Use of Non-Stress Test Alone Versus Biophysical Profile in Management of High-Risk Pregnancy: A comparative study

ABSTRACT

Background:*Choosing between the Non-Stress Test (NST) alone and the Biophysical Profile (BPP) in high-risk pregnancy management has garnered considerable attention. Both methodologies are crucial tools for assessing fetal well-being and guiding clinical decisions. The comparative effectiveness of utilizing NST alone versus integrating the more comprehensive BPP approach has become a pivotal research and medical discourse subject. This exploration delves into each approach's merits and potential limitations, shedding light on their respective roles in optimizing maternal and fetal care for high-risk pregnancies.*

Aim of the study:*The aim of the study was to compare the efficacy of non-stress tests and Biophysical profiles in the management of high-risk pregnancy.*

Methods:*This descriptive research was undertaken at the Department of Gynecology and Obstetrics within Rajshahi Medical College and Hospital in Rajshahi, Bangladesh. The investigation spanned from January 2007 to December 2008, encompassing one year. The study comprised a cohort of 100 patients identified as high-risk pregnant individuals. These participants were segregated into two distinct categories, denoted as Group A and Group B. Each group consisted of 50 patients. Group A adhered to the Biophysical Profile Protocol (BPP), while Group B followed the Non-stress Test (NST) approach.*

Results:*The study included 100 high-risk pregnancy cases at gestational ages 32 to 43 weeks. The biophysical profile (Group A, n=50) and a non-stress test (Group B, n=50) were compared. Demographics and obstetric features varied slightly between groups. Group A's mean±SE age was 25±0.82 years; Group B's was 24.66±0.73. Parity and gravidity showed minor differences. Indications and gestational age determination methods differed between groups. Group A saw more postdated pregnancies (32.00%), while Group B had higher pre-eclampsia cases. Delivery methods also varied; Group A had 64.00% LUCS and 36.00% vaginal deliveries, while Group B had 68.00% LUCS and 32.00% vaginal deliveries.*

Conclusion:*Managing high-risk pregnancies requires vigilant care. Antenatal assessment's vital role in outcome prediction and timely intervention is highlighted by comparing two fetal assessment methods. Abnormal test results better predicted abnormal outcomes, emphasizing the need for larger-scale studies to enhance method evaluation.*

Keywords:*Non-Stress Test, Biophysical Profile, Management, High-Risk Pregnancy.*

Corresponding author:*Dr. Krishna Pada Das, Assistant Professor, Department of Obstetrics and Gynaecology, Khulna Medical College, Khulna, Bangladesh, E-mail:*

INTRODUCTION

The term "high-risk pregnancy" denotes a pregnancy with an escalated likelihood of unfavorable outcomes [1]. Within the realm of maternity care, the focus on managing high-risk cases remains paramount in obstetrics. Substantial enhancements in obstetrics have stemmed from exploring pregnancies with heightened risks [2]. Multiple studies have reported varying prevalence rates of high-risk pregnancies, ranging from 5% to 40% [1,3,4]. Notably, the World Health Organization highlights those certain regions, such as Southeast Asia and specific countries in Africa and Latin America, might experience high-risk pregnancy rates exceeding 30% [1]. Risk-prone pregnancies contribute significantly to low birth weight (LBW) infants, perinatal morbidity, and mortality. A significant contributor to perinatal morbidity and mortality is fetal asphyxia, resulting from dysfunction within the fetoplacental unit [5]. Identifying this complication is crucial, as prompt delivery could lead to the infant's survival. Perinatal asphyxia, characterized by insufficient oxygen (hypoxia) and inadequate perfusion (ischemia) to various organs, poses a threat to both fetus and newborn [6]. While the impacts of hypoxia and ischemia may differ, they are challenging to distinguish clinically and likely contribute to asphyxial injuries.

Approximately 90% of asphyxial incidents occur during the antepartum or intrapartum periods due to placental insufficiency, which hampers oxygen supply and the removal of carbon dioxide and hydrogen ions from the fetus [6]. Conditions that hinder maternal oxygenation decrease blood flow from the mother to the placenta or fetus, impede gas exchange at the placenta or fetal tissue, or heighten fetal oxygen demands can exacerbate perinatal asphyxia. Such factors encompass maternal hypertension (both chronic and preeclampsia), maternal vascular disease, maternal diabetes, maternal hypoxia from pulmonary, cardiac, or renal issues, fetal anemia, fetal or placental hydrops, intrauterine growth restriction (IUGR), and post maturity.

