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A Prospective Study to Know the Role of Modified Biophysical Profile in Predicting the Maternal and Fetal Outcome in High-Risk Pregnancies

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ABSTRACT
High-risk pregnant women have an increased risk of maternal and neonatal morbidity and mortality. Antepartum fetal surveillance is important and should be effective in such conditions. Modified biophysical profile (MBPP) is the method of antepartum surveillance which comprises cardiotocography and amniotic fluid index. AFI is a marker of long-term placental function and NST is a marker of short-term fetal condition. This study aims to assess the role of Modified Biophysical Profile in high- risk pregnancies and assess perinatal outcomes and study the impact of NST and AFI individually in high-risk pregnancies. It is a prospective cohort study conducted on 372 ANC patients with high-risk factors who were evaluated with modified biophysical profile 37 weeks onwards with a non-stress test (NST) for 20 minutes and amniotic fluid index (AFI) with 4 quadrant technique. High-risk pregnancies include preeclampsia, IUGR, oligohydramnios, postdated pregnancy, etc. and various parameters were assessed to determine perinatal and maternal morbidity. All parameters were statistically analyzed. The above study states that the need for LSCS, intrapartum fetal distress, meconium-stained liquor, APGAR score, need for neonatal resuscitation and perinatal morbidity were higher in cases with abnormal MBPP. MBPP is an easy, cost-effective and time-saving measure and hence can be used as a primary antepartum fetal surveillance test to predict perinatal outcomes and provide timely intervention in high-risk pregnancies.

INTRODUCTION

Motherhood is an experience, one filled with a spectrum of emotions. Though a joyful event, it is not always smooth sailing! It is true especially in recent years, as there has been an overall increase in complicated and precious pregnancies. With the acceptance of small family norms, it has become necessary that every wanted conception should successfully end in the birth of a viable healthy baby. To ensure this, close monitoring for the assessment of fetal well-being is required especially for high-risk pregnancies. A high-risk pregnancy is defined as one complicated by a factor or factors adversely affecting the pregnancy outcome (maternal, perinatal, or both). High-risk pregnancy threatens the health or life of the mother or her fetus. It often requires specialized care from specially trained healthcare providers. Some pregnancies become high risk as they progress, while some women are at increased risk for complications even before they get pregnant for a variety of reasons. Early detection and effective management of high-risk pregnancies can contribute substantially to the reduction of maternal and fetal adverse outcomes. 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. The process of birth is the most dangerous journey an individual undertakes[1]. The major goals of antepartum fetal assessment are to determine the presence or absence of fetal asphyxia and when present, to estimate the degree of fetal compromise to strike the clinical balance between the risk of continuing in utero life (conservative management) and the risk associated with delivery (interventional management). The fetal Biophysical Profile is one of the most widely accepted tests in the assessment of fetal well-being in such high-risk cases. The original Biophysical Profile was described by Manning[2], which includes the study of five variables namely:

- 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) was suggested by Nageotte et al4 and it combines the Non-stress test (NST) as a short-term marker of fetal status and the Amniotic Fluid Index (AFI) as a marker of long-term placental function. It is easier to perform and less time-consuming than the complete Biophysical Profile or contraction stress test. Also, MBPP is considered to be as effective as a complete Biophysical Profile. Hence, this study uses the Modified Biophysical Profile as a primary surveillance test in high-risk pregnancies to study its effectiveness in predicting perinatal outcomes.

Aims and Objectives:

- To evaluate the efficacy of Modified Biophysical Profile (Non-Stress Test+Amniotic Fluid Index) as a practical method for antenatal fetal surveillance.
- To correlate Modified Biophysical Profile scoring in high-risk pregnancies with perinatal outcome in terms of.
- Meconium staining of the amniotic fluid.
- Evidence of fetal distress in labor.
- Operative delivery for fetal distress.
- Apgar score at 5 minutes.
- Perinatal morbidity (Admission to Neonatal Intensive Care Unit).
- Perinatal mortality.

MATERIALS AND METHODS

The present prospective cohort study was conducted in the Department of Obstetrics and Gynecology, GBH American Hospital and Medical College, Udaipur from September 2022 to December 2023. The study group comprised high-risk pregnancies at term attending antenatal clinic and those admitted in the antenatal ward.

