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ORIGINAL ARTICLE

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Vibroacoustic stimulation and modified fetal biophysical profile in high risk pregnancy

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OBJECTIVE(S) : To evaluate vibroacoustic stimulated modified fetal biophysical profile in antepartum monitoring of high risk pregnancy.

METHOD(S) : In this prospective randomized controlled study 214 singleton high risk pregnancies were randomized to antepartum monitoring by either modified biophysical profile following vibroacoustic stimulation (VAS/mFBP) (Study Group n=110) or following mock stimulation (mFBP) (Control Group n=104).In modified biophysical profile fetal startle response and fetal heart acceleration under combined B and M mode ultrasonography following vibroacoustic and mock stimulation were observed. Various diagnostic values in predicting adverse perinatal outcome were compared between the two groups.

RESULTS : The maternal demographic factors, gestational age at the inception of monitoring, and primary indication for monitoring were similar between the two groups. Mean testing time was significantly less in the study group, as compared to controls (4.92 $\pm$ 0.82 minutes and 7.77 $\pm$ 1.29 minutes respectively). Of the 110 fetuses in the study group subjected to VAS/mFBP, 107 (97.3%) were reactive and three (2.7%) nonreactive and there were 106 (96.4%) favorable and four (3.6%) adverse perinatal outcomes. Of the 104 fetuses in the control group subjected to mock stimulation (mFBP); 97 (93.3%) were reactive and seven (6.7%) nonreactive and there were 96 (92.3%) favorable and eight (7.7%) adverse perinatal outcomes. The sensitivity, specificity, positive and negative predictive values and accuracy in the study group were 75%, 100%, 100%, 99.1 %, and 99% respectively as compared to 71.4%, 97.9%, 71.4%, 97.9 % and 96.2% respectively in the control group.

CONCLUSION(S) : Vibroacoustic stimulated modified fetal biophysical profile (VAS/mFBP) as a primary means of surveillance in high risk pregnancy is a reliable diagnostic approach.

Key words: vibroacoustic stimulation, modified fetal biophysical profile, high risk pregnancy

Introduction

Fetal biophysical profile (FBP) is a well established method of antepartum surveillance in high risk pregnancy. Classical profile with all parameters takes a long time to perform especially if a fetus with decreased biophysical activity is being examined. This may not be practical in a resource constraint setting. To obviate this difficulty various modifications have been proposed, which take less time to perform without compromising the diagnostic efficiency [1-5]. Observation of fetal startle response to vibroacoustic stimulus was found to be associated with a FBP score of 8 and above [6]. Similarly nonstress test (NST) component has been either selectively used when other biophysical parameters are abnormal [1] or altogether excluded [7]. Estimation of amniotic fluid either by amniotic fluid index (AFI) or single largest amniotic fluid pocket method along with NST has been included in some modified profiles [8-9]. Vibroacoustic stimulation has been reported to wake up the fetus from sleep cycles and hence reduce false positive results [10]. Moreover it also enhances visualization of fetal activity as seen on ultrasound [11]. AFI together with fetal acoustic stimulation under ultrasound M mode scanning has also been used [12]. Doppler and B mode ultrasound have been simultaneously used in which NST component is visualized in M mode along with simultaneous fetal activity assessment

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in B mode [13]. This combines the advantage of simultaneous NST and FBP with reduced testing time.

The present study was carried out to evaluate vibroacoustic stimulated modified fetal biophysical profile in antepartum monitoring of high risk pregnancy. We used a new modified biophysical profile with only two components viz., ultrasonographic observation of fetal startle response to vibroacoustic stimulation and simultaneous observation of fetal heart acceleration.

