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Biophysical profile for fetal assessment in high risk pregnancies.
Cochrane Database of Systematic Reviews 2008, Issue 1. Art. No.: CD000038.
DOI: [10.1002/14651858.CD000038.pub2](https://doi.org/10.1002/14651858.CD000038.pub2).

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[Intervention Review]

Biophysical profile for fetal assessment in high risk pregnancies

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Editorial group: Cochrane Pregnancy and Childbirth Group

Publication status and date: Edited (no change to conclusions), published in Issue 4, 2012.

Citation: Lalor JG, Fawole B, Alfirevic Z, Devane D. Biophysical profile for fetal assessment in high risk pregnancies. *Cochrane Database of Systematic Reviews* 2008, Issue 1. Art. No.: CD000038. DOI: [10.1002/14651858.CD000038.pub2](https://doi.org/10.1002/14651858.CD000038.pub2).

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ABSTRACT

Background

A biophysical profile (BPP) includes ultrasound monitoring of fetal movements, fetal tone and fetal breathing, ultrasound assessment of liquor volume with or without assessment of the fetal heart rate. The BPP is performed in an effort to identify babies that may be at risk of poor pregnancy outcome, so that additional assessments of wellbeing may be performed, or labour may be induced or a caesarean section performed to expedite birth.

Objectives

To assess the effects of the BPP when compared with conventional monitoring (CTG only or MBPP) on pregnancy outcome in high-risk pregnancies.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (October 2007), CENTRAL (*The Cochrane Library* 2006, Issue 4), MEDLINE (1966 to November 2006), EMBASE (1974 to November 2006) and CINAHL (1980 to November 2006).

We updated the search of the Cochrane Pregnancy and Childbirth Group's Trials Register (10 January 2012) and added the results to the awaiting classification section.

Selection criteria

Randomised and quasi-randomised controlled trials involving a comparison of fetal BPP with other forms of antepartum fetal assessment in women with high-risk pregnancies.

Data collection and analysis

Two authors independently assessed eligibility, quality and extracted data.

Main results

We included five trials, involving 2974 women. Most trials were not of high quality. Although the overall incidence of adverse outcomes was low, available evidence from randomised controlled trials does not support the use of BPP as a test of fetal wellbeing in high-risk pregnancies. We found no significant differences between the groups in perinatal deaths (relative risk (RR) 1.33, 95% confidence interval (CI) 0.60 to 2.98) or in Apgar score less than seven at five minutes (RR 1.27, 95% CI 0.85 to 1.92). Combined data from the two high-quality trials suggest an increased risk of caesarean section in the BPP group RR 1.60, 95% CI 1.05 to 2.44, $n = 280$, interaction test $P = 0.03$. However, the number of participating women was relatively small ($n = 280$). Therefore, additional evidence is required in order to be definitive regarding

the efficacy of this test in high-risk pregnancies. Furthermore, the impact of the BPP on other interventions, length of hospitalisation, serious short-term and long-term neonatal morbidity and parental satisfaction requires further evaluation.

Authors' conclusions

At present, there is insufficient evidence from randomised trials to support the use of BPP as a test of fetal wellbeing in high-risk pregnancies.

[Note: The three citations in the awaiting classification section of the review may alter the conclusions of the review once assessed.]

PLAIN LANGUAGE SUMMARY

Biophysical profile for fetal assessment in high risk pregnancies

Not enough evidence to support use of biophysical profile (BPP) for the assessment of fetal well-being in high-risk pregnancies.

Monitoring the baby's well-being in the uterus in pregnancy is often undertaken using a cardiotocograph (CTG) machine. A CTG assesses the pattern of the baby's heartbeats alongside the size of the mother's contractions. However, this is not a very accurate test on its own. So monitoring the baby's movements has also been suggested as a useful addition to predict babies in difficulty. This is because a reduction in fetal movement sometimes precedes a baby's death. It is thought that if the oxygen supply to the baby through the afterbirth (placenta) is insufficient, the baby responds by moving less often. As fetal movement patterns may vary considerably, multiple fetal activities might be a better predictor of poor outcome. Consequently, the biophysical profile (BPP) and modified biophysical profile (MBPP) have been introduced. The BPP uses ultrasound to assess 1) fetal movement, 2) tone, 3) breathing and 4) the amniotic fluid volume that surrounds the baby. In addition, the baby's heartbeat is monitored over a 20-minute period using a CTG machine. This produces a paper tracing of the baby's heart rate, the mother's contractions and when the baby moves. Sometimes a modified BPP is used first (MBPP), involving the CTG trace and the amniotic fluid volume only. If this indicates a possible abnormality, then the full BPP is used. This review of trials compared the BPP (or MBPP) with conventional monitoring (CTG only) on pregnancy outcome in high-risk pregnancies. Five trials involving 2974 women with pregnancies with a high risk of poorer fetal outcome were found. There was no difference between the groups in the number of babies that died, nor in the number of babies who had low Apgar scores. However, although the number of women involved was small, the BPP was associated with a significant increase in induction and caesarean section. However, the data are insufficient to reach a conclusion about the benefit or otherwise of the BPP as a test of fetal wellbeing.

