A PROSPECTIVE TRIAL OF THE FETAL BIOPHYSICAL PROFILE VERSUS MODIFIED BIOPHYSICAL PROFILE IN THE MANAGEMENT OF HIGH RISK PREGNANCIES

A. Jamal[1*], V. Marsoosi [1], L. Eslamian[1] and K. Noori[2]

1) Department of Obstetrics and Gynecology, Shariati Hospital, School of Medicine, Medical Sciences/University of Tehran, Tehran, Iran

2) Department of Epidemiology and Biostatistics, School of Public Health, Medical Sciences/ University of Tehran, Tehran, Iran

Abstract- The original biophysical profile is time consuming and costly. This study was performed to compare diagnostic value of the original fetal biophysical profile to the modified biophysical profile. Patients were selected from high risk pregnancies referred for fetal assessment and were randomly assigned to two groups. The measures of outcomes were perinatal mortality, Cesarean section for abnormal test, meconium-stained amniotic fluid and 5-minute Apgar score < 7. Diagnostic values of tests were assessed in terms of the incidence of abnormal outcome. In addition comparisons between the positive and negative predictive values of each of these tests as well as the sensitivity and specificity of the tests were reviewed. A total of 200 patients were entered into the study; 104 pregnancies were managed by the original biophysical profile and 96 pregnancies by the modified biophysical profile. There were 30 abnormal (31.3%) in modified biophysical profile and 24 (23.1%) abnormal tests in original one. There was significant difference in the incidence of meconium passage between two groups. Cesarean section for abnormal tests was 27 of 30 abnormal test (90%) in modified and 22 of 24 (91.6%) in original profile that was similar in both groups. There was not significant difference in Apgar score < 7 between two groups. We did not find significant difference with comparison of the sensitivity, specificity and negative predictive value of two tests for all measures of outcome except the positive predictive value of meconium passage. Original biophysical profile is more costly and time consuming than modified one.

Acta Medica Iranica 2007; 45(3): 204-208.

Key words: Biophysical profile, Modified biophysical profile, High risk pregnancy

INTRODUCTION

The original biophysical profile defined by Manning *et al.* including five variables of breathing, movement, tone, amniotic fluid and non-stress test needs two phase testing by ultrasound and external Doppler monitor, to record fetal heart rate (1). This double testing needs more time, cost and inconvenience to the system.

The modified BPP, suggested by Nageotte *et al.*, combines the NST as a short term marker of fetal status and the amniotic fluid index as a marker of long term placental function is easier to perform and less time-consuming than the contraction stress test or the complete BPP (2). The advantages of application of

Received: 14 Jul. 2006, Revised: 27 Nov. 2006, Accepted: 3 Jan. 2007

*** Corresponding Author:**
Ashraf Jamal, Department of Obstetrics and Gynecology, Shariati Hospital, School of Medicine, Medical Sciences/University of Tehran, Tehran, Iran
Tel: +98 21 84902415
Fax: +98 21 88029396
E-mail: jamalsh@tums.ac.ir

this rapid test in a busy high risk pregnancy unit with inadequate trained personnel such as our hospital is obvious but the efficacy of collecting two variables and ignore the other variables of complete biophysical profile is still open to challenge.

To determine the efficacy of two variables (AFI and non-stress test) as powerful predictor of adverse outcomes, we designed a randomized trial to compare it with biophysical profile in terms of the sensitivity, specificity as well as the positive and negative predictive values. Determination of the sensitivity, specificity, positive and negative predictive values of fetal assessment tests has more meaningful statistical assessment than referring to the false positive and false negative rates. The question of which test is more valid in fetal well-beings is one factor this study has attempted to answer.

MATERIALS AND METHODS

The study patients were selected from those referred to the Fetal Assessment Unit of Shariati Hospital, Tehran University of Medical Sciences from January 2003 to January 2005. Both hospitalized and non hospitalized patients considered to be high risk pregnancies were included. Indications for testing for the entire sample can be seen in Table 1.