Inclusion Criteria:

- Pregnant females of 18 years of age and more.
- High-risk Singleton pregnancies more than 37 weeks of gestation.
- Hypertensive disorders in pregnancy.
- Bad obstetric history.
- Post dates.
- Gestational Diabetes mellitus/overt diabetes.
- Hypothyroidism.
- Oligohydramnios.
- Anaemia.
- IUGR.
- Rh incompatibility.
- Heart disease complicating pregnancy.

Exclusion Criteria:

- Gravid women with gestational age less than 37 weeks.
- Fetuses with congenital anomalies.
- Intrauterine fetal demise.
- Multifetal pregnancies.
- Previous LSCS.
- Patient refusal or inability to provide informed consent.

Sample Size Estimation: Different recent published studies from India suggest that the prevalence of High-Risk Pregnancies is 37%[5].

By using Cochran's Formula

$$n = \frac{Z^2pq}{d^2}$$

Where n sample size

z = level of confidence

p=expected prevalence or proportion d = precision rate

Here by taking z=1.96 approx., level of confidence of 95% p= 37% (0.37) d = 5% (0.05)

$$n = \frac{4pq}{d^2} = \frac{4X0.37X0.63}{(0.05)^2} = 372$$

Sampling Techniques:

Method of Collection of Data: After taking written and informed consent and fulfilling the inclusion criteria, patients were included in the study. Ethical approval was obtained from the Institutional Review Committee of National Academy of Medical Sciences.

Methods of Study: A detailed history of the pregnant women included in the study was taken and a thorough clinical examination including recording of vital parameters and systemic and obstetric examination was carried out at booking or admission. Patients were registered as booked and unbooked cases during admission. All preliminary investigations including ultrasound were done. The risk factors for which the patient was included were noted. The patients were evaluated with the modified biophysical profile consisting of NST recording for 20 minutes, followed by Amniotic Fluid Index measurement using the four-quadrant technique. Based on the findings of CTG and AFI, they were further divided into 4 categories- reactive CTG and normal AFI, non-reactive CTG and normal AFI, reactive CTG and abnormal AFI, and non-reactive CTG and abnormal AFI. They were then divided into two arms, normal MBPP and abnormal MBPP. Reactive CTG with normal AFI was kept in normal MBPP and the remaining 3 categories were kept in abnormal MBPP arm. If CTG was non-reactive and AFI less than 5 were immediately considered for delivery. Patients with normal test results were allowed to begin labor spontaneously except when delivery was indicated for maternal and obstetric complications. All the patients were closely watched during labor.

Endpoints for assessment of the outcome of pregnancy:

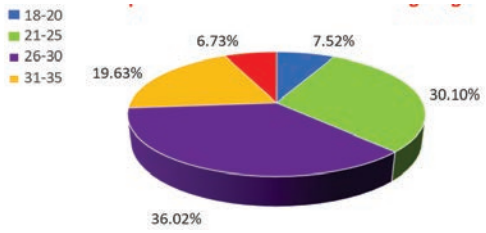
- Thick meconium staining of liquor.
- 5 minute Apgar score.
- NICU admissions.
- Perinatal morbidity.
- Perinatal mortality.

The details like name, age, I.P. No., risk factor, gestational age at delivery, mode of delivery, outcome of delivery, with the details of the prenatal events were noted down in proforma. The details in the proforma were entered into a master chart and various statistical analyses were done.

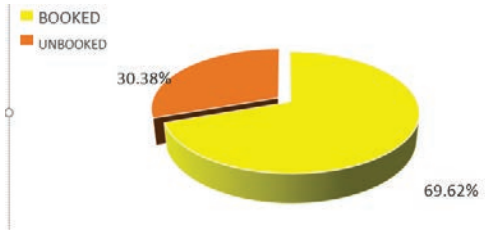
Statistical Analysis: Descriptive statistics such as frequencies and percentages for categorical variables were determined. Association between variables was analyzed by using the Chi-Square test for categorical variables with a p-value less than 0.05 considered statistically significant.

RESULTS AND DISCUSSIONS

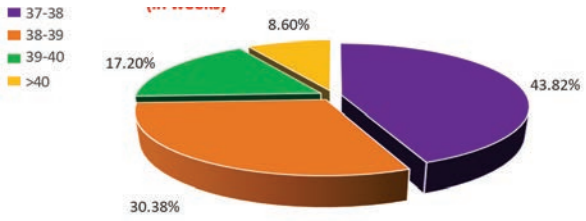
In the present study, out of 372 cases, the majority (36%) belonged to the age group of 26-30 years and only 25 (6.73%) patients in the study group were aged >35 years. 69.6% (259) cases were booked and 30.38% (113)cases were unbooked and a majority (43.8%) among them belonged to the gestational age between 37- 38 weeks and those whose gestational age was >40 weeks constituted only 8.6% of the patients. Most cases were multigravida (55.4%) with 44.6% being primigravidas.