BACKGROUND

Fetal movement is one of the first signs of fetal life and is regarded as a manifestation of fetal wellbeing (Marsal 1983; Rayburn 1990). Pregnant women frequently become aware of fetal activity from 18 to 20 weeks' gestation and maternal perceptions of a reduction or cessation of fetal movements is reported frequently by pregnant women as a cause for concern. The observation that decreased fetal activity preceded fetal death (Sadovsky 1973) stimulated investigations into the value of the monitoring of fetal movements as a mechanism to predict fetal wellbeing (Grant 1989; Rayburn 1982). It has been suggested that in the presence of a persistently (chronic) inadequate oxygen supply (hypoxia), the fetus attempts to reduce the level of oxygen consumption (ACOG 2000; Baskett 1989) through reducing fetal activity. Consequently, maternal counting of fetal movements was proposed as a useful strategy to monitor the fetal condition, with a view to reducing the rate of intrauterine deaths from hypoxia (Moore 1989). Whilst several studies have demonstrated that diminishing or cessation of fetal activity may result in poor pregnancy outcomes (Leader 1981; Moore 1989; Valentin 1986), others have reported the converse (Harrington 1998), arguing that reduced fetal movements may indicate that fetal wellbeing is already compromised (Valentin 1987). In the absence of conclusive evidence that counting fetal movements reduces the antepartum fetal death rate, alternative methods of fetal assessment such as the biophysical profile (BPP) and the cardiotocograph (CTG) have been introduced.

Methods of antenatal assessment of fetal health

Many efforts have been made to develop non-invasive forms of antenatal assessment of fetal wellbeing. As fetal sleeping periods can lead to falsely non-reactive CTG patterns, vibration and sound stimulation (East 2005) and manual fetal manipulation (Tan 2001) have been used in conjunction with fetal heart rate monitoring (Pattison 1999). Such stimuli are intended to provoke fetal movement and a concurrent acceleration in the fetal heart rate, which is an indicator of fetal wellbeing. The concept of simultaneous evaluation of multiple fetal activities using real time ultrasonography led to the introduction of the BPP in the early 1980s. The BPP is a form of fetal assessment that combines the measurement of five biophysical variables as a means of assessing overall fetal wellbeing. The BPP, like other methods of antepartum fetal assessment, is usually started at a gestational age when extra-uterine survival or active intervention for fetal compromise is considered feasible (from 24 weeks).

The intervention - BPP

The BPP combines the assessment of electronic fetal heart rate monitoring (CTG) with four biophysical features, namely (i) fetal movements, (ii) fetal tone, (iii) fetal breathing and (iv) estimation of amniotic fluid volume. These latter four variables are observed using real-time ultrasonography. The fetal heart rate is recorded, usually over a 20-minute period, and is achieved by using a Doppler ultrasound transducer to monitor the fetal heart through the mother's abdomen. Uterine contractions are monitored simultaneously by a pressure transducer on the mother's abdomen. Both transducers are linked to a monitor and this results in a paper trace known as a CTG. In the original BPP proposed by Manning 1980, two points are awarded for each of the following parameters when present, and zero when absent (there is no intermediate score of one): (i) gross body movements - two or more discrete body/limb

