"A RANDOMISED CONTROLLED TRIAL TO COMPARE THE EFFICACY OF RAPID BIOPHYSICAL PROFILE VS MODIFIED BIOPHYSICAL PROFILE FOR INTRAPARTUM FETAL WELL BEING"

By

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Under the guidance of

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LIST OF ABBREVIATIONS

AF – Amniotic fluid

AFV – Amniotic fluid volume

AFI – Amniotic fluid index

BPP - Biophysical profile

CTG – Cardiotocography

FD fetal distress

FHR - fetal heart rate

FGR – Foetal Growth Restriction

LSCS – Lower segment caesarean section

MVP maximum vertical pocket

MBPP – Modified biophysical profile

MVP - Maximum Vertical Pocket

NICU – Neonatal intensive care unit

rBPP – Rapid biophysical profile

SPFM – Sound provoked fetal movement

USG – Ultrasonography

VAST – Vibroacoustic stimulation test

ABSTRACT

BACKGROUND: The aim of this study was to compare the efficacy of Rapid biophysical profile(rBPP) with Modified biophysical profile (MBPP) for intrapartum fetal wellbeing and to predict adverse perinatal outcome.

METHODS: A prospective study was performed on 200 singleton pregnancies between 37-42 weeks of gestation dividing them into 100 each of low risk and high risk group category. Abnormal fetal test was given score <6 for rBPP and <4 for MBPP. The main outcome measured was spearman's correlation coefficient between both the tests and was measured in terms of number of caesarean section for fetal distress, low Apgar scores, NICU admissions for asphyxia and neonatal death.

RESULTS: The data showed a positive correlation between the two tests. Out of the individual variables AFI has 67% sensitivity and 97% specificity in detecting adverse fetal outcome in group I . The sensitivity, specificity, positive predictive value, negative predictive value in predicting adverse outcome by Rbpp and MBPP was found to be 83%,79%,56%,94% and 75%, 89%, 69%, 92% in group I and 92%, 91%, 58%, 99% and 83%,89%, 50% ,98% in group II respectively.

CONCLUSION: rBPP is a simple and rapid test and also does not require an experienced person to interpret the results. Hence can be used as an admission test in busy obstetric set up.

Key Words: modified biophysical profile, rapid biophysical profile, fetal surveillance, perinatal outcome.

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INTRODUCTION

Antepartum and intrapartum fetal monitoring involves the use of electronic fetal monitoring or ultrasound to assess fetal wellbeing as determined by fetal heart rate pattern. Goal of antepartum fetal surveillance is to decrease the incidence of perinatal morbidity and mortality.[1] The important principle in antepartum testing, regardless of the method is that a normal test result is reliable in indicating present fetal wellbeing and is an accurate predictor of a good outcome.[2,3] Antepartum fetal monitoring mainly involves fetal movement assessment, non-stress test, contraction stress test, fetal biophysical profile, modified biophysical profile, umbilical artery doppler velocimetry.[3,4] The aim of fetal monitoring is to detect early fetal response to intrauterine hypoxia so that timely intervention can prevent irreversible neurological damage and death.[5]

The Biophysical profile or Manning's score provides a detailed assessment of behavioral state of the fetus in utero.[6] Manning introduced this test in 1980. It is a well-established method of antepartum fetal surveillance in high risk pregnancy, but this conventional biophysical profile takes a longer time to perform.[7] To obviate this difficulty various modifications have been proposed without compromising the diagnostic efficiency. The two parameters out of five of the full biophysical profile i.e. amniotic fluid and Non Stress test (NST) accounts to Modified biophysical profile. It can reliably predict intrapartum fetal distress and neonatal acidemia.

Fetal vibroacoustic stimulation was noted in 1947 by Beranar and Sontany who observed that fetal heart rate accelerated after acoustic stimulation and in the year 1981, Sadonsky correlated fetal movement with fetal wellbeing.

Observation of fetal startle response to vibroacoustic stimulation is found to be associated with fetal biophysical profile of 8 and above.[8] Vibroacoustic stimulation has been reported to wake up fetus from sleep cycle and hence reduce false positive results.[5,9] Moreover, it also enhances visualization of fetal activity as seen on ultrasound. By reducing the number of non-reactive cardiotocography secondary to fetal sleep states, vibroacoustic stimulator test may be expected to reduce maternal anxiety, overall testing time, perinatal outcome, and obstetrician's anxiety.

Amniotic fluid index and its intrapartum assessment identifies a pregnancy that is at risk for adverse outcome. Amniotic fluid index with fetal acoustic stimulation under ultrasound M mode scan with fetal reactivity and startle response has been used under the profile of rapid biophysical profile rBPP.[10,11] This combines the advantage of simultaneous NST and fetal biophysical profile with reduced testing time.[12]

Intrapartum stimulation tests appear to be useful to prevent and look for fetal acidemia whenever there is a non-reassuring fetal heart rate pattern. Fetal acoustic stimulation used in early intrapartum fetal assessment is a noninvasive screening method for rapid intrapartum assessment of fetal wellbeing.[13] It can be used to differentiate compromised and non-compromised fetus.

The present study is carried out to evaluate Rapid biophysical profile (rBPP) vs Modified biophysical profile (MBPP) in antepartum and intrapartum monitoring of high risk and low risk pregnancy and to correlate with perinatal outcome.

OBJECTIVE

PRIMARY:

To compare the efficacy of Rapid biophysical profile with Modified biophysical profile in intrapartum fetal assessment in high and low risk pregnancy.

OUTCOME:

1. PRIMARY:

   To compare the efficacy of Rapid biophysical profile with Modified biophysical profile in intrapartum fetal assessment.

2. SECONDARY:
   a. Mode of delivery
   b. Number of cesarean section for fetal distress
   c. Apgar score of less than 7
   d. Admission to NICU >24 hours for birth asphyxia
   e. Neonatal mortality
3. Comparison between first and second test result if they don't deliver within 24 hours.

REVIEW OF LITERATURE

Tongsong T et al in 1999 determined the efficacy of rapid biophysical profile, the combination of amniotic fluid index(AFI) and sound provoked fetal movement (SPFM) detected by ultrasound in predicting intrapartum fetal distress in high risk pregnancies, compared with Non-Stress Test (NST). They subjected 1069 high risk singleton pregnancies for both standard NST and rapid BPP and intrapartum continuous fetal heart rate monitoring was performed in all of them. The patients with abnormal NST or abnormal components of rapid BPP were further evaluated with back up tests. Only the last tests performed within 4 days of delivery were included for analysis.

Among 1069 patients tested, 1014had no evidence of intrapartum fetal distress. In comparison to standard NST rapid BPP was more accurate in predicting intrapartum fetal distress with positive predictive value of 78.57 vs 31.63% of NST. Either adequate AFI, normal SPFM or reactive NST in high risk pregnancies has a predictive value of more than 95%. It was concluded that the incidence of fetal fetal compromise among positive, equivocal, or negative tests of rapid BPP are 78.57, 15.82 and 0.9% respectively. The study analysis proved that a positive test, i.e. abnormal AFI and SPFM is suggestive of fetal compromise and prompt delivery should be expedited. An equivocal test, abnormal either AFI or SPFM needs back up test. A negative test i.e. both AFI and SPFM, normal is considered reassuring and routine testing schedule is resumed. If back up tests are abnormal, clinical intervention discussions are made on basis of clinical information available. In conclusion rapid BPP is a simple, rapid and inexpensive means for antepartum surveillance among high risk pregnancies in busy antenatal clinics.

Phattanachindakhun et al conducted a prospective study on 200 singleton pregnancies between 30-42 weeks of gestation, who underwent NST to determine the correlation between rapid biophysical profile, the combination of AFI and SPFM detected by ultrasound and full biophysical profile in terms of normal and abnormal results in year 2010. NST was performed in all patients and then the remaining fetal ultrasound parameters were examined to complete the fetal biophysical profile. After that SPFM was carried out to finish the rBPP test. FBP scoring of >8 was said that fetus was in good condition and rBPP score of 4 characterized reliable fetal reassuring state.

The prevalence of non-reactive NST and or significant deceleration was 1.5% while oligohydramnios and abnormal SPFM were detected as 5% and 2% respectively. Compared to the standard NST, rBPP showed to be significantly superior in terms of correlation with FBP. Also, NST took longer duration, 18 times greater than that of rBPP (21.65+/- 5.47 vs 1.2 +/- 0.32 min). The simplicity, shorter duration and no need of experienced interpreter makes this test rBPP a good choice for antepartum test for fetal wellbeing. This study revealed a significant positive correlation between rBPP and FBP. However, the accuracy of rBPP test with respect to sensitivity, specificity, false positive and false negative results should be extensively verified and larger number of studied population need to be investigated.

A cross sectional study was conducted by Jonathan Czeresnia et al in 2013 on 37 pregnant women who gave birth at their Centre. The clinical applicability of rapid biophysical profile was evaluated comparing results of rBPP to umbilical cord Ph values and Apgar scores.

All 37 pregnant women underwent rBPP tests 24 hours prior to delivery. AFI was measured and SPFM was obtained by stimulatory on cephalic pole with Toitu TR 30 fetal stimulator for 3 seconds. AFI > 5cm and immediate detection of fetal movement by ultrasound was considered normal. A 2ml of blood from umbilical vein was obtained, Ph and PCo2 was calculated. Out of 37 patients 29(78.4%) received rBPP score 4 (normal) and 8 of them (21.6%) received score of 2 (abnormal). There was significant stastical difference ($p < 0.01$) between the Apgar score of rBPP group, while it was not significant with the umbilical cord ph.($p=0.08$). As it was a smaller group and small sample size, ph values were lower in the abnormal group when compared to the normal group. It was also concluded that rBPP, a fast and practical method shows a promising result but must be conducted on a larger population.

A randomized controlled trial was conducted by Sood Atul Kumar in year 2006 on 214 singleton pregnancies with high risk factors. They were all subjected to either modified biophysical profile following VAST or following mock stimulation. Fetal startle response and fetal heart acceleration under combined B and M mode ultrasonography was observed. Observation of fetal startle response to vibroacoustic stimulus found to be associated with FBP score of 8 and above. Correlation was made between FBP within 7 days of delivery and correlated with perinatal outcome.

Mean testing time was significantly less in study group as compared with controls (4.92 ± 0.82 min vs 7.77 ± 1.29 min) with a p value <0.001. There was no significant difference in terms of perinatal outcome and reactivity of fetus with VAST in the two groups. The sensitivity and specificity in the study group was 75% and 100% respectively, with 97.9 % specificity in control group. The accuracy of the test was 99% in study group and 96.2 % in control group. VAS/mFBP has higher predictive value in predicting perinatal morbidity then mFBP alone (100% vs 71.4%

resp). Thus, integrating vibroacoustic stimulation startle response and NST for modified biophysical profile as on time composite fetal assessment reduces the testing time and can be a component for fetal biophysical dynamic assessment.

In a study on 100 women with high risk pregnancy Sambarrey studied relation of perinatal outcome with NST and VAS and its efficacy. Patients with reactive NST were allocated group I and those with non-reactive NST group II and these group of patients were given VAST and if reactive NST thereafter it was considered VAST -ve or else VAST +ve. 52.08% of VAST reactive people had a favorable outcome and 50% of NST non-reassuring had an unfavorable outcome (non-significant p value). The sensitivity, specificity, positive predictive value, and negative predictive value of NST was 50.98%, 51.02%, 50% and 51.2% respectively whereas for VAST it was 88.465, 92.3%, 92% and 88.89% respectively.

It was concluded that VAST is easy to perform, bedside test and cost-effective adjuvant to NST in antenatal fetal assessment of high risk pregnancy in predicting perinatal outcome.

In another study regarding correlation of vibroacoustic stimulation and intrapartum fetal assessment, done by Col. Sood Atul Kumar and Lt. Col Singh Sanjay in the year 2009 it was proved that it is a simple effective highly accurate means for early intrapartum fetal assessment to identify fetus that are either already compromised in early labor or are at increased risk of compromise. In that prospective study, 210 women who were in latent labor were subjected to VAS/mFBP in which fetal startle response and fetal heart acceleration under combined B/M mode USG following VAS were observed. Addition of fetal vibroacoustic stimulation has been reported to increase the sensitivity and decrease false positive results.

The mean testing time was 4.86+/-0.72 min of the 210-fetus subjected, 95.2% were VAS reactive and 94.3% had favorable outcome. It was concluded that VAS/mFBP had high specificity 99% and positive predictive value of 98%, thus implying that it is a reliable diagnostic test for assessing fetal wellbeing. In a resource constrained setting it may be useful as a rapid admission test for fetal wellbeing so that limited perinatal resources can be optimally utilized for a compromised fetus.