No attempt was made to control the sample on the basis of indication, gravidity, parity, or maternal age. On presentation to the testing unit those patients signing an informed consent were invited to participate in this randomized study. Once a patient had a study number for a test, it was managed according to the same test for the entire pregnancy.

All testing was performed while the patient was placed in a semi-recumbent position. Blood pressure was measured at the initiation of the test and every ten minutes thereafter. The non-stress test was performed by fetal heart Doppler monitor (HP, series 50 A) .The non-stress test was allowed to continue until either a reactive pattern was demonstrated or a 40- minute time period was exhausted. Following the non-stress test an ultrasound examination was performed by means of a curvilinear real- time ultrasound (sequoia Model 512, Acuson) with a 3.5 MH transducer. Amniotic fluid index was determined by measuring four quadrant vertical pockets and the other parameters of the biophysical profile were then evaluated according to the original system of Manning *et al.* The observation period was continued as long as it took to identify the desired variables up to maximum of 30 minutes. Simultaneous observation of the parameters was acceptable. Each variable was coded as normal or abnormal according to the criteria described by Manning et al. The entire biophysical profile was then assigned a score of 0 to 10 with a numerical value of 2 given for the presence of each variable.

Non-stress test results were considered abnormal if the test was non-reactive or if the patient had late decelerations or significant variable decelerations. If the non-stress test was shown to be non--reactive in the morning, it was repeated in the afternoon. If a non-reactive pattern persisted in a second test, then the patient was evaluated according to gestational age and the termination of pregnancy or contraction stress test as a back up test was considered. Those patients with significant variable decelerations, late deceleration, or an amniotic fluid index < 5.0 cm were considered for delivery. For the profile score 8 or 10, the test was considered normal and the patient was retested in a week or twice a week. The patients with a score of < 6 in a morning examination were tested again in the afternoon. If a score of < 6 was observed in the repeated test, the patient was considered for delivery according to gestational age or contraction stress test was performed. Antepartum test results were reported to the managing physician as being either normal, abnormal or suspicious, regardless of the protocol to which the patient was assigned. Only the last antepartum test, if given within 7 days of delivery, was included in the data analysis. Thus patients whose last test was > 7 days before delivery were excluded from the data analysis.

The measures of outcome for the purpose of this study were as follows: (1) the presence or absence of perinatal mortality, i.e. a pregnancy resulting in a stillborn infant weighing >500 gm or a neonatal death occurring up to the 28 day of life; (2) the presence or

absence of fetal distress in labor, *i.e.* thick meconium, bradycardia and late deceleration; (3) Cesarean delivery for abnormal antepartum test; (4) the presence or absence of a low 5-minute Apgar score < 7. For the purpose of this study, outcome was considered to be normal if all of the above measures were absent. Abnormal outcome was considered if any or all of the above adverse conditions were present.

Statistic analysis was performed with use of Fisher's exact two tailed analysis or where applicable the Chi square test. For some demographic variables two sample Student *t* test was employed. A *P* value of <0.05 was considered significant.

RESULTS

Two hundred patients were entered into this study and a total of 700 tests were performed with the mean number of tests performed per patient being 3.98 in biophysical and 2.66 in modified profile. Of this number 104 pregnancies were managed by the biophysical profile protocol and 96 by the modified biophysical profile protocol. Indications for the testing can be seen in Table 1.

The earliest gestational age was 29 weeks and the latest was 42.3 weeks with the mean gestational age 37.1 weeks for BPP and 37.6 for modified BPP. The interval of the tests to delivery was 2 days for modified biophysical profile and 2.7 days for biophysical profile. Perinatal outcomes can be seen in Table 2. We had 30 abnormal tests including 18 with AFI < 5 and 21 abnormal non-stress tests for modified biophysical profile and 24 abnormal tests including 23 with AFI < 5 and 8 with score<6 for biophysical profile. There was one neonatal death (29 and 30 weeks) in each protocol, so uncorrected perinatal mortality was1 (1%) in each protocol that after correction for prematurity, perinatal mortality was zero in each protocol. We had 27 cesarean section (28% in total, 90% in 30 abnormal tests) in modified biophysical profile protocol and 22 (21% in total, 91.6% in 24 abnormal tests) in biophysical protocol that was similar in both group. There was significant difference for the incidence of meconium passage between two groups ($P < 0.05$).