Methods

In this prospective randomized controlled study done from April 2003 to June 2005, 214 women with high risk singleton pregnancies detected amongst women attending antenatal clinic,were recruited after taking informed consent. They were randomly allocated by computer generated random numbers kept in sealed envelopes to either vibroacoustic stimulated modified biophysical profile (VAS/mFBP) or mock stimulation (mFBP). Wipro GE LOGIQ ? V4 (Wipro GE Medical Systems, Bangalore, India) machine with C36-3.5 MHz convex array probe was used. Vibroacoustic stimulation was done with EMCO vibroacoustic stimulator (EMCO Health Care Pvt Ltd, Sion, Mumbai, India) with 75 db sound intensity at 1.0 meter and frequency of 75 Hz.

For the ultrasonographic examination the women were placed in supine position with the right hip elevated by 15 degrees. The routine fetal biometric measurements were obtained at the beginning of each examination. After determining the fetal position, the fetal body was scanned continuously in the sagittal section. The depth of the field was adjusted and the fetal heart, chest and abdomen were brought into the same section. M mode was activated and the location of the marker on the fetal heart was carefully selected to get the optimal waveform. When a clear doppler waveform was seen on the screen, the image was frozen. The fetal heart rate was determined using the calipers and then the image was released. Fetal vibroacoustic stimulation was done by placing the stimulator on abdominal wall over fetal head for 3 seconds and fetal startle response was observed in combined B and M mode along with fetal heart acceleration. Fetal startle response was defined as a sudden movement of fetal extremities in response to vibroacoustic stimulus within 2 seconds after the cessation of the stimulus. Fetal heart acceleration was defined as acceleration of 15 or more beats, lasting for 15 seconds or more. If there was no fetal startle response, the stimulus was repeated at one minute intervals for a total of three stimuli. The fetal heart rate was also monitored when a deceleration or acceleration in the heart rhythm unrelated to the fetal movements was detected.

Presence of startle response accompanied by fetal heart acceleration was considered a reactive test .Absence of either or both after three stimulations was considered a nonreactive test. Reactive tests were repeated at weekly intervals for outpatients and biweekly for inpatients. Nonreactive tests with AFI >5 cm were repeated after 24 hours and if still nonreactive further evaluated for delivery. Those with AFI <5 cm were further evaluated for delivery. Results of last FBP within 7 days of delivery were correlated with perinatal outcome. Perinatal morbidity was defined as presence of at least two of the following three variables of adverse perinatal outcome; cesarean delivery for fetal distress, 5 minute apgar score <7, and admission to neonatal intensive care unit (NICU) for more than 24 hours. Various diagnostic values in predicting perinatal morbidity and mortality were compared.

Student t test was used for analysis of continuous variables. Categorical variables were analyzed by Chi square test or Fisher exact test if numbers were small. $P < 0.05$ was considered probability level to reflect significant differences. Odds ratios (OR) and 95% confidence intervals (95% CI) were calculated for categorical data. Standard 'four fold' format was used to calculate various diagnostic values. Statistical software Epi Info Version 3.2.2 (Center for Disease Control and Prevention Atlanta, Georgia, USA) was used for statistical analysis of data.

Results

There was no difference in the maternal age, parity, and gestational age at the inception of monitoring (Table 1). Similarly there was no difference in the various high risk factors amongst the two groups (Table 2). Mean testing time was significantly less in the study group, as compared to controls (4.92 ± 0.82 minutes vs 7.77 ± 1.29 minutes, $P<0.001$). Of the 110 fetuses in the study group subjected to VAS/mFBP, 107 (97.3%) were reactive and three (2.7%) nonreactive and there were 106 (96.4%) favorable and four (3.6%) adverse perinatal outcomes (Table 3). Of the 104 fetuses in the control group, 97(93.3%) were reactive and seven (6.7%) nonreactive and there were 96 (92.3%) favorable and eight (7.7%) adverse perinatal outcomes. The differences between the two groups were not significant. There were two (1.8%) perinatal deaths in the study group and in both of them the test was nonreactive. On the other hand there were three (2.9%) deaths in the control group, out of which two occurred following a nonreactive test and one following a reactive test. There was no statistically significant difference between the two groups.