Pregnant women (30) suspected of growth restriction were recruited in the present study done by Chousawai et al at Chiang Mai Hospital. They all underwent rapid biophysical profile tests i.e. sound provoked fetal movement and amniotic fluid index level. The sensitivity, specificity, negative and positive predictive value of the most recent rBPP before delivery in predicting poor perinatal outcome were calculated and analyzed.

From that study, the antenatal fetal assessment carried out by rBPP had high sensitivity of 100% and specificity of 89%. A negative predictive value of 100% implies that when rBPP is normal, it is assured that there is no fetal distress or any poor fetal outcome. But positive predictive value of 25% suggests that if rBPP is abnormal, other back up methods such as full BPP or color doppler is necessary to assess further the fetal condition. It may be an effective predictor of poor pregnancy outcome in suspected IUGR fetuses and can be used as a backup test to confirm fetal wellbeing in IUGR affected pregnancies.

Papadopoulos V G, Decavalas GO, Kondakis XG and Beratis NG in their prospective randomized study in 2007 on 2833 women verified the effect of vibroacoustic stimulation on biophysical profile and concluded that addition of vibroacoustic stimulation improves the efficacy of biophysical profile score by

reducing false positive rate and improves test accuracy. All women with BPP score </= 8 were grouped into two groups. Both the group patients received 3 s stimulus but group B had an extended time for assessment of 60s compared to group A which had 30s time. Application of vibroacoustic stimulation significantly decreased the number of positive tests (4.74%vs 6.67%, p value <0.05). There was increase in specificity, positive predictive value, and test accuracy.

Prabhu A V, Mahale N, and Mahale A in the year 2015 conducted a prospective study to assess the efficiency of rapid biophysical profile in antepartum fetal surveillance and compare it with standard full biophysical profile. This study included 153 singleton pregnancies between 34-42 weeks of gestation. All of them underwent both standard biophysical profile and new rapid biophysical profile. The outcome was determined as to predict adverse perinatal outcome and compare which method is better.

The data showed positive correlation between the two tests and RBP was 71.4% sensitive and 87.1% specific in predicting adverse pregnancy outcome compared to standard biophysical profile. It was concluded that rapid BPP can be used as good screening test for high risk pregnancies in busy obstetric set up.

M pourissa, S Refahi, M Javid Majd and A Mardi in the year 2008 studied the effect of acoustic stimulation on biophysical profile testing in Iran. The study included about 55 women at 35-42 weeks of gestation who attended the OPD. Using abdominal ultrasound vibroacoustic stimulation was given for 3 seconds. Four parameters of BPP including fetal breathing, gross fetal movement, fetal muscle tone and heart reactivity were assessed. Each of which was scored as 0,1, or 2 before and

after any acoustic stimulation were given. The mean testing time and total mean testing time in both the conditions was compared and calculated. The duration of acoustic stimulation was increased to ten seconds if there was no response with 3 sec stimulation.

The mean testing time in terms of increase in fetal heart rate about 15 beats per minute was 13.5 and 2.6 min before and after acoustic stimulation(AS) respectively (p=0.001). The overall mean testing time was 24 minutes before AS vs 5 minutes following AS (p=0.001). the mean biophysical score was 7 before acoustic stimulation and 7.6 after it. There was a significant difference between BPP scores in both conditions (p=0.038). acoustic stimulation is a helpful adjunct in the management of high risk pregnancies. The results achieved in this approach showed that applying AS caused fetus to wake up and respond to stimulation rapidly. It decreased the test duration time and improved BPP score results. They thus concluded that sound induced accelerations predicted fetal wellbeing and that sound stimulation significantly shortened mean testing time.

A study was conducted in year 2017 by Dr Amir Shaikh and Dr Yogiraj Chidre regarding comparison of biophysical profile and modified biophysical profile in prediction of fetal outcome in pregnancy induced hypertension.200 patients >34 weeks of gestation with pregnancy induced hypertension were made in two groups with 100 each, with one group for conventional biophysical profile and the second group modified biophysical profile. Group A underwent BPP according to Manning et al with its 5 variables into consideration., and a score of 2 was given for each variable if positive. The two parameters AFI and NST under the modified biophysical profile was done for the other group and similarly score of 2 each was given. Fetal outcome was measured in terms of Apgar scores and wellbeing of the infant.

The sensitivity of the BPP score was higher than that of MBPP which was only 55.6% sensitive, while specificity of latter was marginally higher. The false positive and false negative values were comparable in both the groups. The predictive positive and negative value were similar in both the groups. It was concluded that as BPP is more expensive and time consuming, MBPP was a better substitute.

ANTEPARTUM AND INTRAPARTUM FETAL SURVEILLANCE:

The goal of surveillance is to reduce the incidence of fetal asphyxia and to prevent moderate and severe asphyxia.[14,1516] Because intrapartum fetal asphyxia is partial and often fetal compensation may be satisfactory for some time, this interval provides a window of opportunity during which the occurrence of an exposure to asphyxia can be confirmed and appropriate intervention can be initiated before the threshold of decompensation has been reached.[141718]

Ideally fetal intrapartum surveillance should begin with the onset of labor. Intrapartum fetal asphyxia may occur before fetal assessment is initiated. When fetal surveillance begins, the duration of the record must be sufficient to permit interpretation of the pattern of fetal heart rate behavior.[19]

AMNIOTIC FLUID INDEX:

Amniotic fluid volume is an important indicator of fetal wellbeing.[1] Abnormalities of amniotic fluid volume are associated with increased incidence of fetal and neonatal morbidity and mortality.[20] The technique of measuring the maximum vertical pocket (MVP) depth was first described by Manning and Platt as a part of biophysical profile in 1980.[2.] In 1984 Chamberlain and Manning determined high risk pregnancies undergoing ultrasound examinations and the relationship between MVP and perinatal outcome. MVP demonstrated a poor negative predictive power for perinatal morbidity. Several studies have concluded that AFI < 5cm correlated with higher rate of nonreactivity and variable decelerations on CTG and great likelihood of adverse fetal outcome.[14,21]

CTG:

Cardiotocography (CTG) is a test of intrapartum fetal surveillance. CTG monitoring is widely used to assess fetal wellbeing.[18] Interpretation of a CTG tracing requires both qualitative and quantitative description of:

- Uterine activity (contractions)
- Baseline fetal heart rate (FHR)
- Baseline FHR variability
- Presence of accelerations
- Periodic or episodic decelerations
- Changes or trends of FHR patterns over time.

According to **NICE (NATIONAL INSTITUTE OF HEALTH AND CARE EXCELLENCE)** guidelines in 2007, there is a classification of individual FHR features[17] :

Feature	Baseline Rate(bpm)	Variability	Deceleration	Acceleration
REASSURING	110-160	>/5	None	Present
NON-REASSURING	100-109	<5 for >40 minutes but <90 minutes	Typical variable deceleration with over 50% of contractions occurring for > 90 minutes	Absence of accelerations within otherwise normal CTG is of uncertain significance
	161-180			
			Single prolonged deceleration <80 bpm up to 3 min	
ABNORMAL	<100	<5 for>/90 minutes	Atypical variable or late or both decelerations occurring over 50 % of contractions in a 30 min period	
	>180			
	Sinusoidal pattern for more than 10 minutes		Single prolonged deceleration <80 bpm for >3 minutes	

2015 FIGO Intrapartum Fetal Monitoring Guidelines[22]

FIGO has recently modified the guidelines on intrapartum fetal monitoring with the following interpretation:

- **Normal**: No hypoxia/acidosis, no intervention necessary to improve fetal oxygenation state:
  - Baseline 110-160 bpm
  - Variability 5-25 bpm
  - No repetitive decelerations (decelerations are defined as repetitive when associated with > 50% contractions)
- **Suspicious**: Low probability of hypoxia/acidosis, warrants action to correct reversible causes if identified, close monitoring or adjunctive methods:
  - Lacking at least one characteristic of normality, but with no pathological features.
- **Pathological**: High probability of hypoxia/acidosis, requires immediate action to correct reversible causes, adjunctive methods, or if this is not possible expedite delivery. In acute situations immediate delivery should be accomplished
  - Baseline <100 bpm
  - Reduced or increased variability or sinusoidal pattern
  - Repetitive late or prolonged decelerations for > 30 min, or > 20 min if reduced variability (decelerations are defined as repetitive when associated with > 50% contractions)
  - Deceleration > 5 min

VIBROACOUSTIC STIMULATOR

VIBROACOUSTIC STIMULATION (VAS):

Fetal VAS, produced by an electronic artificial larynx has been used as a primary and adjunctive method of FHR testing.[5] It produces a broadband acoustic signal and a complex vibratory component. The stimulator is applied to maternal abdomen in the region of fetal head and generates a 3D pulse. The vibrator used is hand held battery operated EDAN vibroacoustic fetal stimulator with a 110db sound and frequency of 75hz.

The FHS acceleration that commonly follows VAS is thought to result from afferent reflex pathways activated by stimulation of Meissner's corpuscles rather than relatively intense sound pressure level. The typical VAS response of a healthy term fetus show at least a 10 beat per minute rise in baseline occurring within 10 seconds and lasting from 5-10 minutes. VAS when combined with NST and BPP is shown to shorten the testing time of both the tests. [12,23]

Vibroacoustic stimulated fetal startle response observed under ultrasound can be used as rapid antepartum test. A reactive FHR tracing, whether occurring spontaneously or after VAS is thought to convey a reliable assessment of fetal wellbeing.[24] VAS has received considerable attention and has been employed as a part of antepartum fetal surveillance in an attempt to improve test specificity and efficiency.[25] Ultrasound assisted VAS is helpful in reducing the number of falsely abnormal results. Various studies show safety of vibroacoustic stimulation and no adverse effects on either neurologic development or hearing in children exposed to stimuli in utero.[12]

SOUND PROVOKED FETAL MOVEMENT:

Startles are quick generalized movements that always begin in the limbs and often spread to the trunk and neck.[12] The duration of startle is 1 second or less. Usually these movements occur singly but sometimes they may be repetitive. Startles can be superimposed incidentally on a general movement. The fetal startle response following VAS has been associated with a BPP score of or greater than.[8,9]

MODIFIED BIOPHYSICAL PROFILE:

Biophysical Profile (BPP) is a prenatal ultrasound evaluation of fetal well-being involving a scoring system, with the score being termed **Manning's score.**[14,26,27]**.** It is often done when a non-stress test (NST) is nonreactive or for other obstetrical indications.

Full BPP scoring system by Manning et al.

BIOPHYSICAL PROFILE	NORMAL (SCORE 2)	ABNORMAL (SCORE 0)
Fetal breathing movements	One/ more episodes of FBM>30 sec in 30 min	Absent or no episode of FBM >30 sec in 30 min
Gross body movements	3/more discrete body or limb movements in 30 min	2 or less episodes of body/limb movements in 30 min
Fetal tone	1/more episodes of extremity extension and subsequent flexion	Either slow extension with return to partial flexion or movement of limb in full extension or absent fetal movements
NST	2/more accelerations of 15 beats per minute for 15 sec within 20-40 min	0/1 acceleration within 20-40 min
AFI	>5cm	<5cm

Interpretation:

Score: 8-10 normal fetus

Score: 6 fetal hypoxia is suspicious

Score: 0-4 fetal hypoxia

The "Modified Biophysical Profile" consists of the NST and amniotic fluid index.The modified biophysical profile combines the non-stress test with the amniotic fluid index, which is the sum of measurements of the deepest cord-free amniotic fluid pocket in each of the abdominal quadrants, as an indicator of long-term function of the placenta.[11] An amniotic fluid index of more than 5 cm is thought to be adequate. The modified biophysical profile is considered normal if the nonstress test is reactive and the amniotic fluid index is greater than 5 cm and abnormal if the nonstress test is nonreactive or the amniotic fluid index is 5 cm or less.

The test has

- Excellent positive and negative predictive value
- Easy to perform
- Has clearly defined points.