Graph 1: Distribution of Cases According to Age

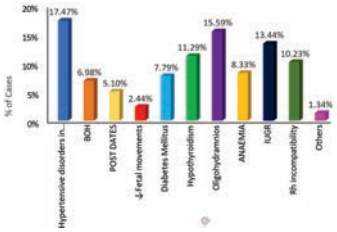


Graph 2: Distribution of Booked and Unbooked Cases



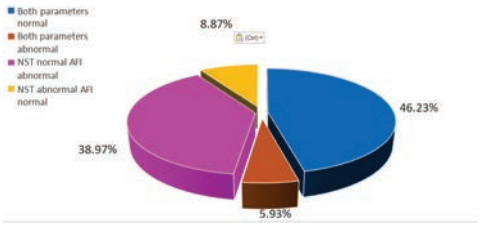
Graph 3: Distribution of Cases According to Gestational Age (in Weeks)

Graph 4: Distribution of Cases According to Gravida



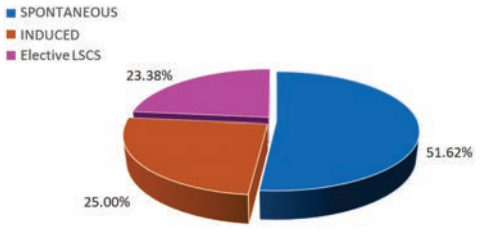
Graph 5: Distribution of Cases According to High-Risk Factors

The risk factors with which the patients presented were., hypertensive disorders in pregnancy which included mild and severe pre-eclampsia and gestational hypertension (17.47%), which formed the majority of cases followed by oligohydramnios (15.5%), and IUGR (13.44%).

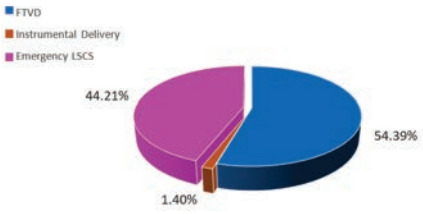


Graph 6: Distribution of Cases According to MBPP Test Results

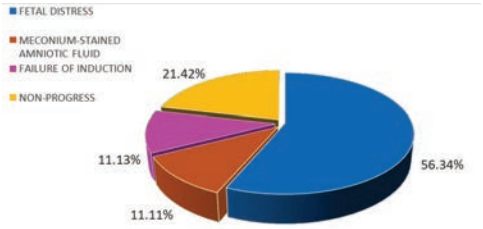
Among the modified biophysical profiles done in 372 patients both parameters (NST and AFI) were normal in 172 patients (46.23%), both parameters were abnormal in 22 patients (5.93%), NST was reactive and AFI was inadequate in 145 patients (38.97%), AFI was adequate and NST was non-reactive in 33 patients (8.8%). Out of the total, 192 (51.6%) were managed for spontaneous progression of labor and 93 (25%) patients were induced depending on the MBPP score and Bishop score.



Graph 7: Distribution of Plan of Management in Total Patients



Graph 8: Distribution of Cases According to Mode of Delivery



Graph 9: Distribution of Cases Based on Indications for Emergency LSCS

However, 87 (23.38%) patients were electively taken up for cesarean section. Out of the 285 patients who were managed for spontaneous progression of labor and were induced, 155 (54%) had a full-term vaginal delivery with 4 (1.4%) patients undergoing instrumental delivery. However, the remaining 126 (44%) patients were taken up for emergency cesarean section because of various high-risk factors, fetal distress being the most common one seen in 56% (71 out of 126) cases.

Among the modified biophysical profiles done in 372 patients when both parameters (NST and AFI) were normal (171 patients), 53 (30.9%) patients underwent LSCS and 119 (69%) patients had a vaginal delivery, when both parameters were abnormal (22 patients) all 22 (100%) patients underwent LSCS when NST was reactive and only AFI was inadequate (145 patients) 50 (34.5%) patients had vaginal delivery and 95(65.5%) of them underwent LSCS, when AFI was adequate and NST was non-reactive(33 patients) 31 patients (93.9%) underwent LSCS and 2 (6%) patients had a vaginal delivery. The P-value in each of these cases was <0.001 which was highly significant (Table 1). This suggests that the cesarean section rate is high when either both parameters are abnormal or when NST is abnormal.

