVD		S	Y	F	2.4	9	N	N
54	5083	Danamma	27	N	2	1	1	0	0	post.dt	41wks	1	R	10cms	2Days	FTVD		S	Y	F	3.3	9	N	N
55	7246	Savita	19	Y	1	0	0	0	0	G.Htn	36wks	1	NR	9cms	4hrs	Em.LSCS	Fet.Dist	N	N	F	2.8	7	Y	N
56	7592	Shantabai	22	N	4	2	1	1	1	S.PE	33wks	1	NR	4cms	5hrs	PTVD		S	Y	M	1.5	6	Y	Y
57	7594	Shobha	21	N	1	0	0	0	0	S.PE	36wks	1	R	8cms	8hrs	Em.LSCS	CPD	S	Y	F	3	9	N	N
58	8040	Danamma	21	N	1	0	0	0	0	post.dt	42wks	1	R	6cms	12hrs	FTVD		S	Y	F	2.9	8	Y	N
59	8124	Riyana	22	Y	1	0	0	0	0	S.PE	35wks	2	R	10cms	16hrs	PTVD		N	Y	F	2.4	9	N	N
60	366	Renuka	23	Y	1	0	0	0	0	RHD	35wks	2	NR	9cms	8hrs	FTVD		S	Y	F	3	5	Y	N
61	3089	Kavita	20	Y	4	1	0	2	1	BOH	35wks	1	R	15cms	6hrs	PTVD		N	N	F	1.5	9	N	N
62	589	Kamala	24	Y	1	0	0	0	0	↓FM	37wks	1	NR	14cms	2hrs	Em.LSCS	Fet.Dist	N	Y	M	2.8	7	Y	N
63	462	Shabana	25	Y	2	1	1	0	0	post.dt	41.2wks	1	R	10cms	8hrs	FTVD		S	Y	F	3.4	9	N	N
64	14287	Mohini	20	N	1	0	0	0	0	G.Htn	37wks	1	R	13cms	24hrs	FTVD		N	N	F	1.9	9	N	N
65	14063	Neela	20	N	3	1	0	1	1	BOH	37wks	1	NR	11cms	4hrs	Em.LSCS	Fet.Dist	N	Y	F	2.3	9	Y	N
66	13787	Saraswati	19	N	2	0	0	1	0	post.dt	41.2wks	1	NR	14cms	2hrs	Em.LSCS	Fet.Dist	N	Y	M	2.9	9	N	N
67	13879	Lakshmi	20	N	2	1	0	0	1	post.dt	41.4wks	1	NR	10cms	2hrs	Em.LSCS	Fet.Dist	N	Y	M	2.9	9	N	N
68	14789	Irawwa	25	Y	3	2	0	0	2	BOH	38wks	1	R	15cms	24hrs	FTVD		N	N	F	2.7	9	N	N
69	15673	savita	26	N	1	0	0	0	0	G.Htn	36wks	1	R	13cms	14hrs	FTVD		N	N	M	2.9	9	N	N
70	16543	Mahadevi	30	Y	6	3	1	2	2	BOH	34wks	4	NR	15cms	2hrs	Em.LSCS	Fet.Dist	N	Y	F	2.3	8	Y	N