RAPID BIOPHYSICAL PROFILE:

Rapid biophysical profile (rBPP) is a simple inexpensive and faster method of fetal surveillance.[15] It is a combination of amniotic fluid index (AFI) and sound-provoked fetal movement (SPFM) detected by ultrasound. There is no need of high resolution ultrasound equipment. It identifies both acute fetal hypoxia marker (SPFM) and chronic hypoxia indicator (AFI). It is used in predicting intrapartum fetal distress in high-risk pregnancies. Rapid BPP is a reliable predictor of intrapartum fetal distress with higher sensitivity and specificity. It was proposed by Tongsong et al in the year 1999.[11]

The three components of rBPP (SPFM, AFI and VAST(USG)), are examined simultaneously using a real time USG machine with a transducer frequency of

3.5MHz[5] Fetal movement detected by USG following vibroacoustic stimulation with fetal reactivity i.e. increase in fetal heart rate of more than 15 beats from baseline was considered normal.[4,28,29] The SPFM reflects the neurologic state of the fetus at the time of the test (acute variable) and the AFI reflects the placental function (chronic variable). The time required to perform this test is approximately 2 minutes and it demands much less experience and skill from the examiner when compared to the BPP. Addition of fetal vibroacoustic stimulation with ultrasound increases the sensitivity and reduces false positive results.[7,30] Sources have also studied increase in FHR on USG after giving VAS as a component of rBPP.[8] Increase in FHS beats by 15 is considered normal. Absence of either or both i.e. startle response and FHR reactivity after 3 stimulus was considered nonreactive (positive test).

MATERIALS AND METHODS

SOURCE OF DATA: Pregnant women admitted in BLDE UNIVERSITY'S, Shri B. M. Patil Medical College Hospital, and Research Centre, Vijayapur.

METHODS OF COLLECTION OF DATA:

PERIOD OF STUDY: October 2016- October 2017

SAMPLE SIZE:

With anticipated mean difference of unfavorable outcome between two study groups (modified BPP and rapid modified BPP) as 3.1%and anticipated standard deviation as 8.4%, the minimal sample size per group was 190. with 90% power and 5% level of significance

FORMULA USED:

$$n = \frac{(Z_\alpha + Z_\beta)^2 * 2SD^2}{MD2}$$

z- z statistic at a level of significance

MD- anticipated mean differences

SD- anticipated standard deviation

STATISTICAL ANALYSIS**:**

- Data was analyzed using mean +/- standard deviation, chi square test for association, comparison of mean using t test and diagrammatic representation.

  Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of each test was calculated and analyzed.

- Total of 200 cases was studied.

INCLUSION CRITERIA:

1. Antenatal cases between 18yrs and 35 yrs.
2. Gestational age from > 37 weeks
3. Singleton pregnancy
4. Consenting to participate
5. In latent labor
6. No major congenital anomaly of fetus
7. High risk pregnancy i.e.
    - Pregnancy with hypertension
    - Pregnancy with growth restriction
    - Pregnancy with oligohydramnios (moderate: AFI 5-8cm, severe <5cm)
    - Prolonged pregnancy gestational age >42 weeks
    - Gestational age >41 weeks
    - Preexisting or gestational diabetes
    - Moderate anemia (Hb 7-10gm%)
    - Previous two abortions, first and second trimester abortions
    - Previous intrauterine death
    - Previous preeclampsia, intrauterine growth Retardation, oligohydramnios
8. Low risk pregnancy i.e.
    - No complications in the present or previous pregnancy

EXCLUSION CRITERIA:

1. Antenatal cases <37 weeks of gestation
2. Severe Anemia in pregnancy (Hb<7)
3. Major fetal congenital anomalies
4. Multiple gestation
5. Maternal pulmonary disorder
6. Cardiovascular disorders of pregnancy
7. Previous cesarean section
8. Eclampsia
9. Abruption
10. Malpresentation
11. Not consenting to participate

METHODOLOGY:

A prospective study was performed on 200 singleton pregnancies fulfilling all the above enlisted inclusion and exclusion criteria in latent labor.

All patients underwent modified BPP (AFI + NST) and rapid BPP (AFI + vibroacoustic stimulated startle response and acceleration of FHR on USG i.e. more than 15 beats from baseline)

Score:

- Modified BPP: AFI>5; score is 2, reactive NST; score is 2 - total 4
- Rapid BPP: AFI >5; score is 2, fetal startle response with fetal heart rate acceleration on USG; score is 4 - total 6[1]

AFI was calculated using four quadrant method, values over 5 cm was considered normal. All of them underwent NST as a part of conventional modified BPP. NST was observed for

a. basal heart rate
b. variability
c. presence of at least 2 accelerations and absence of decelerations.

SPFM was obtained using fetal stimulation by positioning stimulator on cephalic pole, stimulus to be applied for 3 seconds.[8] The immediate detection of fetal movement by ultrasound and fetal heart rate acceleration of 15 beats from baseline, if both positive was given score 4. If there was no startle response, VAST was repeated at 1 min interval for a maximum of 3 times. If startle response was present, but no increase in fetal heart rate or there was fetal heart rate reactivity, but no startle response it was given a score of 2.

In absence of response, another stimulus was given with vibrator at an interval of 1 min for maximum three stimuli over 10min trace.[7] If there is response its considered reactive. If no acceleration it was considered as positive result. The vibrator used was hand held battery operated EDAN vibroacoustic fetal stimulator with 110db sound and frequency of 75hz.

Total MBPP and rBPP scores were calculated for all the patients, outcome was analyzed for each of them in terms of mode of delivery, number of LSCS for fetal distress, Apgar score, NICU admission for hypoxia and neonatal death.

If they didn't deliver within 24 hours the test was repeated.

RESULTS

STATISTICS:

DEMOGRAPHIC ANALYSIS:

TABLE 1: AGE WISE DISTRIBUTION

Age (Years)	Group 1		Group 2		Chi square test
	Frequency	Percent	Frequency	Percent	
<20	9	9.0	12	12	
20-24	63	63.0	60	60	P=0.8886 NS
24-29	23	23.0	24	24	
30+	5	5.0	04	04	
Total	100	100.0	100	100.0	

Values are n (% of cases). P-values by Chi-Square test. P-value <0.05 is statistically significant. *P-value<0.05, **P-value<0.01, ***P-value<0.001. NS: Statistically Non-Significant.

Comments:

1. The distribution of age of the cases studied did not differ significantly across both the study groups.
2. Statistically there is no significant difference between two groups

TABLE 2: COMPARISON OF AGE BETWEEN TWO GROUPS

Groups	N	Mean	Std. Deviation	Std. Error Mean	Unpaired t test
Group1	100	23.08	3.428	.343	P=0.301
Group2	100	22.59	3.248	.325	NS

NS- Statistically there is no significant difference between two groups (p=0.301)

FIGURE 1. COMPARISON OF AGE BETWEEN TWO GROUPS

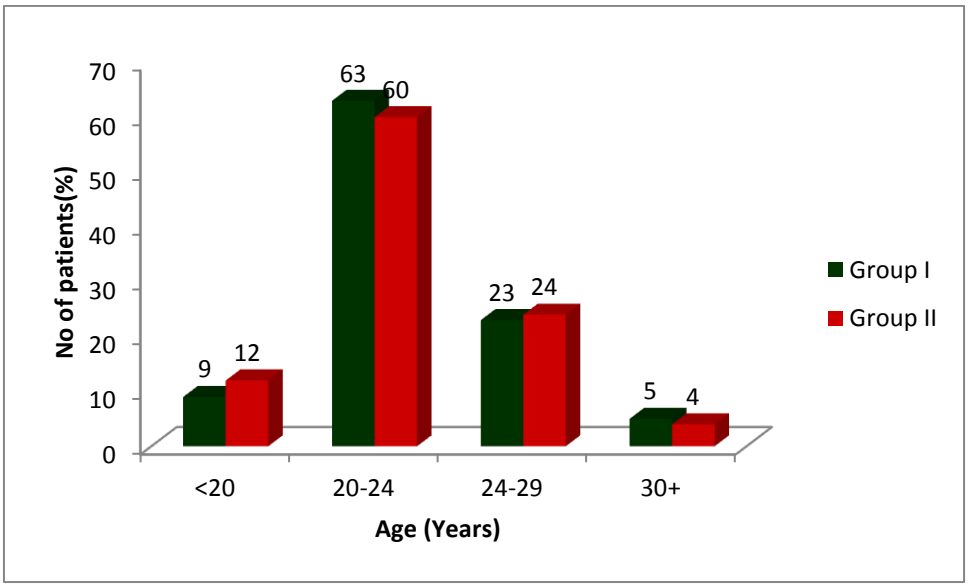


TABLE 3: GESTATIONAL AGE WISE DISTRIBUTION

GA	Group 1		Group 2		Chi square test
	Frequency	Percent	Frequency	Percent	
<40	42	42.0	87	87	P=0.0001*
40-41	51	51.0	13	13	
42-43	7	7.0	0	0	
Total	100	100.0	100	100.0	

* Statistically there is a significant difference between two groups

TABLE 4: COMPARISON OF GESTATIONAL AGE BETWEEN TWO GROUPS:

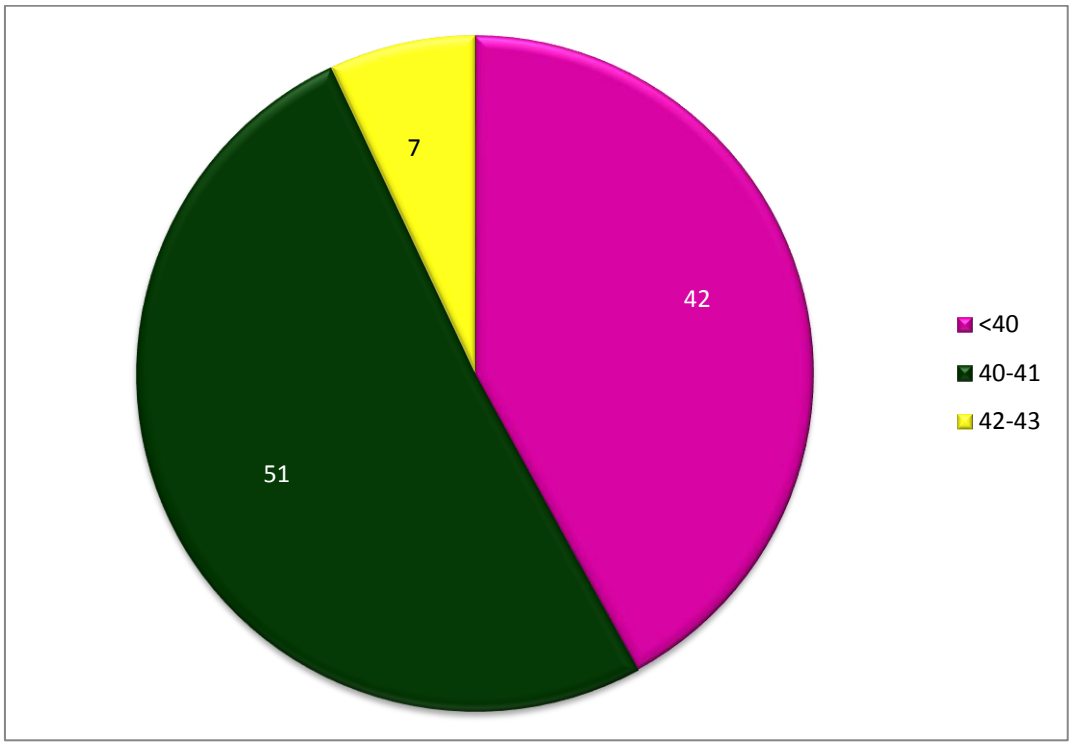
Groups	N	Mean	Std. Deviation	Std. Error Mean	Unpaired t test
Group1	100	39.72	1.325	.133	P=0.0001*
Group 2	100	38.57	.931	.093	

Values are n (% of cases). P-values by Chi-Square test. P-value <0.05 is considered to be statistically significant. *P-value<0.05, **P-value<0.01, ***P-value<0.001. NS: Statistically Non-Significant.

Comments:

1. Statistically there is a significant difference between two groups (p<0.0001) Maximum distribution of gestation between 37-40 weeks in group II and others in group I.
2. Patients with gestational age > 41 weeks belong to high risk category. They were not included in group II, so that P value was significant.
3. The mean gestational age of subjects in group I was 39.72 weeks as compared to 38.57 weeks in group II.

FIGURE 2. DISTRIBUTION OF GESTATIONAL AGE IN GROUP I:



Comments:

3. Graph depicting distribution of gestational age.

4. Maximum subjects were in range of 40-41 weeks of gestation.

TABLE 5: DISTRIBUTION ACCORDING TO PARITY

	Group I	Group II	Chi square test
Primigravida	49	67	P=0.0714 NS
Primipara	11	6	
Multigravida	29	21	
Multipara	11	6	

Values are n (% of cases). P-values by Chi-Square test. P-value <0.05 is considered to be statistically significant. *P-value<0.05, **P-value<0.01, ***P value< 0.001. NS: Statistically Non-Significant.