Thick meconium staining of liquor was observed among 38 out of 372 cases. When both parameters (NST and AFI) were normal, out of 172 patients 3 (1.75%) patients had thick meconium-stained liquor, when both parameters were abnormal 11(50%) out of 22 patients had thick meconium-stained liquor, when NST was reactive and AFI was inadequate 17 patients of 145 had thick meconium-stained liquor and when AFI was adequate and NST was non-reactive 7(21%) patients had thick meconium-stained liquor.

Among the 372 cases, an APGAR score of <7 at 5 minutes was observed among 25 cases. When both parameters (NST and AFI) were normal, 4 (2.3%) patients had an APGAR score of <7 and 168 (98.2%) patients had APGAR >7 (p-value 0.003). When both parameters were abnormal, 12 (54.5%) patients had an APGAR score of <7 and 10 patients (45.5%) had APGAR >7 with a highly significant p-value of <0.001. When NST was normal and AFI was abnormal 6 (4.1%) patients had an APGAR score of <7 (p-value 0.06) and when AFI was normal and NST was abnormal 3 (9%) patients had an APGAR score of <7 (p- value 0.52) (Table 2).

Table 1: Correlation of MBPP Results with Mode of Delivery

MBPP test results (No. of cases)	LSCS (n=201)		Vaginal Delivery (n=171)		
	Number	%	Number	%	P- value
Adequate AFI and Reactive NST	53	30.9	119	69.1	<0.001 (HS)
Inadequate AFI and Non- Reactive NST	22	100	0	0	<0.001 (HS)
Reactive NST and Inadequate AFI	95	65.5	50	34.5	<0.001 (HS)
NST abnormal AFI normal	31	93.9	2	6.1	<0.001 (HS)

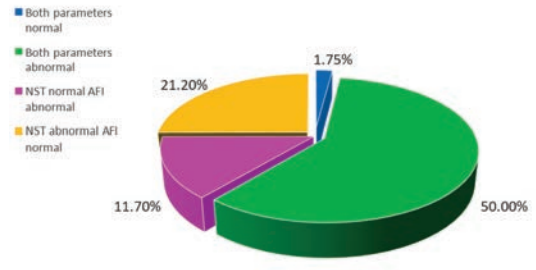
HS= Highly Significant

Table 2: Correlation of MBPP Result with APGAR score at 5 minutes (N= 372)

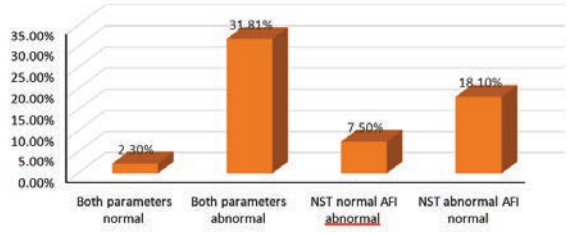
MBPP Test Results (No. of cases)	APGAR <7 (n=25)		APGAR >/=7 (n=347)		
	Number	%	Number	%	P- value
Adequate AFI and Reactive NST	4	2.3	168	98.2	0.003 (S)
Inadequate AFI and Non- Reactive NST	12	54.5	10	45.5	<0.001 (HS)
Reactive NST and Inadequate AFI	6	4.1	139	95.8	0.06 (NS)
NST abnormal AFI normal	3	9.09	30	90.9	0.52 (NS)

Table 3: Correlation of Perinatal Mortality with MBPP Test Result and Risk Factors

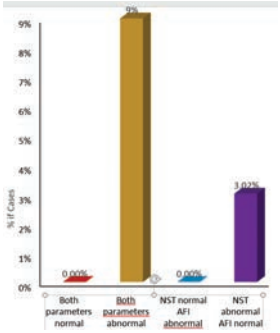
RKFactor	NST	AFI	GA In Weeks	WT in kg	Cause of Death
IUGR	0	8	37	0.900	low birth weight
Oligohydramnios	0	2-3	37	2.56	Meconium aspiration
IUGR	0	1	37	1.00	Low birth weight with sepsis