Detecting at-risk fetuses in utero using objective clinical methods has only emerged over the past few decades. The preferred method should ideally be convenient, noninvasive, and yield accurate and promptly available results. In other words, the ideal antepartum test should be sensitive and specific. Inadequate sensitivity might lead to missed

cases of asphyxiated fetal death (false negatives). At the same time, poor specificity might result in unwarranted intervention for normal fetuses (false positives), leading to avoidable morbidity and mortality in fetuses, neonates, and mothers.

A range of tests has been employed for fetal evaluation. Initial approaches involved biochemical tests measuring endocrine products, such as placental enzymes (e.g., alkaline phosphatase), human placental lactogen, and oestriol. Although some showed associations with fetal outcomes, none proved accurate enough to serve as reliable adjuncts to clinical management. Consequently, the biophysical fetal monitoring method has primarily supplanted the biochemical approach. Two significant biophysical tests are the nonstress and fetal biophysical profiles (BPP).

The nonstress test assesses the presence or absence of fetal heart rate acceleration during fetal movement. It is a straightforward means of evaluating antepartum fetal heart rate and was introduced by Hammacher et al. in 1968 [7,8]. A nonstress test measures fetal heart rate variables using a cardiotocograph. The baseline fetal heart rate ranges from 120 to 160 bpm, with a beat-to-beat variation of at least five bpm. Fetal heart rate acceleration correlates with fetal movement. Evertsen et al. defined a reactive pattern as two or more accelerations of at least 15 bpm in amplitude and lasting at least 15 seconds, coupled with fetal movement during a 20 to 40-minute observation period [9]. Other deviations, like decelerations in conjunction with uterine contractions, can also be observed during a nonstress test.

In the late 1960s, real-time B-mode ultrasound emerged as a revolutionary clinical tool, providing dynamic insight into fetal behavior and structure. Fetal breathing movements were recognized as a standard intrauterine characteristic, and their sensitivity to hypoxia garnered interest for their potential to predict fetal compromise [10,11]. Accurately measuring fetal breathing movements and assessing fetal movement and amniotic fluid volume have contributed to antepartum fetal risk evaluation. Manning et al. proposed the fetal biophysical profile scoring method 1980, which combines fetal breathing, gross fetal movement, fetal tone, amniotic fluid volume, and a nonstress test [12]. A prospective clinical study by Manning et al. in 1987 involving over 12,000 referred high-risk pregnancies demonstrated a decrease in perinatal mortality and stillbirth rates with this approach [13]. Comparable outcomes were observed in studies conducted by other institutions involving 19,221 high-risk pregnancies [13]. Similarly, NST was proposed as a primary screening tool for antepartum heart rate monitoring [14], serving as a reliable indicator of fetal well-being. Distinguishing between normal and compromised fetuses profoundly impacts prenatal care planning, the timing of interventions, and neonatal morbidity. Appropriate monitoring can avert premature interventions in high-risk scenarios, while abnormal biophysical scores can trigger early delivery and immediate neonatal care. The comparative advantages of BPP and NST in antenatal fetal monitoring remain uncertain. This study compares the effectiveness of nonstress tests and biophysical profiles in managing high-risk pregnancies.

METHODOLOGY & MATERIALS

This descriptive study was conducted at the Department of Gynecology and Obstetrics, Rajshahi Medical College and Hospital, Rajshahi, Bangladesh. The study enrolled 100 patients from January 2007 to December 2008 (One year). The selected 100 high-risk pregnant patients were divided into two groups (Group A and Group B). 50 patients were distributed to each group; Group A: Biophysical profile protocol (BPP), Group B: Non-stress test (NST). A written informed consent was taken from every patient and Ethical approval was obtained from the Ethical Review Committee of Rajshahi Medical College to carry out this study.

Inclusion criteria:

- Patients age from 18 to 35 years old.
- Pregnant woman between 32-43 weeks of gestation.
- Postdated pregnancy
- Preeclampsia/Chronic hypertension.
- Decreased or less foetal movement.
- Patients without diabetes mellitus.
- History of stillbirth, intrauterine death (Poor obstetric history).
- Intrauterine Growth Restriction (IUGR)
- Rh-Isoimmunisation.
- Pregnancy with Grade III and /or IV heart disease.
- Mild to moderate antepartum haemorrhage under conservative treatment with the aim to reach up to 37 weeks of pregnancy.