Comments:

1. The distribution of parity did not differ significantly across the study groups (P-value>0.05 for all).
2. Maximum cases were primigravida in both group I and II, 49 and 67 cases respectively.

FIGURE 3. DISTRIBUTION ACCORDING TO PARITY

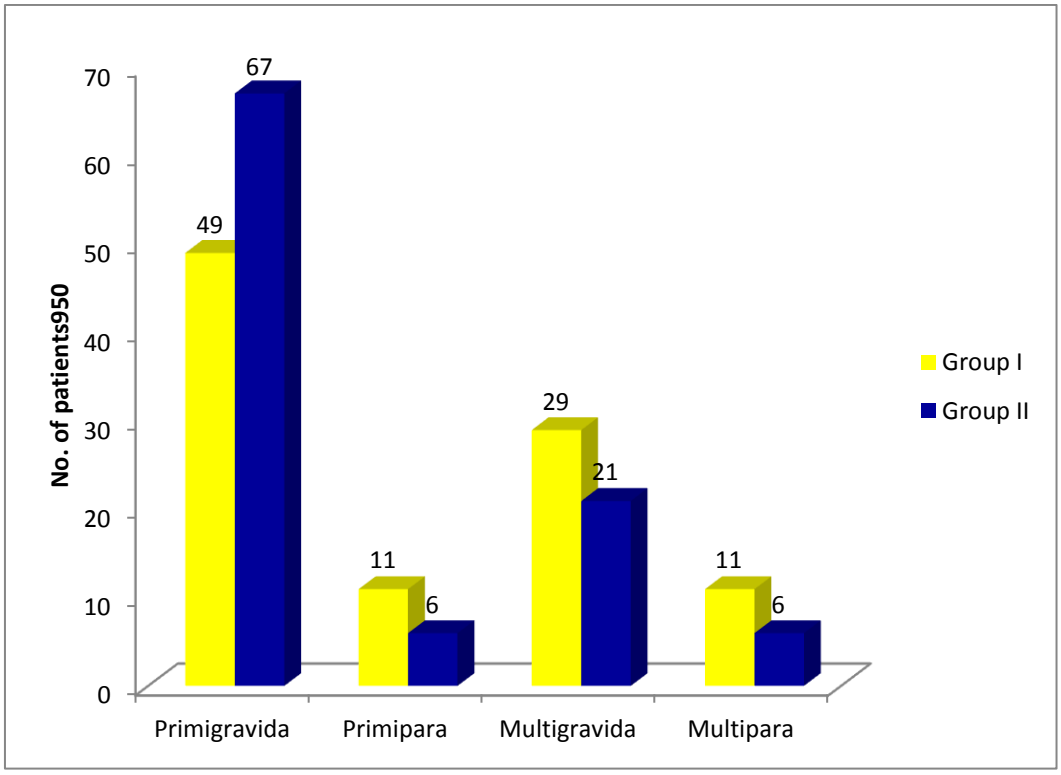


TABLE 6: HIGH RISK FACTORS

GROUP I

Risk factors	Frequency	Percent
PREVIOUS PREECLAMPSIA, IUGR, OLIGOHYDRAMNIOS		
Yes	01	99
No	99	01
MODERATE ANAEMIA		
Yes	10	10
No	90	90
GESTATIONAL HYPERTENSION		
Yes	22	22
No	78	78
MILD PREECLAMPSIA		
Yes	94	94
No	06	06
SEVERE PREECLAMPSIA		
Yes	07	07
No	93	93
IUGR		
Yes	05	05
No	95	95
SEVERE OLIGOHYDRAMNIOS	AFI < 5cm	
Yes	23	23
No	77	77
MODERATE OLIGOHYDRAMNIOS	AFI 5-8cm	
Yes	38	38
No	62	62

Comments:

1. The two groups were divided according to presence or absence of these high risk factors.
2. Maximum cases had mild preeclampsia i.e. 94, next being moderate oligohydramnios 38 cases.

FIGURE 4. HIGH RISK FACTORS

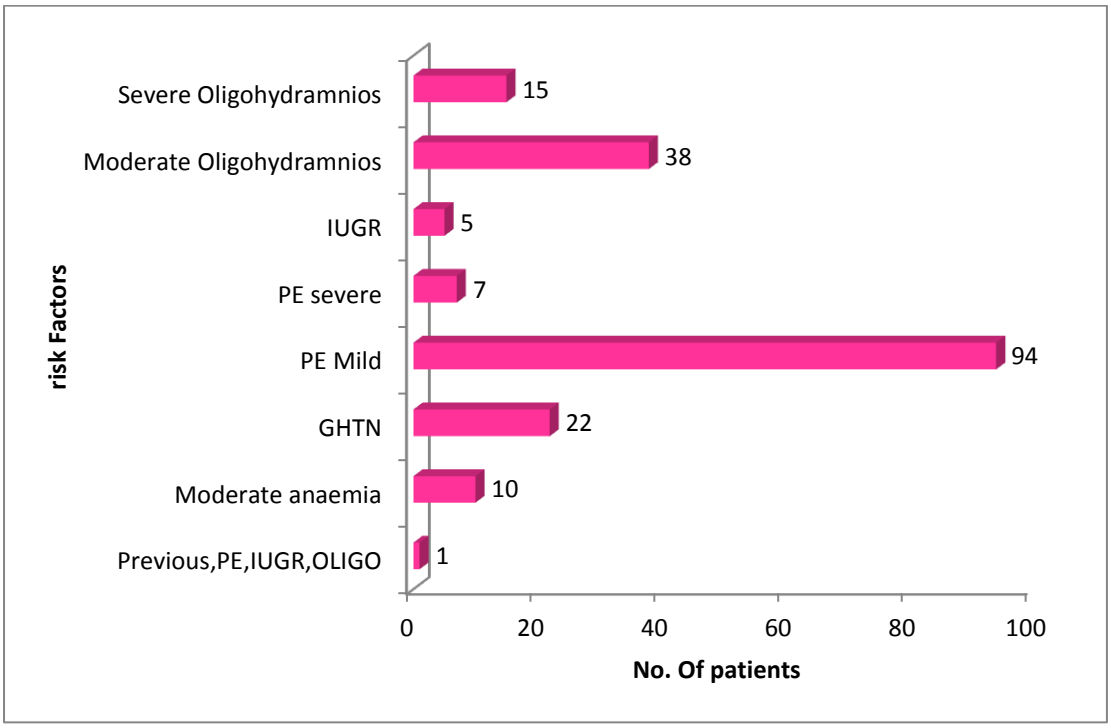


TABLE No 7: MATERNAL AND PERINATAL OUTCOME WITH EACH TEST PARAMETER

Parameter	Group 1				P VALUE
	NON FAVOURABLE		FAVOURABLE		
	N	%	N	%	
AFI<5 cm	16	66.7	7	9.2	<0.001*
AFI>5 cm	8	33.3	69	90.8	
CTG Non-reactive	17	70.8	1	1.3	<0.001*
CTG Reactive	7	29.2	75	98.7	
VAST(USG) Non-reactive	14	58.3	10	13.2	<0.001*
VAST(USG) Reactive	10	41.7	66	86.8	
SPFM Negative	15	62.5	15	19.7	<0.001*
SPFM Positive	9	37.5	61	80.3	
MBPP Low score	18	75.0	8	10.5	<0.001*
MBPP Full score	6	25.0	68	89.5	
RBPP Low score	20	83.3	16	21.1	0.010*
RBPP Full score	4	16.7	60	78.9	

Note: * significant at 5% level of significance ($p<0.05$)

Parameter	Group 2				P VALUE
	NON FAVOURABLE		FAVOURABLE		
	N	%	N	%	
AFI<5 cm	0	0.0	0	0.0	<0.001*
AFI>5 cm	12	100.0	88	100.0	
CTG Non-reactive	10	83.3	0	0.0	<0.001*
CTG Reactive	2	16.7	88	100.0	
VAST(USG) Non-reactive	9	75.0	8	9.1	<0.001*
VAST(USG) Reactive	3	25.0	80	90.9	
SPFM Negative	7	58.3	7	8.0	<0.001*
SPFM Positive	5	41.7	81	92.0	
MBPP Low score	10	83.3	10	11.4	<0.001*
MBPP Full score	2	16.7	78	88.6	
RBPP Low score	11	91.7	8	9.1	<0.001*
RBPP Full score	1	8.3	80	90.9	

Note: * significant at 5% level of significance ($p<0.05$)

RBPP full score: 6/6, low score 4/6, 2/6, 0/6

MBPP full score 4/4, low score 2/4, 0/4

FIGURE NO 5: MATERNAL AND PERINATAL OUTCOME WITH AFI

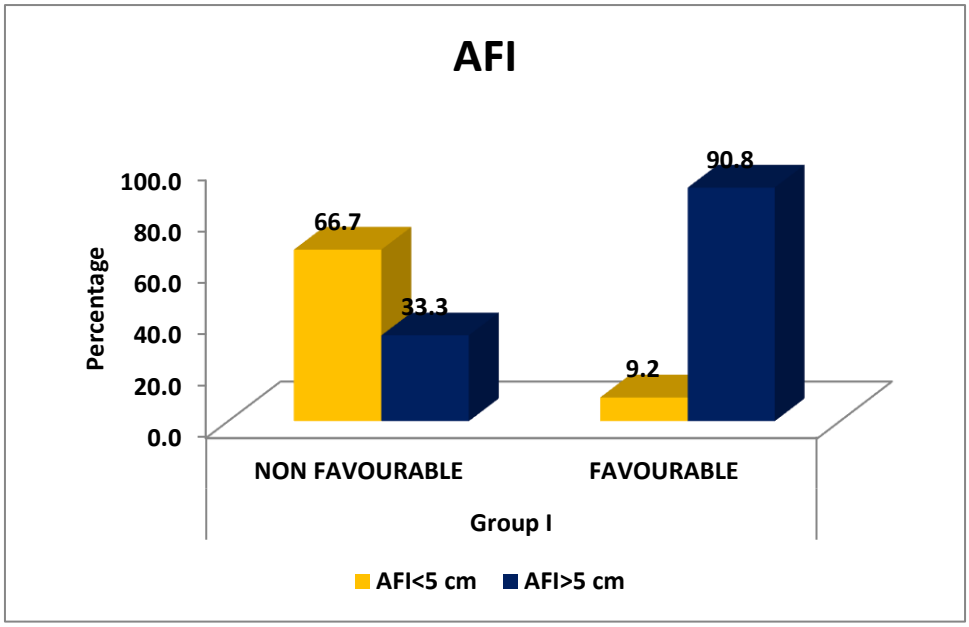


FIGURE NO 6: MATERNAL AND PERINATAL OUTCOME WITH CTG

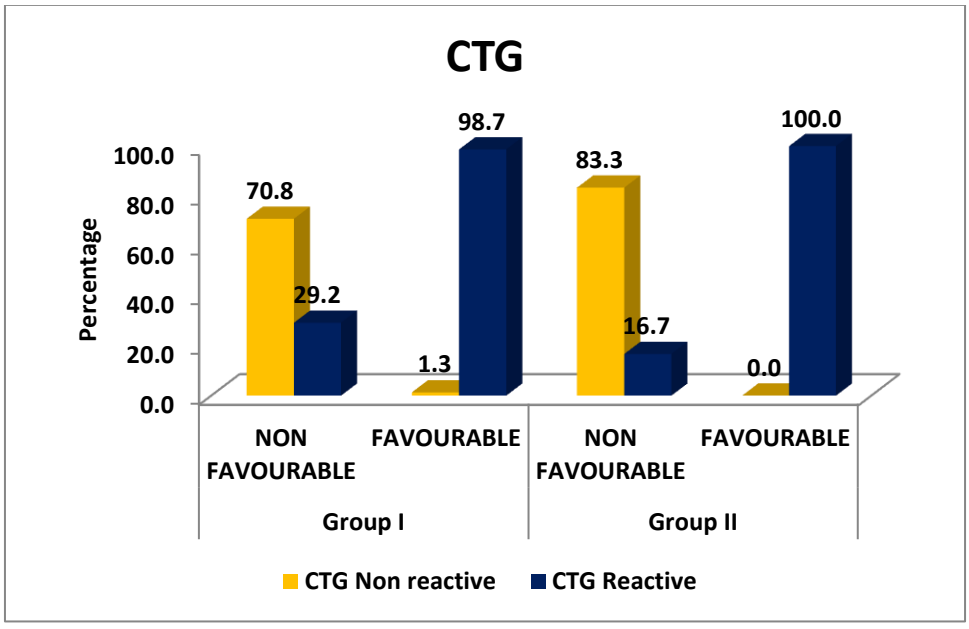


FIGURE NO 7: MATERNAL AND PERINATAL OUTCOME WITH VAST(USG)