Graph 10: Correlation of MBPP Results with Staining of Liquor Meconium



Graph 11: Distribution of Perinatal Morbidity Associated with MBPP Test Results



Graph 12: Distribution of Perinatal Mortality Associated with MBPP Results

When both the parameters (NST and AFI) were normal among 172 patients, perinatal morbidity was present only in 4 cases (2.3%), when both parameters were abnormal 7 out of 22 cases (31.81%) had perinatal morbidity. Out of 145 cases where NST was normal and AFI was abnormal, perinatal morbidity was present in 11(7.5%) cases and when AFI was normal and NST was abnormal 6 cases (18.1%) out of 33 had perinatal morbidity. This suggests that whenever both parameters were abnormal or even one was abnormal there was an increased incidence of perinatal morbidity. In our study, there were 3 perinatal mortalities out of the total 372 cases. All the cases were term pregnancies of 37 weeks of gestation. Among the two cases with IUGR as the risk factor, low birth weight with sepsis was the cause of death. However, in the case of oligohydramnios as the risk factor, the cause of death was meconium aspiration. MBPP was abnormal in all the 3 cases (Table 3).

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 a primary surveillance test for high-risk patients. The two parameters are the Non-Stress Test (NST), which is a short-term marker of fetal status and Amniotic Fluid Index (AFI), a long-term marker of placental function. The study group consisted of 372 pregnant females with high-risk factors in each of them with a majority of them being booked cases (70%) in the age group of 26-30 years (36%). However, in studies conducted by Anusha[3,4,5], Shalini[6], Nalamaru and Reddy[7] and Jha S and Dangal[8], the majority of the patients were up to the age of 25 years. The majority of our study population had a gestational age between 37- 38 weeks (43.8%) and the least being post-dated pregnancies (8.6%) which was comparable with the study conducted by Shalini[6]. However, in studies conducted by Jha S and Dangal[8] and Borade[9], the

majority of the cases were above 40 weeks of gestation but none were post-term. About 55% of cases in our study were multigravidas and 45% were primigravidas. This was comparable with the studies conducted by Anusha[5] and Shalini[6] where 42% and 44% of patients were primigravidas respectively. The major risk encountered in our study was hypertensive disorders of pregnancy which was seen in 17% of the cases. In the studies conducted by Anusha[5] and Shalini[6], similar to our study, hypertension was the most predominant risk factor seen in 46% and 35% of cases respectively. The second most common risk factor was oligohydramnios (16%) which was also seen in the study conducted by Shalini[6], however being the most common risk factor in the study conducted by Begum[10]. However, post-datism was the most common risk factor in studies conducted by Jha S and Dangal[8] and Borade[9].