Exclusion criteria

- Pregnant women who had no apparent risk factor.
- Pregnant women who were in early labour.
- Patients with gestational age less than 32 weeks.
- Fetal anomalies.
- Intrauterine death.
- Multiple pregnancies.
- Uncontrolled diabetic

The patient was positioned semi-recumbently with a slight tilt to the left side. Blood pressure was initially measured, followed by subsequent measurements every 10 minutes during the test. The Non-Stress Test (NST) was conducted using a cardiotocographic device (Sonicaid Meridian 800) with a 2 MHz transducer. After confirming the fetus's position through abdominal palpation, the appropriate position for the transducer on the fetal side of the abdomen was determined. Aquasonic coupling gel was applied to the abdomen over the fetal side and onto the transducer's surface. The transducer was carefully adjusted until the distinct sound of the fetal heartbeat became audible. A stretch belt was secured around the abdomen and fastened on the opposite side. The test continued until either a responsive pattern was detected or until 20 minutes had passed since the test began. The results were then used to classify the test as reactive or nonreactive. In a total of 50 cases, 60 non-stress tests were conducted. The Biophysical Profile (BPP) test was initiated with the NST procedure mentioned earlier. Subsequently, a real-time B-mode ultrasound scan with a 3.5 MHz transducer was performed. As defined by Manning et al. [12], various fetal parameters, including fetal breathing movement, overall fetal body movement, fetal tone, and qualitative amniotic fluid volume, were assessed and recorded. The evaluation process continued for 30 minutes to identify these variables. Each variable was then categorized as either normal or abnormal. In addition to these five parameters, supplementary information such as gestational age, fetal presentation, placental position, placental grade, fetal heart movement, and any significant congenital anomalies were also documented. The time taken to complete the BPP observation for each patient was also noted. This entire process was carried out for a total of 50 cases. Patients subjected to the nonstress test protocol were managed based on predefined criteria outlined by Evertsen et al. [9]. If the NST yielded a reactive result, the patient was scheduled for a repeat test every week. In cases where the nonstress test result was nonreactive, a retest was conducted within the next 24 hours. Should the nonreactive pattern persist, delivery options were considered for the patient. For instances involving diabetes mellitus, testing occurred twice weekly. Clinical factors encompassing gestational age, maternal health, and obstetric considerations were also considered during decision-making.

The information was organized in appropriate tables and graphs based on their relationships. A description accompanied each table and graph to facilitate clear comprehension. Statistical analysis was conducted using the Statistical Package for the Social Sciences (SPSS) program on the Windows platform. Mean and standard deviation (SD) were used to express continuous variables, while frequency and percentage were employed for categorical variables. Student's t-test was employed to compare continuous variables between groups, while the Chi-Square test was used for comparing categorical variables. The statistical significance of the findings was determined using a confidence interval of 95.0% and a significance level of $P<0.05$. Results with these criteria were regarded as statistically significant.

RESULTS

This study selected 100 cases of high-risk pregnancies of different gestational ages ranging from 32 to 43 weeks. Among them, 50 cases were managed by biophysical profile protocol (Group A), and 50 cases were managed by non-stress test (Group B). Table 1 shows the two groups' demographic and obstetric characteristics like age, gravidity and parity. In Group A, the mean±SE age was 25±0.82 years, and in Group B, the mean±SE age was 24.66±0.73 years. The parity was 0.96±0.16 vs 0.84±0.125, and the gravidity was 2.16±0.186 vs 2.02±0.15 respectively. Table 2 shows the indication for the testing in both groups of patients. In Group A, postdated pregnancy was (32.00%) high than in Group B. Pre-eclampsia was higher in Group B than in Group A. Table 3 shows the determination of gestational age of pregnant women in both groups. In Group, out of the 50 participants, 17 individuals (34.00%) had their gestational age determined solely based on the date of LMP and clinical examination. In contrast, 33 individuals (66.00%) had their gestational age determined using LMP, clinical examination, and early USG and out of the 50 participants in Group B, 19 individuals (38.00%) had their gestational age determined solely based on the date of LMP and clinical examination. In contrast, 31 individuals (62.00%) had

their gestational age determined using LMP, clinical examination, and early USG in Group A, consisting of 50 participants; Lower Uterine Segment Cesarean Section (LUCS) delivered 32 individuals (64.00%), while 18 individuals (36.00%) had an expected vaginal delivery. In Group B, also with 50 participants, 34 individuals (68.00%) had delivery by Lower Uterine Segment Cesarean Section (LUCS), and 16 individuals (32.00%) had a standard vaginal delivery (Table 4).