Various diagnostic values in terms of adverse perinatal outcome in the study group were; sensitivity 75%, specificity

Table 1: Maternal demography.

	VAS/mFBP (N=110)	mFBP (N=104)	P
Age (years)	26.4± 4.5	25.5 ± 3.5	0.09
Parity	2.1 ± 0.9	1.9 ± 0.7	0.08
Gestational age (weeks) at inception of monitoring	35.1 ± 2.5	35.9 ± 2.1	0.59

Values are Mean ± SD

Table 2. Primary indication for monitoring (High risk factors).

Indication	VAS/mFBP (N=110)	mFBP (N=104)	P
Intrauterine growth retardation	27(24.5)	24(23.0)	0.80
Pregnancy induced hypertension	20(18.1)	22(21.1)	0.58
Bad obstetric history	18(16.3)	14(13.5)	0.55
Decreased fetal movements	15(13.6)	13(12.5)	0.80
Postdated pregnancy	10(9.0)	16(15.4)	0.15
Diabetes mellitus	06(5.4)	05(4.8)	0.83
Antepartum hemorrhage	04(3.6)	03(2.9)	0.75
Others	10(9.0)	07(6.8)	0.52

Values in parentheses indicate percentages.

Table 3. Test results and perinatal outcome.

	VAS/mFBP (N=110)	mFBP (N=104)	P	Odds Ratio (95%CI)
Testing time (minutes)	4.92 ± 0.82 [a]	7.77 ± 1.29 [a]	<0.001	
Test results				
Reactive	107 (97.3)	97 (93.3)	0.20	2.57 (0.57-15.78)
Nonreactive	03 (2.7)	07 (6.7)		
Perinatal outcome				
Favorable	106 (96.4)	96 (92.3)	0.19	2.21 (0.57-10.31)
Unfavorable	04 (3.6)	08 (7.7)		
Perinatal deaths	02 (1.8)	03 (2.9)	0.67	0.62 (0.05-5.57)

[a] Mean ± SD, Values in parentheses indicate percentages,

100%, positive predictive value 100%, negative predictive value 99.1 %, and accuracy 99%. While in the control group they were; sensitivity 71.4%, specificity 97.9%, positive predictive value 71.4%, negative predictive value 97.9%, and accuracy 96.2 %(Table 4). Diagnostic values in terms of perinatal deaths were sensitivity 100%, specificity 100%, positive predictive value 100%, negative predictive values 100 %, and accuracy 100% in the study group and sensitivity 66.7%, specificity 99%, positive predictive value 66.7%, negative predictive value 99 % and accuracy 98% in the control group (Table 5).

Table 4: Comparison of diagnostic values in predicting perinatal morbidity.

	VAS/mFBP (n=110) (95% CI)	mFBP (n=104) (95% CI)
Sensitivity	3/4; 75%(21.9-98.7)	5/7; 71.4%(30.3-94.9)
Specificity	106/106; 100%(95.6-100)	95/97;97.9%(92.0-99.6)
Positive predictive value	3/3; 100%(31-100)	5/7;71.4%(30.3-99.6)
Negative predictive value	106/107; 99.1%(94.2-100)	95/97; 97.9(92.0-99.6)
Accuracy	99%	96.2%

Table 5. Comparison of diagnostic values in predicting perinatal deaths.