movements within 30 minutes; (ii) fetal tone - one or more episode of active extension with return to flexion of fetal limb(s) or trunk (opening and closing of hands are considered normal tone); (iii) fetal breathing movement - at least one episode of fetal breathing lasting more than 20 seconds within 30 minutes; (iv) amniotic fluid volume - one or more pockets of amniotic fluid measuring more than 2 cm in the vertical axis. These pockets must be free of umbilical cord or fetal small parts (the measurement of the single deepest pool (SDP) is recorded in order to calculate the overall BPP score) and (v) fetal heart rate reactivity, i.e. two or more episodes of fetal heart rate acceleration of more than 15 beats per minute and of more than 15 seconds duration within 20 minutes. Equal weight is given to each of the five parameters. A maximum score of 10 can be achieved and the test is complete once all of the variables have been observed. For the test to be judged abnormal and a score of zero awarded for the absence of fetal movement, fetal tone or fetal breathing movements, a period of not less than 30 minutes must have elapsed. When each of the four ultrasound variables are normal, the CTG may be excluded as it adds little to the predictive accuracy of the BPP, as a BPP score of 8/8 is reassuring (Manning 1995). However, if one or more of the four ultrasound variables are abnormal, the antenatal CTG should be performed. Observational data have shown that at a cut off score ≤ 4 , the sensitivity of the scoring system (i.e. the ability of the test to correctly identify those babies who are truly not compromised) was 12.5% and specificity 99.23%. At a score of ≤ 8 , sensitivity and specificity were 70.83% and 91.53%. When compared to each individual assessment variable, the positive predictive value for abnormal perinatal outcome improved when all variables were combined (Begum 1996).

The modified BPP (CTG and ultrasonic assessment of amniotic fluid)

The BPP is relatively time consuming to perform and consequently several groups (Clark 1989; Nageotte 1994) have made minor amendments to the BPP as originally conceived, including variations in the method of estimating amniotic fluid. A shortened version of the BPP, known as the modified biophysical profile (MBPP), consists of: (i) recording an antenatal CTG (with or without vibroacoustic stimulation) combined with (ii) ultrasound measurement of the amniotic fluid. The MBPP is employed as a first-line screening test (Archibong 1999) and should be followed by the complete BPP as a back-up test when indicated. The amniotic fluid can be assessed using one of two techniques: (i) measurement of the SDP or (ii) measurement of the Amniotic fluid index (AFI). AFI assessment is performed according to the technique described by Phelan 1987, whereby the pregnant uterus is divided into four quadrants and the deepest pocket of amniotic fluid in each quadrant is obtained. The AFI is the sum of these four measurements.

Conventional monitoring - usually CTG only

The antenatal CTG assesses fetal heart rate pattern in response to fetal movement. In the past, the term non-stress test has been used synonymously with antenatal CTG monitoring in order to highlight the absence of uterine activity or contractions. However, when used in isolation from other methods of assessment of fetal wellbeing, the antenatal CTG is associated with high false-negative and high false-positive results (Evertson 1979; Schiffrin 1979). Therefore, it was suggested that the combination of multiple biophysical variables would reduce both the false-negative and

the high false-positive results associated with measuring a single variable only (Manning 1980; Vintzileos 1983).

Physiological basis of the ultrasound parameters of the BPP

The physiological and pathological basis of the BPP is the observed association between hypoxia (low levels of oxygen) and alterations of measures of central nervous system performance such as fetal heart rate patterns, fetal movement and fetal tone, which have been observed in both human and animal fetuses (Manning 1980; Natale 1979). Hypoxaemia (reduced blood oxygen levels) results in the redistribution of regional blood flow, leading to a reduction in fetal renal blood and fetal oliguria (reduced urine production) and, thus, less amniotic fluid. However, it is known that factors other than hypoxaemia may affect BPP parameters. These include gestational age (Baskett 1988), administration of steroids (Deren 2001), magnesium sulphate (Carlan 1991; Peaceman 1989) and excessive transducer pressure on maternal abdomen (Flack 1994). As a result, concerns have been raised regarding the limitations of individual tests, i.e. CTG or BPP only for the assessment of fetal wellbeing. Consequently, other tests such as doppler velocimetry (Neilson 1996) have also been proposed, in addition to or instead of the BPP. Although observational studies have suggested that the BPP confers benefits for those tested by a reduction in the fetal death rate (Platt 1985), given the considerable financial and manpower costs involved in performing the BPP and potential for harm by increasing the risk of obstetric interventions (labour induction, caesarean section) that may conceivably lead to prematurity and maternal complications, it is important to examine if the BPP confers benefit or harm for the individual woman carrying a high-risk pregnancy.

Indication for additional methods of assessment of fetal health

Although the majority of pregnancies proceed without complication and culminate in the birth of a healthy baby to a well mother, some pregnancies are more complex. High-risk pregnancy is one in which a particular condition places the mother, the developing fetus, or both at higher-than-normal risk for complications. These may occur antenatally, in labour or postnatally. Factors can be divided into maternal and fetal causes such as high blood pressure in the mother or growth restriction in the fetus. For example, growth restriction secondary to placental insufficiency is a significant cause of perinatal mortality (stillbirth or neonatal death) and morbidity (complications of prematurity) internationally. High-risk pregnancies require additional monitoring. However the outcome varies, depending on the particular condition and its severity.