Table 1: Comparison of demographic and obstetric characteristics of study subjects.

Variable	Group A (N=50)	Group B (N=50)	P-value
	Mean±SE	Mean±SE	
Age (Years)	25±0.82	24.66±0.73	NS
Parity	0.96±0.16	0.84±0.13	NS
Gravidity	2016±0.18	2.02±0.15	NS

Table 2: Indications for the study population by major high-risk factor present.

Primary High-risk Factor	Group A (N=50)		Group B (N=50)	
	N	%	N	%
Postdated Pregnancy	16	32.00	11	22.00
Pre-eclampsia	12	24.00	14	28.00
Reducedfoetalmovement	9	18.00	9	18.00
Diabetes mellitus (all classes)	6	12.00	3	6.00
Bad obstetric history	5	10.00	7	14.00
Antepartum haemorrhage (APH)	1	2.00	4	8.00
Heart Disease	2	4.00	0	0.00
RH Isoimmunization	0	0.00	2	4.00

Table 3: Early clinical examination of gestational age.

Group	LMP and clinical examination		LMP and clinical Examination andUSG	
	N	%	N	%
Group A (N=50)	17	34.00	33	66.00
Group B (N=50)	19	38.00	31	62.00

Table 4: Mode of delivery.

Variables	Group A (N=50)		Group B (N=50)		P value
	N	%	N	%	
Delivery by LUCS	32	64.00	34	68	NS
Normal Vaginal Delivery	18	36.00	16	32	NS

Table 5: Gestational age of pregnant woman in both groups.

Gestational age in weeks at the time of the examination	Group A (N=50)		Group B (N=50)	
	No	%	No	%
Upto 36 Weeks	13	26.00	12	24.00
From 37 to 40 weeks	21	42.00	25	50.00
More than 40 weeks	16	32.00	13	26.00

Table 6: Indications of caesarean section in both groups.

Variables	N	%	Variables	N	%
High risk pregnancies with normal biophysical profile score (N=17)			High Risk Pregnancies With reactive non-stress test (N=17)		
Post dated pregnancy with less fetal movement	6	35.29	Post dated pregnancy	1	5.88
Severe preeclampsia	3	17.65	Less fetal movement	1	5.88
Pregnancy With diabetes mellitus	3	17.65	Severe preeclampsia	8	47.06

Diabetes mellitus with preeclampsia	1	5.88	Pregnancy With diabetes mellitus	2	11.76
Pregnancy with poor obstetric history	2	11.76	Pregnancy with poor obstetric history	1	5.88
Pregnancy With heart disease	1	5.88	Pregnancy with antepartum haemorrhage	3	17.65
Pregnancy with antepartum haemorrhage	1	5.88	Pregnancy with Rh negative	1	5.88
High risk pregnancies with abnormal biophysical profile score (N=15)			High Risk Pregnancies With non-reactive non-stress test (N=17)		
Post dated pregnancy with less fetal movement	6	40.00	Post dated pregnancy	5	29.41
Severe preeclampsia	6	40.00	Less fetal movement	4	23.53
Pregnancy With diabetes mellitus	1	6.67	Severe preeclampsia	3	17.65
Diabetes mellitus with preeclampsia	-	0.00	Pregnancy With diabetes mellitus	-	0.00
Pregnancy With bad obstetric history	1	6.67	Pregnancy With bad obstetric history	4	23.53
Pregnancy With heart disease		0.00	Pregnancy with antepartum haemorrhage	1	5.88
Pregnancy with antepartum haemorrhage	1	6.67	Pregnancy with Rh negative	-	0.00

Table 7: Interval between last tests done and delivery of the women.

Variables	Group A (N=50)		Group B (N=50)	
	N	%	N	%
On the date of examination (0)	23	46.00	20	40.00
One day after examination (1)	19	38.00	21	42.00
Within 2-4 Days of Examination	4	8.00	3	6.00
Within 5-6 Days of Examination	4	8.00	6	12.00

Table 8: Evalution of foetal assessment by foetral biophysical profile.