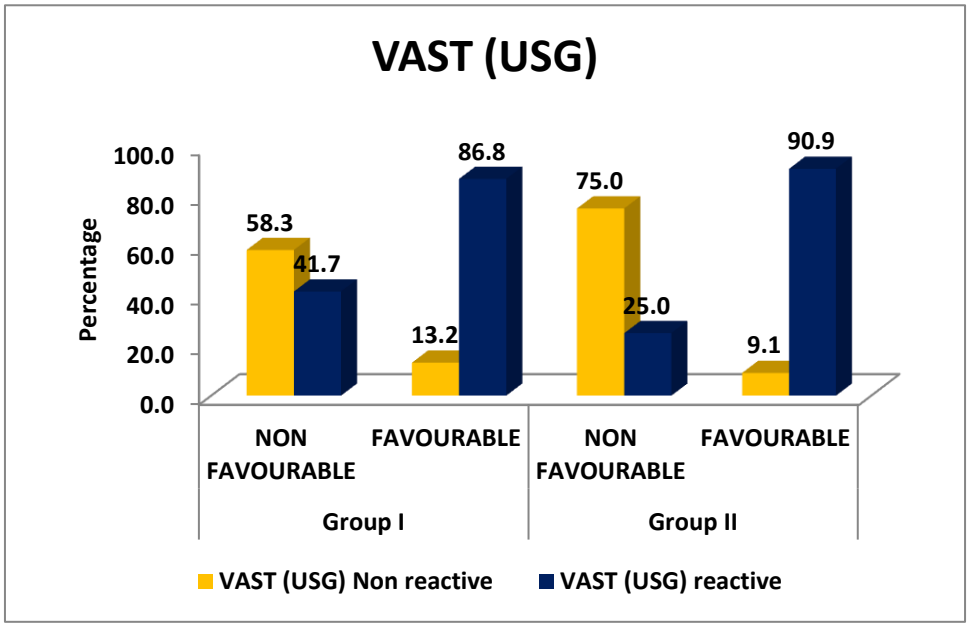


FIGURE NO 8: MATERNAL AND PERINATAL OUTCOME WITH SPFM

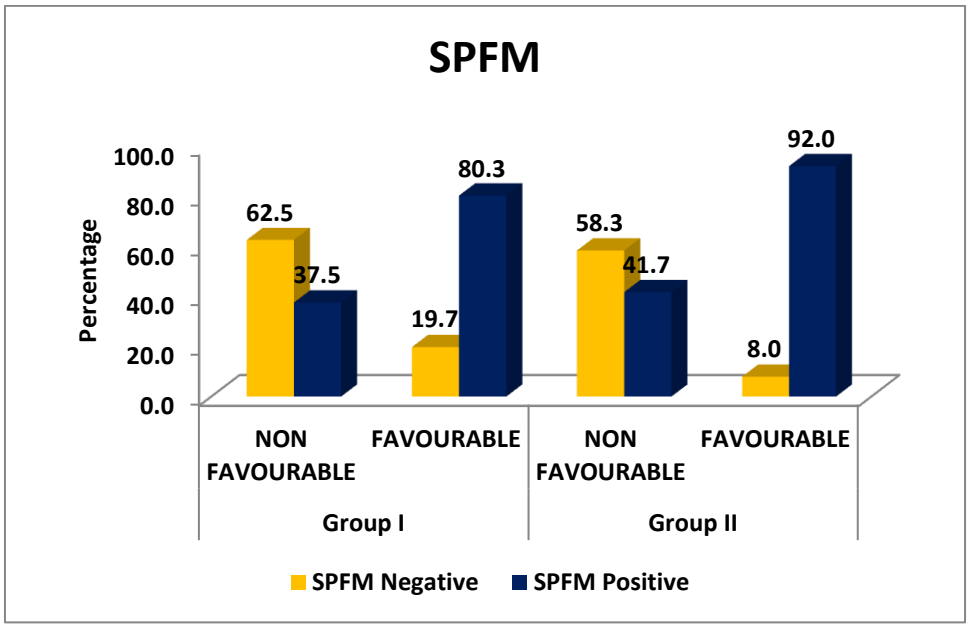


FIGURE NO 9: MATERNAL AND PERINATAL OUTCOME WITH MBPP

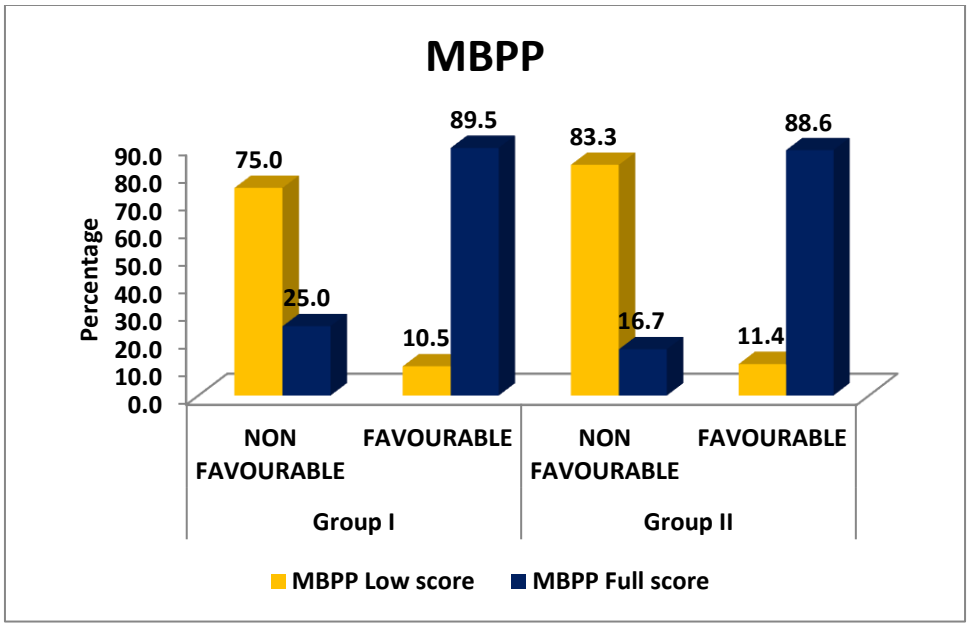


FIGURE NO 10: MATERNAL AND PERINATAL OUTCOME WITH RBPP

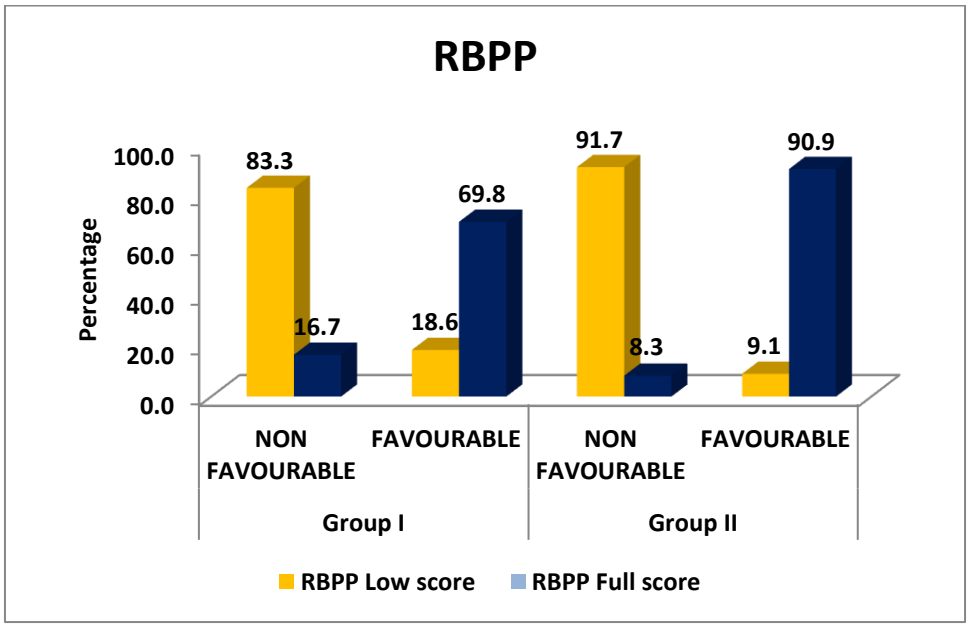


TABLE NO 8: ACCURACY OF DIAGNOSTIC TEST RESULTS IN DETECTING THE MATERNAL AND PERINATAL OUTCOME

Parameter	Group 1				
	Sensitivity	**Specificity**	**PPV**	**NPV**	**Accuracy**
AFI	67%	91%	70%	90%	85%
CTG	71%	99%	94%	91%	92%
VAST(USG)	58%	87%	58%	87%	80%
SPFM	63%	80%	50%	87%	76%
MBPP	75%	89%	69%	92%	86%
RBPP	83%	79%	56%	94%	80%

Parameter	Group 2				
	Sensitivity	**Specificity**	**PPV**	**NPV**	**Accuracy**
AFI	-	-	-	-	-
CTG	83%	100%	100%	98%	98%
VAST(USG)	75%	91%	53%	96%	89%
SPFM	58%	92%	50%	94%	88%
MBPP	83%	89%	50%	98%	88%
RBPP	92%	91%	58%	99%	91%

COMMENTS:

1. Single parameters when taken into account have different specificity and sensitivity in detecting fetal adverse outcome.
2. There are better results in group II compared to group I as there are no high risk factors and the outcome is better.

TABLE NO 9: MODE OF DELIVERY WITH EACH TEST PARAMETER

Parameter	Group 1				P VALUE
	Vaginal		Caesarean		
	N	%	N	%	
MBPP Normal Score	62	95.4	12	34.3	<0.001*
MBPP Low score	3	4.6	23	65.7	
RBPP Normal Score	56	86.2	8	22.9	<0.001*
RBPP Low score	9	13.8	27	77.1	

Note: * significant at 5% level of significance ($p<0.05$)

Parameter	Group 2				P VALUE
	Vaginal		Caesarean		
	N	%	N	%	
MBPP Normal Score	74	97.4	6	25.0	<0.001*
MBPP Low score	2	2.6	18	75.0	
RBPP Normal Score	75	98.7	6	25.0	<0.001*
RBPP Low score	1	1.3	18	75.0	

Note: * significant at 5% level of significance ($p<0.05$)