Table 1. Indication for testing*

Complications	MBPP (n= 96)	BPP (n= 104)
Diabetes	18 (19%)	45 (43%)
Preeclampsia	4 (4%)	5 (5%)
Chronic hypertension	4 (4%)	7 (7%)
IUGR	18 (19%)	17 (16%)
PROM	1 (1%)	0 (0%)
Postdates	15 (16%)	5 (5%)
History of stillbirth	2 (2%)	3 (3%)
Decreased fetal movement	18 (19%)	8 (8%)
Uncertain date	2 (2%)	2 (2%)
Oligohydramnios	2 (2%)	4 (4%)
Polyhydramnios	0 (0%)	1 (1%)
Heart disease	4 (4%)	4 (4%)
Pulmonary disease	1 (1%)	0 (0%)
SLE	1 (1%)	1 (1%)
Renal disease	2 (2%)	1 (1%)
other	2 (2%)	1 (1%)

Abbreviations: MBPP, modified biophysical profile; BPP, biophysical profile; IUGR, intrauterine growth retardation.
* Data are given as number (percent).

There was no significant difference in Apgar score < 7 and the overall adverse outcome between two protocols. Diagnostic values of two tests are shown in Table 3. In terms of comparison of diagnostic values of the fetal biophysical profile and the modified biophysical profile in determining abnormal outcome, both tests had similar sensitivity, specificity and negative predictive value but there was significant difference in positive predictive value of meconium passage between two tests.

Table 2. Perinatal outcomes

Outcome parameter	MBPP (n=96)	BPP (n=104)	*P* value
Abnormal test	30 (31.3%)	24 (23.1%)	0.19
Perinatal mortality	1 (1%)	1 (1%)	1.00
Meconium passage	17 (17.7%)	6 (5.8%)	0.01
C/S for abnormal test	27 (28.1)	22 (21.2%)	0.33
Apgar score ≤ 7	9 (9.4%)	4 (3.9%)	0.15
Overall adverse outcomes	32 (33.3%)	26 (25%)	0.21

Abbreviations: MBPP, modified biophysical profile; BPP, biophysical profile; C/S, caesarean section.
* Data are given as number (percent).

Table 3. Comparison of performance characteristics of fetal biophysical profile and modified BPP for all outcome parameters

Outcome	Sensitivity			Specificity			Positive predictive value			Negative predictive value		
	MBPP	BPP	*P*	MBPP	BPP	*P*	MBPP	BPP	*P*	MBPP	BPP	*P*
Overall abnormal outcome	87.5	84.6	0.75	96.9	97.4	0.84	93.3	91.7	0.82	93.9	95.0	0.78
Meconium passage	76.5	50.0	0.23	78.5	78.6	0.99	43.3	12.5	0.02	93.9	96.3	0.52
Cesarean delivery for abnormal test	92.6	95.5	0.68	94.6	97.2	0.46	89.3	91.3	0.81	96.4	98.6	0.42
Apgar score <7	88.9	75.0	0.52	76.5	79.0	0.68	28.6	12.5	0.19	98.5	98.8	0.89

Abbreviations: MBPP, modified biophysical profile; BPP, biophysical profile.

DISCUSSION

We did not find significant difference in the sensitivity, specificity, positive and negative predictive value of two tests for overall abnormal outcome. Significant difference in the positive predictive value of meconium-stained amniotic fluid between two protocols seems to be incidental, besides this marker is not a strong predictor of recent asphyxia insult. Young and co-workers randomized 683 women to the original BPP or the modified one and found no difference in effectiveness of two tests (3).