Test Result	Overall abnormal outcome		P value
	Present	Absent	
Group A (N=50)			
Normal (N=33)	4(12%)	29(88%)	<0.001
Abnormal (N=17)	12(70%)	5(30%)	
Group B (N=50)			
Normal (N=33)	4(12%)	29(88%)	<0.001
Abnormal (N=17)	12(70%)	5(30%)	

Table 9: Comparison of performance characteristics of foetal biophysical profile and nonstress test for each of the different foetal outcome.

Outcome	Group A (N=50)		Group B (N=50)	
	N	%	N	%
Positive Predictive value				
Overall abnormal outcome	35	70.00	30	60.00
Low 1-minuteAPGAR score	44	88.00	39	78.00
Low 5-minuteAPGAR score	35	70.00	30	60.00
Admission in Pediatrics word	48	96.00	47	94.00
Negative Predictive value				
Overall abnormal outcome	43	86.00	43	86.00
Low 1-minuteAPGAR score	40	80.00	40	80.00

Low 5-minuteAPGAR score	43	86.00	43	86.00
Admission in Pediatrics word	15	30.00	16	32.00
Sensitivity				
Overall abnormal outcome	37	74.00	36	72.00
Low 1-minuteAPGAR score	35	70.00	35	70.00
Low 5-minuteAPGAR score	37	74.00	36	72.00
Admission in Pediatrics word	36	72.00	35	70.00
Specificity				
Overall abnormal outcome	42	84.00	40	80.00
Low 1-minuteAPGAR score	46	92.00	43	86.00
Low 5-minuteAPGAR score	42	84.00	40	80.00
Admission in Pediatrics word	41	82.00	37	74.00

DISCUSSION

By evaluating the tests for antepartum foetal assessment, one can make a more meaningful statistical assessment of these tests by the positive predictive value, negative predictive value, sensitivity and specificity. Thus, the clinician can judge the probability of abnormal outcomes based on known test results. A truly valid test can only be judged by determining the sensitivity and specificity of the tests. The sensitivity of a given test is an index of its reliability in detecting a problem. On the other hand, a test's specificity indicates how accurately a problem's absence will be predicted. The present study was carried out to determine the relative prognostic value of the foetal biophysical profile and nonstress test. The prognostic value of these tests was assessed in terms of the incidence of the abnormal outcome of the foetus. The aim of the study also included a comparison of the positive predictive value. negative predictive value, sensitivity and specificity between the tests (foetal biophysical profile and non-stress test). Patients were selected randomly. Alternate cases were allocated to the two study groups. Care was taken to maintain strict standards for patient entry and avoid personal bias for selection. This process of randomization was similar to that of Platt et al. (1985), but Manning et al. (1987) used randomization based on coin-flip, where there was more chance of unequal distribution [13,15]. Adequate randomization was achieved in this study as the groups were comparable concerning mean age, parity and gravidity. Both the selected groups contained the common high-risk pregnancy in our hospital and included patients who were elderly and of low parity and gravidity. Gravidity was slightly higher due to any induced abortion or MR and a history of repeated pregnancy loss. One of the objectives of antepartum surveillance in high-risk patients is determining gestational age. One excellent means of determining a woman's gestational age is by date of last menstrual period (LMP), clinical examination and ultrasonography [16]. In this study, gestational age was determined following the above procedure in 66% of women in BPP and 62% of women in the NST groups. In 34% of cases of BPP and 38% of cases of NST groups, gestational age was determined only by LMP, and clinical examination and ultrasound reports were unavailable. The selection of high-risk pregnancy in this study was similar to many published studies, such as by Manning et al. (1996,1980,1987) and Platt et al. (1985), but not in agreement with Coopland et al., who used a scoring system [10,12,13,15,17,18]. Concerning the mode of delivery, there was a high incidence of caesarean section in this study. The high incidence of caesarean section in this study was due to obstetrical indications, like post-dated pregnancy, severe pre-eclampsia, and antepartum haemorrhage. The shorter the test to delivery interval, the more prognostic the test's result in predicting foetal outcome [19]. In the present study. In most cases, delivery occurred within one day of the last test. Platt et al. (1987) reviewed the impact of foetal testing to determine whether biophysical tests for antenatal foetal assessment make any difference [15]. During the 15-year review period, more than 200,000 pregnancies were managed, and 17,000 underwent antepartum testing. They concluded that such testing benefitted high-risk pregnancies compared to those not. In this study, the evaluation of abnormal tests concerning overall abnormal pregnancy outcomes was done. Abnormal tests were more predictor of abnormal outcomes than normal tests, similar to the observation of Platt et al. (1985) [15]. Specific outcomes, i.e. low 1-minute Apgar score, low 5-minute Apgar score, and admission into the Paediatric world in cases of abnormal test in both BPP and NST, were similar to that of Platt et al. (1985) [15]. However, a contrasting opinion on the benefit of antenatal foetal testing was shown by Thacker and Barkelman (1986) [20]. In this study, the incidence of abnormal tests was higher in both BPP and NST groups (34% vs 36%) than in other studies but similar to the findings of Phelan (1981) [13,15,21]. The higher incidence of abnormal tests seems to be due to the inclusion of high-risk cases with a risk of intrauterine hypoxia and because of strict standards maintained to include patients in the study sample. There were also interobserver and interobserver variations in the interpretation of test results. There is also a difference in the criteria for interpreting tests in different studies, especially for NST. In the present study, the sensitivity and specificity of BPP were 75% and 85%. respectively,