FIGURE NO 11: MODE OF DELIVERY WITH MBPP

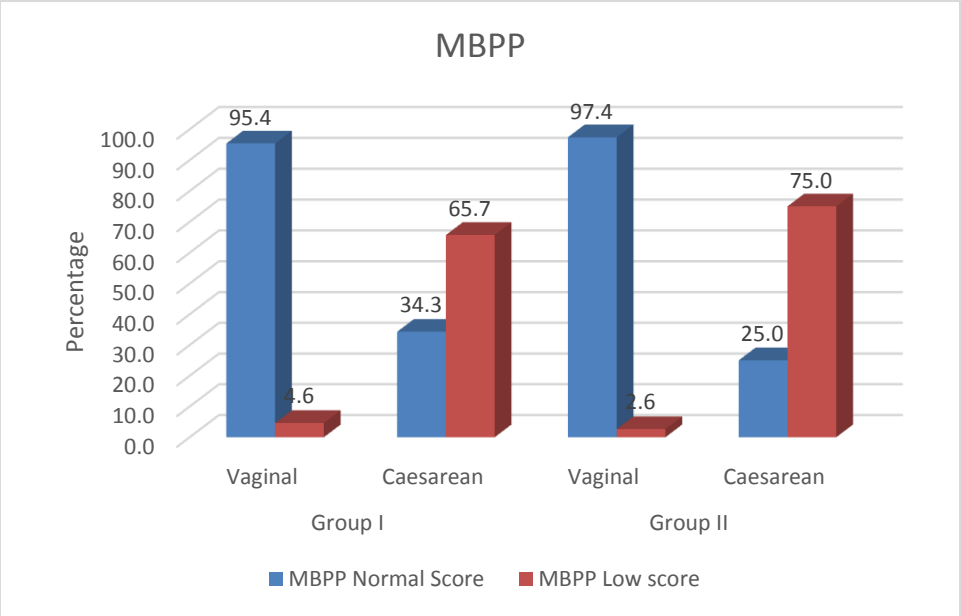


FIGURE NO 12: MODE OF DELIVERY WITH RBPP

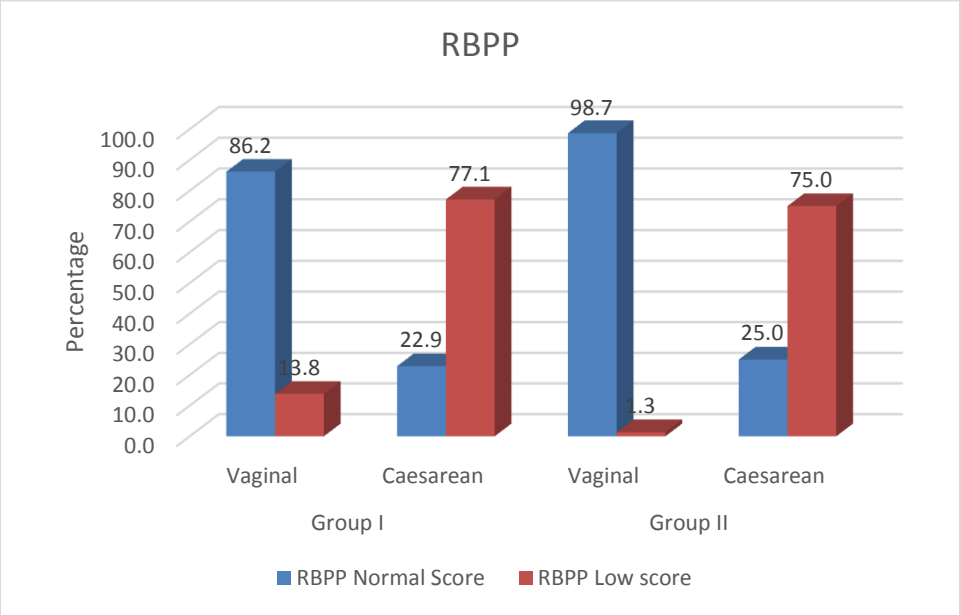


TABLE NO 10: ACCURACY OF DIAGNOSTIC TEST RESULTS IN DETECTING THE MODE OF DELIVERY

Parameter	Group 1				
	Sensitivity	**Specificity**	**PPV**	**NPV**	**Accuracy**
MBPP	95%	66%	84%	88%	85%
RBPP	86%	77%	88%	75%	83%

Parameter	Group 2				
	Sensitivity	**Specificity**	**PPV**	**NPV**	**Accuracy**
MBPP	97%	75%	93%	90%	92%
RBPP	99%	75%	93%	95%	93%

COMMENTS:

1. Mode of delivery very much depended on the scores of MBPP and rBPP.
2. The rate of cesarean section was more with those who had low scores of either MBPP or rBPP.

TABLE NO 11: NUMBER OF LSCS FOR FETAL DISTRESS WITH EACH TEST PARAMETER

Parameter	Group 1				P VALUE
	Yes		No		
	N	%	N	%	
MBPP Low score	15	83.3	11	13.4	0.011*
MBPP Normal Score	3	16.7	71	86.6	
RBPP Low score	17	94.4	19	23.2	<0.001*
RBPP Normal Score	1	5.6	63	76.8	

Note: * significant at 5% level of significance ($p<0.05$)

Parameter	Group 2				P VALUE
	Yes		No		
	N	%	N	%	
MBPP Low score	8	66.7	12	13.6	0.023*
MBPP Normal Score	4	33.3	76	86.4	
RBPP Low score	11	91.7	8	9.1	<0.001*
RBPP Normal Score	1	8.3	80	90.9	

Note: * significant at 5% level of significance ($p<0.05$)

FIGURE NO 13: NUMBER OF LSCS FOR FETAL DISTRESS WITH MBPP

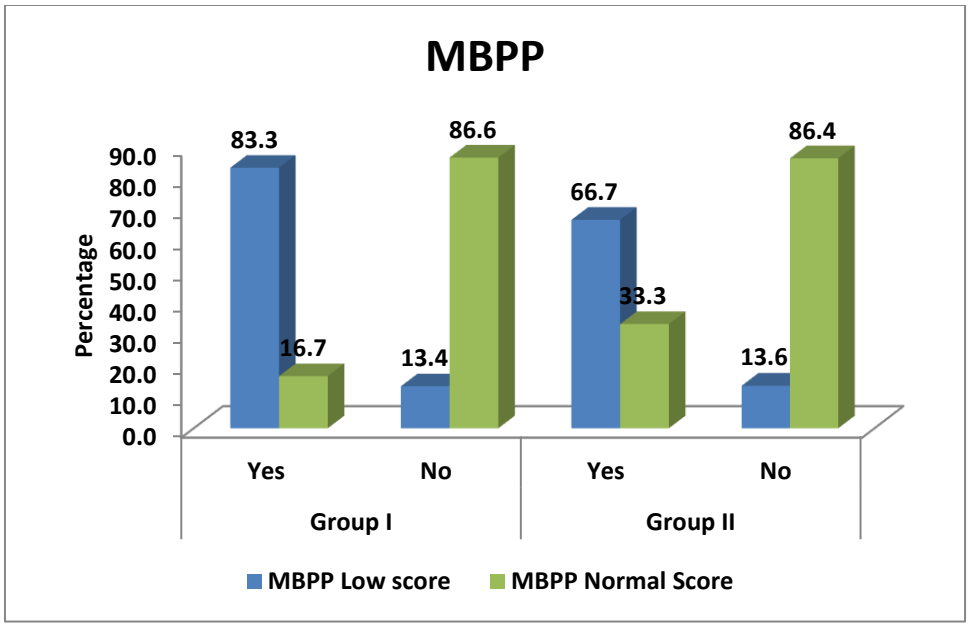


FIGURE NO 14: NUMBER OF LSCS FOR FETAL DISTRESS WITH RBPP

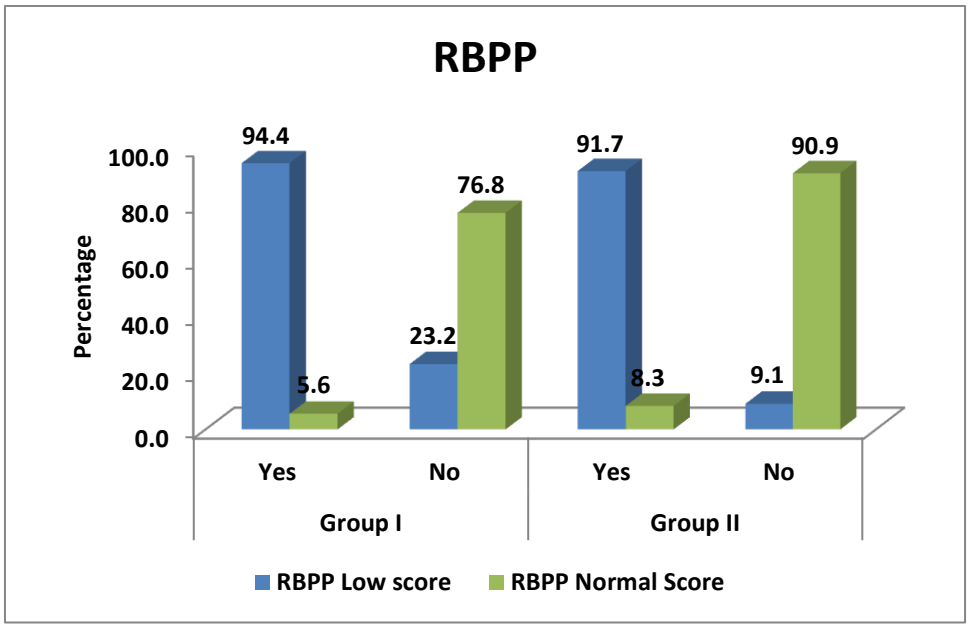


TABLE NO 12: ACCURACY OF DIAGNOSTIC TEST RESULTS IN DETECTING THE NUMBER OF LSCS FOR FETAL DISTRESS

Parameter	Group I				
	Sensitivity	**Specificity**	**PPV**	**NPV**	**Accuracy**
MBPP	83%	87%	58%	96%	86%
RBPP	94%	77%	47%	98%	80%

Parameter	Group II				
	Sensitivity	**Specificity**	**PPV**	**NPV**	**Accuracy**
MBPP	67%	86%	40%	95%	84%
RBPP	92%	91%	58%	99%	91%

COMMENTS:

1. rBPP is sensitive in detecting fetal distress and thus more number of cesarean section for fetal distress
2. The diagnostic accuracy with rBPP is similar in both the groups, whereas it is more sensitive with MBPP in group II compared to group I

TABLE NO 13: ASSOCIATION OF PERINATAL OUTCOME WITH MBPP AND RBPP SCORES IN GROUP I

Parameter	Group I (N)			P VALUE
	AG<7	NICU FOR ASPHYXIA	NEONATAL DEATH	
MBPP Low score	0	4	0	<0.001*
MBPP Normal Score	1	1	1	-
RBPP Low score	0	4	0	<0.001*
RBPP Normal Score	1	1	1	-

Note: * significant at 5% level of significance (p<0.05)

FIGURE NO 15: ASSOCIATION OF PERINATAL OUTCOME WITH MBPP AND RBPP SCORES IN GROUP I

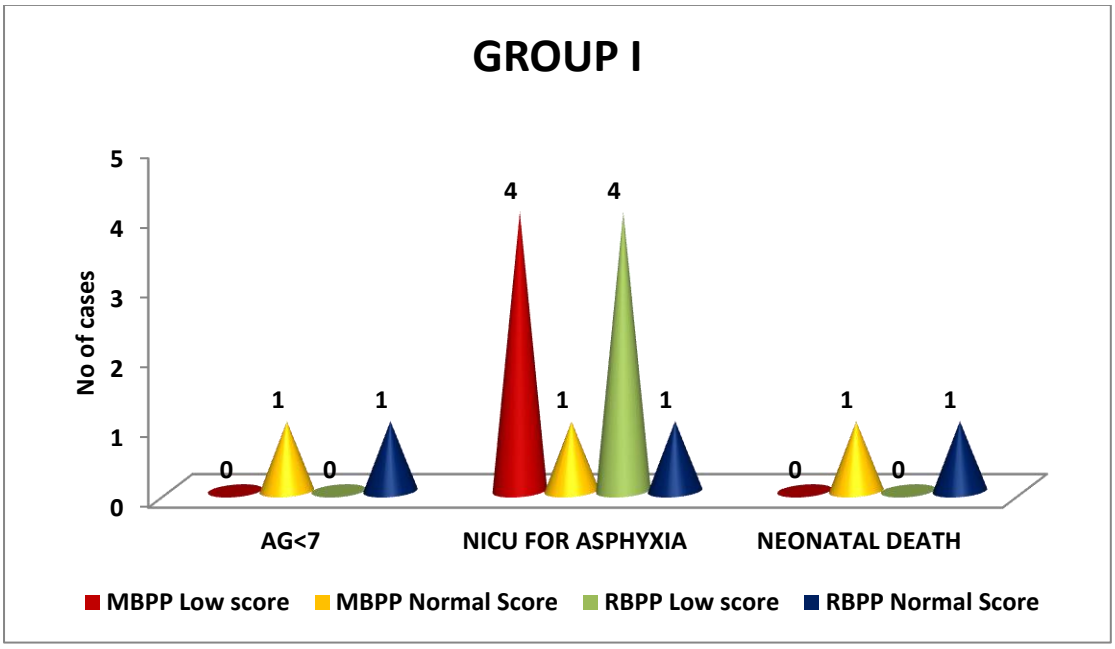
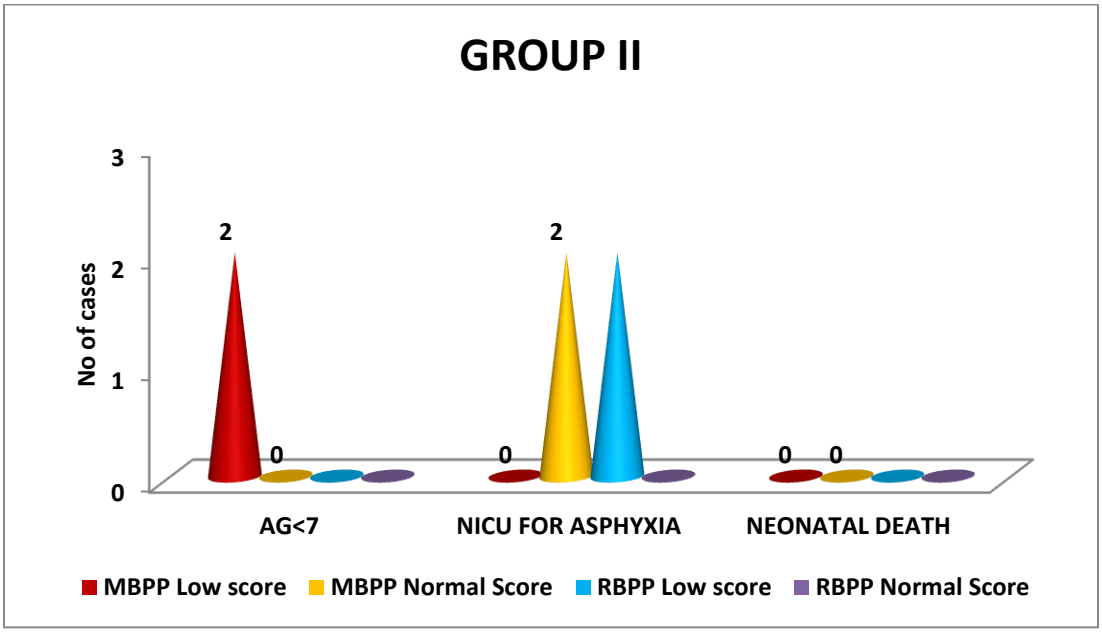