The MBPP test conducted in 372 patients was normal in 46.2% of cases, 5.9% of tests were abnormal, NST reactive and AFI inadequate in 38.9% of cases and NST non-reactive and AFI adequate in 8.8% of cases. Similar results were seen in studies conducted by Shalini[6], Borade[9] and Begum[10] i.e. majority of the test results were normal in 54%, 67% and 76% of cases respectively and both parameters were abnormal in 9%, 6% and 5% cases respectively. In our study, out of 372 patients, the majority (192,51.6%) were managed for spontaneous progression of labor and 93(25%) were induced. However, in studies conducted by Nalamaru and Reddy[7] and Borade[9], 22% and 29.3% respectively were managed for spontaneous progression and 27% and 71% respectively were induced. In our study, 87(23.38%) patients underwent elective LSCS which was comparable to the study conducted by Nalamaru and Reddy[7] in which 24% of patients underwent elective LSCS. Out of all the patients who were managed for spontaneous progression and induced, 54% had full-term normal delivery which was comparable to studies conducted by Anusha[5], Shalini[6], Nalamaru and Reddy[7] and Borade[9] in which 51%, 67%, 49% and 60% respectively underwent vaginal delivery. Only 1.4% of cases in my study had instrumental delivery which was comparable to 3% of patients undergoing instrumental delivery in the study conducted by Borade[9]. About 44% of patients were taken up for emergency LSCS in our study which was comparable to the studies conducted by Anusha[5] and Borade[9] in which 33% and 37% respectively underwent emergency LSCS. In our study, the incidence of emergency LSCS for fetal distress was very high (56.3%) which was similar to studies conducted by Shalini[6] and Borade[9]. Hence continuous electronic fetal monitoring should be done in anticipation of fetal distress for cases with abnormal MBPP. It was seen that with normal MBPP results (both parameters normal), the majority of the patients (70%) delivered vaginally and only 30% underwent LSCS and vice versa was seen with abnormal MBPP results. However, in cases where NST was reactive but AFI was inadequate, about 66% of patients underwent LSCS and only 34% had a vaginal delivery and in patients having non-reassuring NST but adequate AFI, about 94% of patients were taken up for LSCS and only 6% had a vaginal delivery. The results were comparable with studies conducted by Anusha[5] and Borade[9]. This shows that when MBPP was normal, the mode delivery was not affected, whereas when it was abnormal, the operative intervention was increased showing the ability of the MBPP to predict fetal compromise. Hence, patients with abnormal MBPP should be meticulously monitored and delivered where services for emergency LSCS are available round the clock. When studied concerning the MBPP, showed that whenever both the test results were abnormal, we had 50% cases showing thick meconium. When the test results were abnormal concerning only NST, only 21% had thick meconium. When the test results were abnormal concerning only AFI, 11% of patients had thick meconium. Hence from the above results, it is seen that the incidence of perinatal morbidity concerning meconium is increased when both MBPP parameters were abnormal and more so when NST was abnormal compared to AFI abnormal when individual parameters were considered. The results are similar to the studies by Anusha[5] and Borade[9]. An APGAR score of <7 was seen in only 2% of cases with normal MBPP scores. But when both parameters were abnormal, 55% of cases had a score <7. When NST was normal but AFI abnormal, 4% of cases had an APGAR score of <7 and when NST was abnormal and AFI normal, 9% of cases had a low score. This indicates that compared to normal MBPP when MBPP is abnormal or when any one of the parameters (NST and AFI) is abnormal there is an increased incidence of low APGAR score. P- value was significant (<0.001) with normal MBPP and with both abnormal MBPP (both parameters abnormal). This signifies the value of MBPP as an antepartum surveillance tool to predict perinatal morbidity.

Similar results were seen in a study conducted by Shalini[6]. The parameters used to assess the perinatal outcome were thick meconium- stained liquor, APGAR score <7, NICU admission, perinatal morbidity and perinatal mortality. In our study, those babies requiring NICU admission were taken as having perinatal morbidity. In our study, 28 babies were admitted to NICU. When MBPP was abnormal (both parameters abnormal) 7 cases (32%) had perinatal morbidity and 9% had perinatal mortality. In 145 cases when only AFI was abnormal and NST normal, there were 11 cases (7.5%) with perinatal morbidity and none with perinatal mortality. Among 33 cases with abnormal NST and normal AFI, 6 cases (18.1%) had perinatal morbidity and 1 case (3%) with perinatal morbidity. With normal MBPP results, there was only 2.3% morbidity and no perinatal mortality. When both parameters were abnormal, there was an increased

incidence of both perinatal morbidity and mortality. When only AFI is, abnormal there is an increase in the incidence of perinatal morbidity and there is no perinatal mortality and when only NST is, abnormal there is an increase in both perinatal morbidity and mortality. These results were comparable with the study of Shalini[6]. In our study, there were 3 neonatal mortalities. Two cases were of IUGR babies and the third one was of severe oligohydramnios. All the 3 mortalities had an abnormal MBPP score. The fetus with inadequate AFI has statistically more chances of having perinatal morbidity as AFI is a marker of long-term fetal and placental condition which is comparable to Rezaie Kahkhaie[11]. Hence, all fetuses with abnormal MBPP and more so with oligohydramnios have to be delivered in centers with good perinatal care facilities, well-equipped NICUs, and efficient neonatologists.

CONCLUSION

Modified biophysical profile (MBPP) is an 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 a good perinatal outcome. At the same time, when MBPP is abnormal, it indicates that the fetus may be compromised. When considered individually, abnormal AFI was associated with an increased incidence of perinatal morbidity and abnormal NST was associated with an increased incidence of perinatal morbidity as well as perinatal mortality. MBPP can be used as a primary antepartum fetal surveillance test to predict perinatal outcomes and provide timely intervention in high-risk pregnancies. However, at times it can give a false positive or false negative result as well. The number of patients included in this study was 372. To formulate a definitive protocol, further multicentric studies with larger samples and with a multidisciplinary approach should be conducted.

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