Although there was 54 abnormal tests (twenty four in biophysical and 30 in modified biophysical), no contraction test was carried out as a back up test. This was due to maternal or fetal clinical indications and the physician's decision that would not allowed the contraction stress test to be done. High incidence of C/S for abnormal tests (90% for 54 abnormal tests) is reflective of the aggressive intervention in our unit. In fact the decision to proceed with C/S is based on factors such as subjective interpretation of fetal heart rate tracing, the time of day, the day of the week, the availability of NICU in the case of prematurity, the underlying medical complication, the on call physician and the individual's experiences, whether the parturient is managed by residents or attending staff, whether continuous electronic tracing or intermittent auscultation is used during labor and finally considering the medicolegal aspects. Estimation of amniotic fluid volume is a heavily weighted parameter of antenatal fetal surveillance in some centers (4) and it is also necessary for every planned delivery, low or high risk in our center. Cesarean section rate is almost 90% for isolated oligohydramnios in our center while recent reports in the literature, however, have suggested the AFI is a poor predictor of perinatal outcome. Kreiser *et al.* evaluated 150 low-risk patients and found no increase in poor perinatal outcome in cases of isolated oligohydramnios (5). Magann *et al.* and Williams et al have found similar results (6, 7). In a meta-analysis of the relationship between AFI and perinatal outcome, Chauhan *et al.* came to the conclusion that there was an association between oligohydramnios and an increased incidence of cesarean delivery for non reassuring fetal heart rate patterns and low Apgar score; however, insufficient data related it to neonatal acidosis the only objective assessment of fetal well-being and called for further prospective studies with large enough numbers to properly evaluate the relationship (8). Oligohydramnios in our study such as study by Morris et al has likely lead to increased obstetric intervention without improving outcome (9).

Both tests in this study showed similar efficacy, the decision of which test should be used to determine fetal well-being must be based on the physician's own institution, availability of ultrasound equipment, and the skill of the individual performing the tests.

Conflict of interests

We have no conflict of interests.

REFERENCES

1. Manning FA, Platt LD, Sipos L. Antepartum fetal evaluation: development of a fetal biophysical profile. Am J Obstet Gynecol. 1980 Mar 15; 136(6):787-795.
2. Nageotte MP, Towers CV, Asrat T, Freeman RK. Perinatal outcome with the modified biophysical profile. Am J Obstet Gynecol. 1994 Jun; 170(6):1672-1676.
3. Young D, Delaney T, Nogue K et al. Randomized trial of original, modified and selective fetal biophysical profiles. Am J Obstet Gynecol. 2003; 187: 143.
4. Ott WJ. Current perspectives in antenatal fetal surveillance. Ultrsound Rev Obstet Gynecolo. 2003; 3: 1-18.
5. Kreiser D, el-Sayed YY, Sorem KA, Chitkara U, Holbrook RH Jr, Druzin ML. Decreased amniotic fluid index in low-risk pregnancy. J Reprod Med. 2001 Aug; 46(8):743-746.
6. Magann EF, Chauhan SP, Kinsella MJ, McNamara MF, Whitworth NS, Morrison JC. Antenatal testing among 1001 patients at high risk: the role of ultrasonographic estimate of amniotic fluid volume. Am J Obstet Gynecol. 1999 Jun; 180(6 Pt 1):1330-1336.
7. Williams K, Wittmann BK. The sensitivity and specificity of subjective and a semi-quantitative technique of amniotic fluid volume assessment in predicting intrapartum morbidity. Ultrasound Obstet Gynecol. 1993 May 1; 3(3):180-184.
8. Chauhan SP, Sanderson M, Hendrix NW, Magann EF, Devoe LD. Perinatal outcome and amniotic fluid index in the antepartum and intrapartum periods: A meta-analysis. Am J Obstet Gynecol. 1999 Dec;181(6):1473-1478.
9. Morris JM, Thompson K, Smithey J, Gaffney G, Cooke I, Chamberlain P, Hope P, Altman D, MacKenzie IZ. The usefulness of ultrasound assessment of amniotic fluid in predicting adverse outcome in prolonged pregnancy: a prospective blinded observational study. BJOG. 2003 Nov; 110(11):989-994.