TABLE NO 14: ASSOCIATION OF PERINATAL OUTCOME WITH MBPP AND RBPP SCORES IN GROUP II

Parameter	Group II (N)			P VALUE
	AG<7	NICU FOR ASPHYXIA	NEONATAL DEATH	
MBPP Low score	2	0	0	<0.001*
MBPP Normal Score	0	2	0	<0.001*
RBPP Low score	0	2	0	<0.001*
RBPP Normal Score	0	0	0	-

Note: * significant at 5% level of significance (p<0.05)

FIGURE NO 16: ASSOCIATION OF PERINATAL OUTCOME WITH MBPP AND RBPP SCORES IN GROUP II



Comments:

1. There is a significant association between the score of MBPP and rBPP and the perinatal outcome.

2. Perinatal outcome was assessed in terms of Apgar score at 5 minutes <7, NICU admission for asphyxia and neonatal death.
3. Subjects with normal MBPP and rBPP score still had adverse perinatal outcome.

TABLE NO 15: ASSOCIATION OF MBPP AND RBPP SCORES WITH ADVERSE OUTCOME IN GROUP I

	MBPP Normal Score	**MBPP Low score**	**p value**
RBPP Normal Score	7	5	0.020*
RBPP Low score	0	10	

Note: * significant at 5% level of significance ($p<0.05$)

TABLE NO 16: ASSOCIATION OF MBPP AND RBPP SCORES WITH ADVERSE OUTCOME IN GROUP II

	MBPP Normal Score	**MBPP Low score**	**p value**
RBPP Normal Score	7	3	0.139
RBPP Low score	0	2	

Comments:

1. When MBPP and Rbpp scores together was assessed, there was an association seen in group I.
2. No association was seen in group II.

RESULTS:

During the study period 200 patients underwent fetal biophysical profile testing. They were divided into two groups with group A 100 subjects with high risk factors and group B 100 subjects without any risk factors. All the patients underwent Modified biophysical profile (NST + AFI) and Rapid biophysical profile (FHR by USG + SPFM + AFI) and fetal outcome was assessed in terms of number of cesarean section for fetal distress and perinatal outcome with Apgar scores, NICU admission for asphyxia and neonatal death.

There was no difference in maternal age and parity in the two groups. The mean maternal age of the patients was 23.08 years and 22.59 years in group I and group II. The mean gestational age among the patients was 39.72 weeks and 38.57 weeks in the two groups respectively. Majority (49 and 67) of the cases were primigravida in both the groups respectively. The groups were divided according to the presence or absence of high risk factors as enumerated before. Among the high risk factors, mild preeclampsia accounted for 94% of the cases, with moderate oligohydramnios being next about 38%. The individual parameters of MBPP and rBPP was assessed. Amniotic fluid index is a common component of both MBPP and rBPP. There were 77 cases of AFI > 5cm in group I with 8 of them having non favorable outcome. Out of 23 cases of AFI <5cm, 16 of them had a non favorable outcome and only 7 had good outcome, with a significant p value <0.001. According to our study AFI is 67% sensitive and 91% specific in detecting adverse perinatal outcome. CTG also has a good role in predicting outcome with 99% specificity and 92% accuracy in group I and 100% specificity and 98% sensitivity in group II. Vibroacoustic stimulation on USG is thought to convey a reliable result in assessing fetal wellbeing. Among 24 patients of nonreactive VAST(USG), 14 of them had non

favorable outcome with specificity of 87% and negative predictive value of 87% in group I cases. The same when seen in group II VAST (USG) had 91% specificity and 96% positive predictive value in detecting non favorable outcome. Another component of rapid biophysical profile, i.e. startle response when assessed, it showed an accuracy of 76% and 88% in detecting adverse outcome respectively in group I and group II. With 70 cases having positive startle response, 9 cases had non favorable outcome in group I.

All patients underwent both modified biophysical profile and rapid biophysical profile. Out of all the patients who had full score of modified biophysical profile, 6 of them had non favorable outcome whereas 18 of them with low score had poor outcome, having a statistically significant. P value MBPP has 75% sensitivity and 86 % accuracy in detecting adverse perinatal outcome in group I with values being 83% and 88 % respectively in group II. Three patients with full score of MBPP had their babies with NICU admission for asphyxia and one had a perinatal death. Among 18 patients with low score of MBPP, 3 of them had AFI > 5 cm and 2 among them underwent emergency LSCS for fetal distress with no NICU admissions and 8 of them had non reassuring CTG and in that 7 of them went for emergency LSCS for fetal distress and 2 among them had NICU admission for asphyxia. One patient with reassuring CTG underwent emergency LSCS with NICU admission for asphyxia.

Correlation of individual components of rapid biophysical profile and the score of rBPP was made. Only 4 cases of full score rBPP had adverse perinatal outcome in comparison to 20 cases in low score subjects with significant statistical difference and with a positive predictive value of 94 % and 83 % sensitivity in group I. The same results when analyzed in group II, only 1 with full score had a bad outcome and 11 with low score, thus with a sensitivity of 92% and specificity of 91%

and accuracy of 91%. Among the subjects with full score 6 of them underwent emergency LSCS with no adverse outcome to the fetus. Out of the subjects with full scores 3 of them who delivered by vaginal route had NICU admissions and one perinatal death. Among the 40 subjects with poor rBPP scores, 12 of them underwent emergency LSCS for fetal distress with one NICU admission in that. There were 3 patients with score 0 and all three of them underwent emergency LSCS for fetal distress and 1 among them had NICU admission for asphyxia.

Mode of delivery was also analyzed depending on the MBPP and rBPP scores. 95% of them with full MBPP score had vaginal delivery whereas only 4 % of them with low MBPP scores had vaginal delivery. 12 subjects with normal MBPP score and 23 of them with low score underwent emergency LSCS, accuracy of 85 % and sensitivity of 95% in group I. When analyzed with rBPP scores, the rate of cesarean section for low score is more with specificity of 77% and accuracy of 83%.

The study included the number of subjects undergoing emergency LSCS for fetal distress as a secondary outcome and when that outcome was correlated with the scores of MBPP and rBPP it was concluded that, in group I rBPP score was a better predictor with a sensitivity of 94%, negative predictive value of 98% and 80% accuracy, compared to MBPP which has 83 % sensitivity and 96% negative predictive value. In group II also rBPP was a better predictor with 92% sensitivity and 91% specificity for detecting fetal distress.

The other secondary outcomes of our study were babies with low Apgar scores at 5minute of less than 7, NICU admission for asphyxia and neonatal death. There were 4 cases of NICU admission for asphyxia with low MBPP and rBPP scores and 1

case of poor outcome with neonatal death even with a full score of MBPP and rBPP with significant P value of <0.001.

Correlation between MBPP and rBPP was done and association between the two in detecting poor outcome was sought. With full score of both MBPP and rBPP, 7 cases with adverse outcome were detected. With both scores being low in group I, 10 cases had poor outcome. When compared to group II only 2 cases had adverse outcome with both scores poor thus having not a significant association between both MBPP and rBPP scores. Rapid biophysical profile has excellent sensitivity and negative predictive value, thus can detect fetal distress and poor outcome if the result is positive. But if results are negative, the outcome is not reliable.

Four patients went in for second test as they didn't deliver within 24 hours. Among them 1 was from group I who had full MBPP and rBPP score and delivered vaginally. 3 patients were from group II, 1 was a primigravida with full score delivered vaginally, second one was multigravida with full score; normal vaginal delivery and the last one had full score but underwent emergency LSCS for fetal distress but with no NICU admission.

DISCUSSION

Fetal biophysical profile is a noninvasive, accurate method of antenatal and intrapartum fetal assessment. It provides immediate individual results with very low false positive rates.[2] A reactive test indicates low risk of adverse effect and such a reliable fetal admission test helps identify fetus who is at risk of jeopardy so that with limited resources fetal distress can be identified early and better managed.[6]

Rapid biophysical profile provides an assessment of fetal condition with the help of ultrasound and sound provoked fetal movements and FHR reactivity with amniotic fluid index to identify both acute and chronic markers of intrauterine fetal hypoxia.[7] It is more reliable to detect sound provoked fetal movement by ultrasound instead of maternal perception of fetal movements.

A study done by Sood Atul Kumar in the year 2007 on vibroacoustic stimulation with USG, FHS reactivity and SPFM and modified biophysical profile in high risk pregnancy on 214 women, there was reduced testing time (4.92min) compared to control of (7.77 min). VAS provoked biophysical profile was more specific 100%, with 100% positive predictive and 99 % negative predictive value; compared to controls with 97 % specificity, 71% positive predictive value and 97 % negative predictive value. It concluded that VAS stimulated fetal biophysical profile is a reliable means of fetal surveillance. Bur in our study each parameter of rBPP was analyzed and sensitivity, specificity was detected for each of them and rBPP was equally effective as MBPP.

Another similar study done by Akshay Prabhu, N Mahale and Ajit Mahale on correlation between full biophysical profile and rapid biophysical profile in antepartum fetal surveillance in 2017 proved that rBPP is superior with a sensitivity

of 71.42 %, specificity of 87.05% and negative predictive value of 96.80%.and thus can be used a screening test for high risk pregnancies.

In our study, compared to Modified biophysical profile, Rapid biophysical profile has 83 % sensitivity, 94 % negative predictive value and 86% accuracy in group I and 92% sensitivity and 91% accuracy in group II in detecting adverse perinatal outcome. This assures that whenever this profile is normal, there is wellbeing of the fetus. Abnormal AFI or sound provoked fetal movements and fetal nonreactivity on stimulation indicates fetus is at jeopardy, which is also supported by high rate of negative predictive value. Prompt delivery should be expedited once there is abnormal AFI or SPFM or both or either and an equivocal test requires back up test.

Our present study has demonstrated a correlation between RBPP and MBPP and has shown superiority of RBPP to NST with shorter duration of time. The reliability of the test included the fact that

a. Baseline characteristics of both the groups are same
b. Both the tests are performed on all the patients in both the groups
c. FHR tracings were interpreted by the same person in both the group of patients
d. Sample was adequate to detect the power of the test
e. Intrapartum fetal distress was used as end point, depending on both modified BPP and rapid BPP findings.[10]

TABLE NO 17: COMPARISON OF RESULTS WITH OTHER STUDIES:

AUTHOR	METHOD		RESULTS	
			Sensitivity	**Specificity**
1.SOOD ATUL KUMAR[9]	Evaluate vibroacoustic stimulation with USG and modified biophysical profile	rBPP	100%	100%
		BPP	66.7%	99%
AMIR SHEIKH et al[1]	Compare biophysical profile and modified biophysical profile	MBPP	55.6%	96.3%
		BPP	70.8%	93.4%
AKSHAY PRABHU et al[32]	Correlation between full biophysical profile and rapid biophysical profile	RBPP	71.4%	87.3%
OUR STUDY	Compare Rapid biophysical profile with Modified biophysical profile	**Group I**		
		rBPP	83%	79%
		MBPP	75%	89%
		Group II		
		rBPP	92%	91%
		MBPP	83%	89%

Phattanachindakun et al when conducted a study on correlation between full biophysical profile and rapid biophysical profile, they could conclude that there is a good correlation among the two with a significant P value. rBPP was significantly superior in terms of correlation with full biophysical profile (r_s = 0.67 vs 0.33) and the duration of NST was 18 times more than that required for rapid biophysical profile.

When only pregnancy induced hypertension was used as the risk factor and comparison was made between biophysical profile and modified biophysical profile by Shaikh et al, MBPP proved to be superior with a specificity of 96% and a positive predictive value of 72%.