which is consistent with the findings of Thacker and Barkelman (1986), who showed a sensitivity of over 50% [20]. Concerning NST, sensitivity was 73% in this study and specificity 80%. Thacker and Barkelman (1986) showed a sensitivity of over 50% and a specificity of over 55% [20]. Concerning comparing the predictive value of the foetal biophysical profile and nonstress test, there was no remarkable difference in positive predictive value, negative predictive value sensitivity and specificity. The results are almost similar to Manning et al. (1987) and Platt et al. (1985) [13,15]. In the present study, specificity concerning the low 5-minute Apgar score was higher (85% vs. 80%) in BPP than in the NST group, which is consistent with the study by Platt et al. (1985), which showed significant differences for the positive predictive value of the overall abnormal outcomes, which is not similar to the present study [15]. The difference may be due to variations in test interpretation and interobserver or interobserver variation in their study and the small sample size in the present study. There is a general trend shown in different studies that the focal biophysical profile appears to be more predictive in diagnosing foetal conditions than the nonstress test. Statistically, this suggestion was not found to be true in the present study and studies done by Manning et al. (1987) and Platt et al. (1985) [13,15]. A relatively small sample size may be a reason. The abnormality presumed for newborns diagnosed by NST and BPP was almost similar. It supports my hypothesis postulated before head. Regarding perinatal mortality, Manning et al. (1980) showed prospectively that the foetal biophysical profile markedly decreased the number of antepartum deaths compared to a historical control group [12]. In a study by Platt et al. (1985), the PNM rate for the study population overall was lower than that observed in their medical centre during the same period (12 per 1000 compared to 19 per 1000) [15]. In the study by Platt et al. (1985), no significant difference was observed when PNM was compared between the groups managed by the NST and BPP [15].

Limitations of the study: The study's limitations include potential selection bias as the choice between the Non-Stress Test (NST) and Biophysical Profile (BPP) might be influenced by clinician preference, affecting the generalizability of results. Retrospective data collection could lead to incomplete records and inaccuracies. The study's timeframe might not account for recent advancements in high-risk pregnancy management. External factors impacting pregnancy outcomes, such as maternal lifestyle and socioeconomic status, might not be fully controlled. Lastly, the study assesses short-term outcomes; long-term effects of using NST or BPP exclusively warrant further investigation.

CONCLUSION

The present study evaluated two tests (BPP and NST) as predictors of foetal outcome. For both BPP and NST groups, abnormal tests were better predictors of abnormal outcomes. Comparison of sensitivity, specificity, and positive and negative predictive values between BPP and NST showed no remarkable difference. Therefore, we can continue to perform NST as an antepartum surveillance technique for the foetus because it is less expensive and less time-consuming, as there is a record on the basis on which clinicians can take decisions. More expertise is needed for performing and interpreting the test. Required equipment is less expensive than complicated real-time USG. Concerning IUGR, postmaturity or oligohydramnios, we can use BPP as a supplementary test which may improve the outcome. Moreover, the obstetrician's decision and assessment of cases for severity must be the preliminary criteria. As the present study included a small sample size, further randomized studies with a larger sample size may confirm the results of the present study.

Ethical approval: *The study was approved by the Institutional Ethics Committee.*

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