	VAS/mFBP (n=100) (95% CI)	mFBP (n=100 (95% CI)
Sensitivity	2/2; 100% (19.8-100)	2/3; 66.7%(12.5-98.2)
Specificity	108/108 100%(95.7.100)	100/101; 99.0%(93.8-99.9)
Positive predictive value	2/2 100% (19.8-100)	2/3; 66.7%(12.5-98.2)
Negative predictive	108/108 100% (95.7-100)	100/101;99.0%(93.8-99.9)
Accuracy	100	98

Discussion

Fetal biophysical profile is a reliable antepartum test for determination of fetal well being. While low scores are associated with very high perinatal morbidity and mortality, normal scores virtually assure an uncomplicated intrauterine survival for a period of 3 days to 1 week, especially if placental problems and cord accidents are excluded [14]. False-negative results in cases of subsequent fetal death reflect events that are subsequent to the last normal test result [15]. However, performing FBP sometimes takes too much time, especially if a fetus with diminished biophysical activities is being examined. Ultrasonographic observation can take up to 30 minutes, and the NST needs another 20 minutes which may have to be extended to 40 minutes when it is nonreactive.

Some modifications to the test protocol have been suggested in order to overcome the problems related to biophysical profile score like; selective NST or altogether exclusion of

NST [1,7], estimation of amniotic fluid either by AFI or single largest pocket method along with NST [8-9], or AFI together with fetal acoustic stimulation [12]. However, these short protocols have aroused objections because the diagnostic value of the whole profile is reported to be greater than that of any combination of the components [14]. Vintzileos et al[16] reported that the NST is not only a sensitive indicator of fetal condition, but that it can also select fetuses who are candidates for a cord accident and therefore should be an integral part of fetal biophysical monitoring. In the present study a modified NST was integrated into the ultrasonographic part of the FBP.

Vibroacouctic stimulation has been shown to shorten the testing period and reduce false positive results by awakening fetus from 1F or 3F states [3]. Observation of fetal startle response to vibroacoustic stimulus has been found to be associated with a FBP score of 8 [6]. In our study we have included startle response to vibroacoustic stimulation as the component for fetal biophysical dynamic assessment. Thus the modified biophysical profile in the present study integrates vibroacoustic stimulation, startle response, and NST as a one time composite fetal assessment in a much shorter testing time.

The distribution of VAS/mFBP test results viz., 97.3 % reactive and 2.7% nonreactive tests is similar to that reported by Manning [17] across a large population of high-risk pregnancies studied, but there was no difference between the two groups. Reactive test represents indirect evidence that the fetal central nervous system is anatomically and functionally intact and therefore not hypoxemic. Mortality reflects a failure of compensation, whereas immediate morbidity is a reflection of either compensation per se (e.g. low apgar score) or failure of compensation with added stress (fetal distress in labor). Both VAS/mFBP and mFBP demonstrated a high accuracy in predicting perinatal morbidity. But VAS/mFBP had a higher positive predictive value than mFBP alone (100% vs 71.4% respectively). However in predicting perinatal mortality VAS/mFBP combination was more efficient as it had a higher sensitivity (100%) and positive predictive value (100%) as compared to mFBP (66.7% and 66.7% respectively), which is similar to that reported earlier [4].

In a Cochrane review by Tan and Smyth [11] it was concluded that by reducing the number of nonreactive cardiotocography secondary to fetal sleep states and reducing the testing time, fetal vibroacoustic stimulation may help perinatal resources to be better utilized and by evoking fetal movements, it may be useful in ultrasound examination and evaluation of fetal wellbeing. However, there was insufficient evidence for recommending routine use of fetal vibroacoustic stimulation. Similarly in another Cochrane review Alfirevic and Neilson [18] concluded that, there was not enough evidence from randomized trials to evaluate the use of biophysical profile as a test of fetal well being in high risk pregnancies.

In the present study the sample size was relatively small. Larger studies with adequate power are needed to validate the efficiency of VAS/mFBP. Fetal or neonatal acidemia by fetal scalp blood/umbilical artery blood sampling was not studied as an outcome measure as the facility for the same was not available. Although AFI was not included in the mFBP as such, it was routinely assessed in all cases and was taken into consideration for further evaluation of women with nonreactive tests.

Conclusion

Because of high accuracy, ease of administration, and a shorter testing time, vibroacoustic stimulated modified fetal biophysical profile as a primary means of surveillance in high risk pregnancy is a reliable diagnostic approach.

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