In our study intrapartum fetal assessment carried out by MBPP has sensitivity 75%, Specificity 89% with positive predictive value of 69% and negative predictive value 92% with 86% accuracy in group I. Compared with RBPP whose sensitivity is 83%, specificity 79% with positive predictive value of 56% and negative predictive value of 94% with accuracy of 80%.

The same when analyzed in group II subjects MBPP has sensitivity 83%, Specificity 89% with positive predictive value of 50% and negative predictive value 98% with 88% accuracy. Compared with RBPP whose sensitivity is 92%, specificity 91% with positive predictive value of 58% and negative predictive value of 99% with accuracy of 91%.

The theoretical disadvantage of RBPP is that FHS deceleration with poor outcome cannot be detected. Rare cases of variable decelerations with normal AFI can be missed in these cases and the conventional NST proves to be beneficial.[10] Some studies have also reported cases of fetal decelerations on VAS application.[31]

Conventional MBPP uses Ultrasound and NST machine. Both these machines are kept in two different places and require 20min minimum for NST and about 3-5 min for AFI estimation. But in Rbpp all can be done in one machine and saves time and is equally efficient.

Irrespective of the type of admission test, all patients in labor require strict intrapartum fetal monitoring to detect fetal distress due to cord accidents, abruption etc which can happen in due course and does not rely on the admission test and results. Regarding safety of acoustic stimulation, studies have been done on hearing loss following in utero exposure and have found no adverse effects.[12]

CONCLUSION

Rapid biophysical profile has equal sensitivity and specificity as Modified biophysical profile in detecting poor perinatal outcome in high risk as well as low risk patients. As all the components of rapid biophysical profile can be seen by ultrasound machine with help of vibroacoustic stimulation in a single setting, it reduces the testing time.

It is a simple test which does not require an experienced person to interpret the results. It is an effective screening test for fetal assessment in busy obstetric centre.[8,32]

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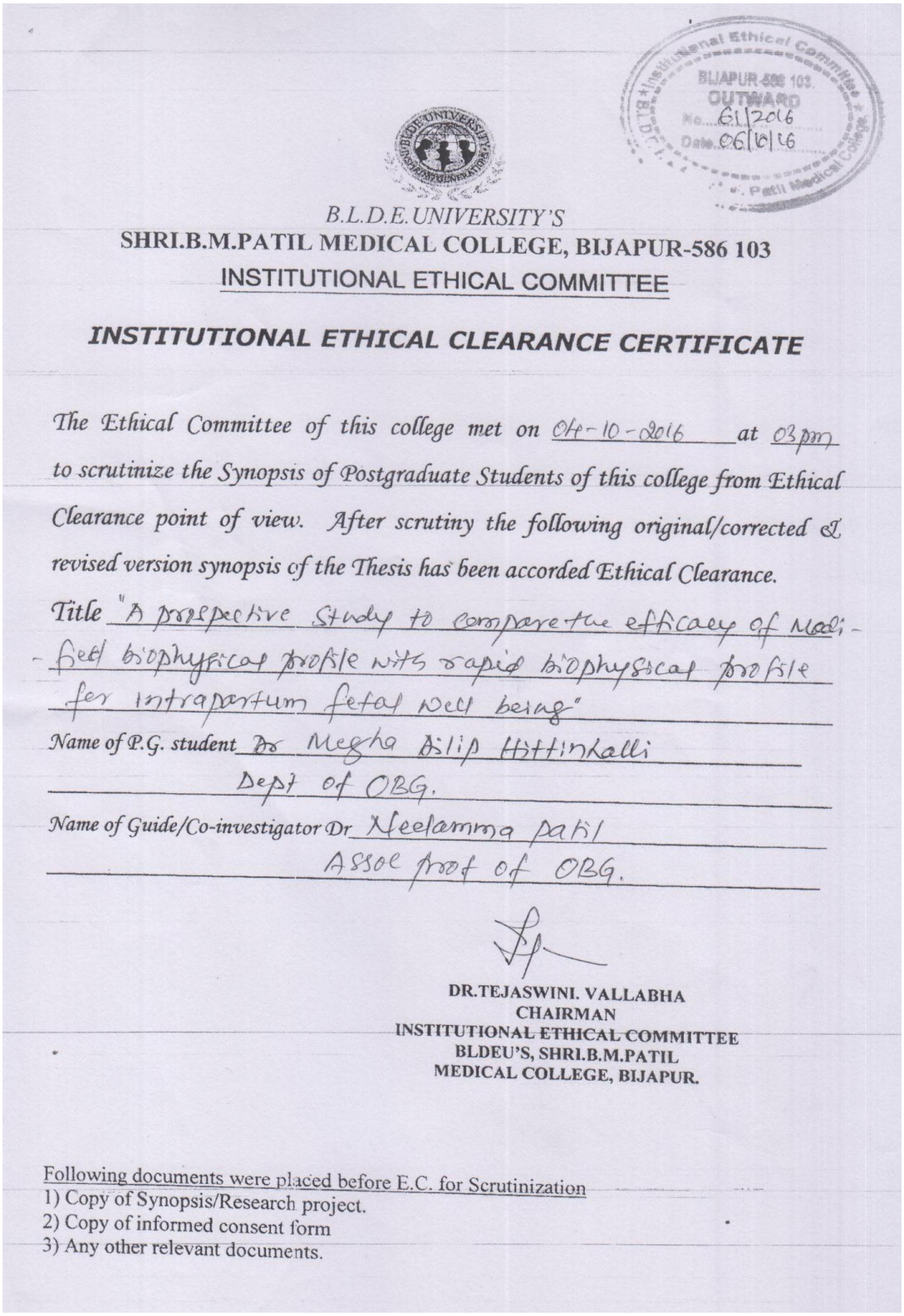
ANNEXURES

ETHICAL CLEARANCE CERTIFICATE



B.L.D.E. UNIVERSITY'S
SHRI.B.M.PATIL MEDICAL COLLEGE, BIJAPUR-586 103
INSTITUTIONAL ETHICAL COMMITTEE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 04-10-2016 at 03pm to scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected & revised version synopsis of the Thesis has been accorded Ethical Clearance.

Title "A prospective study to compare the efficacy of Modified biophysical profile with rapid biophysical profile for intrapartum fetal well being"

Name of P.G. student Dr Megha Dilip Hittinkalli
Dept of OBG.

Name of Guide/Co-investigator Dr Neelamma patil
Assoc prof of OBG.

DR.TEJASWINI. VALLABHA
CHAIRMAN
INSTITUTIONAL ETHICAL COMMITTEE
BLDEU'S, SHRI.B.M.PATIL
MEDICAL COLLEGE, BIJAPUR.

Following documents were placed before E.C. for Scrutinization
1) Copy of Synopsis/Research project.
2) Copy of informed consent form
3) Any other relevant documents.

SAMPLE INFORMED CONSENT FORM

TITLE OF THE TOPIC	**:**	"A PROSPECTIVE STUDY TO COMPARE EFFICACY OF MODIFIED BIOPHYSICAL PROFILE WITH RAPID BIOPHYSICAL PROFILE FOR INTRAPARTUM ASSESSMENT OF FETAL WELL BEING"
DURATION OF STUDY	:	FROM OCT 2016 TO OCTOBER 2017.
PRINCIPAL INVESTIGATOR	:	Dr. MEGHA DILIP HITTINHALLI POST GRADUATE, DEPARTMENT OF OBSTETRICS AND GYNECOLOGY, B.L.D.E.UNIVERSITY'S, SHRI B.M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH VIJAYPUR – 586103, KARNATAKA.
PG GUIDE NAME	:	Dr. NEELAMMA PATIL. ASSOCIATE PROFESSOR DEPARTMENT OF OBSTETRICS AND GYNECOLOGY, B.L.D.E.UNIVERSITY'S, SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH, VIJAYPUR – 586103, KARNATAKA.

PURPOSE OF RESEARCH

I have been informed that this will be a prospective study to compare the efficiency of modified biophysical profile with rapid modified biophysical profile in patients admitted to BLDE University's Shri B.M. Patil Medical College Hospital & Research Centre, Vijayapur, and Karnataka.

I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice for either being included or not in the study.

PROCEDURE

I/my ward have been explained that I will be a part of this study. My history and physical findings will be recorded and evaluated in a systematic way. I/my ward will undergo AFI measurement and VAST response on USG and NST, I may be asked for follow-up.

RISK AND DISCOMFORTS

I/my ward understand that this procedure does not have any proved major risks, but if any side effects occur, I will be given appropriate care and treatment.

BENEFITS

I/my ward understand that this study will help in reducing the testing time and prove whether it can be a good predictor of perinatal outcome.

CONFIDENTIALITY

I/my ward 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 of BLDE University's Shri .B. M .Patil Medical College. 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 securely**.** If the data are used for publication in the medical literature or for teaching purpose no names will be mentioned**.** I understand that the relevant designated authority are permitted to have an access to my medical records and to the data produced by the study for audit purpose. However, they are required to maintain confidentiality**.**

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time. Dr Megha Dilip Hittinhalli is available to answer my questions or concerns. I/my ward understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this 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 and that a copy of this consent form will be given to me for careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I/my ward understand that my participation is voluntary and 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/my ward also understand that Dr. Megha Dilip Hittinhalli will terminate my participation in this study at any time after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly to my participation in this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation will 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 this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Date: Dr. Neelamma Patil (Guide) Dr. Megha Dilip Hittinhalli (Investigator)

STUDY SUBJECT CONSENT STATEMENT:

I/my ward confirm that, Dr. Megha Dilip Hittinhalli has explained to me the purpose of research, the study procedure, that I will undergo and the possible discomforts as well as benefits that I may experience.

I/my ward have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give consent to participate as a subject in this research project.

_____ _____

(Participant) Date

_____ _____

(witness to signature) Date

PROFORMA

Name: IP No.

Age: Case no.

Address: Contact no.

DOA: DO study:

Chief complaints:

OBSTETRICS HISTORY: ML: OB Score:

Details:

Menstrual history: L.M.P.: E.D.D: POG:

USG – ( ) E.D.D: POG:

Corrected E.D.D:

Past History:

Family History:

Personal History: Diet: Appetite: Sleep:

Bowel/Bladder:

General Physical Examination:

Pallor/icterus/cyanosis/clubbing/pedal edema/lymphadenopathy:

Pallor: P.R.: B.P.:

Temperature: Height: Weight:

Breast: Thyroid: Spine:

Systemic Examination: C.V.S R.S:

Per Abdomen:

Fundal height(GA):

Presentation:

Symphysiofundal height:

Auscultation: FHS:

Fetal liquor ratio (clinical):

Per speculum:

Per vaginal examination:

DIAGNOSIS:

INVESTIGATIONS:

Hb%: TC: DC: PC: BT: CT:

Urine Routine:

PIH Profile: LFT –

RFT –

PT: APTT: INR:

USG: Gest, Age- Anomalies- EFW-

Placental Location: Fetal growth: oligo:

Any others:

TEST RESULTS:	YES	NO
AFI (USG) >5cm:	☐	☐
CTG Reactive:	☐	☐
SPFM:	☐	☐
FHR ACCELERATIONS ON USG:	☐	☐

Repeat test results if don't deliver within 24 hours:	YES	NO
AFI (USG) >5cm:	☐	☐
CTG Reactive:	☐	☐
SPFM:	☐	☐
FHR ACCELERATIONS ON USG:	☐	☐

HIGH RISK FACTOR:

OUTCOME MEASURES:

PREGNANCY OUTCOME:

Mode of delivery: indication:

Date of delivery:

Time of delivery:

PERINATAL OUTCOME:

Weight of baby:

Sex of baby:

Apgar score: 1min:

5min:

NICU admission:

Duration of NICU admission:

Perinatal mortality:

REMARKS:

KEY TO MASTER CHART

CNo	- Case number
GA	- Gestational age
Ob score	- Obstetric score
Primi	- Primigravida
Prev abor	- Previous abortion
Prev IUD	- Previous intrauterine death
Multi	- Multigravida
PE	- Preeclampsia
IUGR	- Intrauterine growth retardation
Mod	- Moderate
GHTN	- Gestational hypertension
Oligo	- Oligohydramnios
GDM	- Gestational diabetes
Pregest	- Pregestational diabetes
AFI	- Amniotic fluid index
CTG	- Cardiotogography
VAS	- Vibroacoustic stimulation
SPFM	- Sound provoked fetal movement

MBPP	- Modified biophysical profile
rBPP	- Rapid biophysical profile
AG 1	- Apgar at 1 minute
AG 2	- Apgar at 5 minutes
NICU	- Neonatal intensive care unit
Perin	- Perinatal
Neo	- Neonatal