OBJECTIVES

The objective of this review is to assess the effects of the BPP when compared with conventional monitoring (CTG only or MBPP) on pregnancy outcome in high-risk pregnancies.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised and quasi-randomised studies comparing the fetal biophysical profile (scoring system derived from the assessment of electronic fetal heart rate monitoring (cardiotocograph (CTG))

with four biophysical features namely, (i) fetal movements, (ii) fetal tone, (iii) fetal breathing and (iv) estimation of amniotic fluid volume) with conventional monitoring (usually CTG) or MBPP as in the Alfirevic 1995 trial). As earlier trials may not have used strictly random allocation, we planned to include trials that employed a quasi-randomised method of treatment allocation, such as alternation by hospital number or woman's date of birth.

Types of participants

Pregnant women with singleton, high-risk pregnancies at greater than 24 completed weeks' gestation not in labour, and their babies. High-risk pregnancies included the presence of any one or more of the following risk factors: hypertension, intrauterine growth restriction, post-term (i.e. greater than 42 completed weeks' gestation), intrauterine infection, preterm rupture of the membranes, diabetes, previous stillbirth/intrauterine death, history of decreased fetal movements, antepartum haemorrhage, premature labour, Rhesus disease, and anaemia during pregnancy.

Types of interventions

Biophysical profile versus conventional monitoring (usually CTG or MBPP).

For the purpose of this review, the following operational definitions are used.

The biophysical profile includes ultrasound monitoring of fetal movements, tone, breathing, ultrasound assessment of amniotic fluid volume and an antenatal CTG. The antenatal CTG is defined as a hard copy recording of the fetal heart rate and uterine activity performed on the woman during pregnancy. The MBPP is any modification in scoring components, duration of examination or definitions of normality/abnormality, or both.

Control group of interest includes: conventional monitoring.

Types of outcome measures

Outcomes of interest for the infant

- (1) Perinatal mortality in normally formed infants.
- (2) Severe neonatal morbidity.

Short-term/condition at birth

- (3) Acidemia as indicated by umbilical arterial cord blood or neonatal blood within one hour of birth (or both) with a pH less than seven or base deficit greater than 12 mmol/l, or both.
- (4) Five minute Apgar score less than seven.
- (5) Hypoxic ischemic encephalopathy (HIE). This is an identified cause of brain damage in newborns and refers to a diminished amount of oxygen in the blood, and a reduced amount of blood perfusing the brain. Infants with HIE may show evidence of compromise in utero, prolonged low Apgar scores with neurological symptoms such as coma, hypotonia/or seizures, respiratory symptoms such as periodic breathing or apnoea, or develop haemorrhagic lesions after birth.
- (6) Evidence of multi-organ compromise within the first 24 hours after birth: for example, renal failure, hepatic injury, cardiac damage, respiratory complications, or haematological insult.

Long-term

(7) Cognitive impairment - decrease in developmental quotient (70 or less).

(8) Disability to include non-ambulant cerebral palsy at or after 12 months of age or sensory impairment (visual/hearing), or both.

Other

(9) Incidence of admission to neonatal special care or intensive care unit, or both.

(10) Respiratory distress syndrome.

(11) Transient tachypnoea of the newborn.

(12) Sepsis.

(13) Prematurity.

(14) Length of stay in neonatal special care or intensive care unit, or both.

(15) Birthweight less than 10th centile.

Outcomes of interest for the mother

1. Induction of labour.

2. Induction of labour for abnormal fetal assessment (abnormal CTG tracing or biophysical profile score).

3. Caesarean section.

4. Caesarean section for abnormal fetal assessment.

5. Caesarean section for intrapartum fetal acidosis as defined by fetal blood sample (FBS) pH less than 7.2 or for abnormal fetal heart rate pattern where a FBS was not taken.

6. Incidence of antenatal admissions.

7. Incidence of fetal blood sampling.

8. Length of postnatal hospital stay.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (October 2007). We updated this search on 10 January 2012 and added the results to [Studies awaiting classification](#).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of EMBASE;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and EMBASE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the [Cochrane Pregnancy and Childbirth Group](#).

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-

ordinator searches the register for each review using the topic list rather than keywords.

In addition, we searched CENTRAL (*The Cochrane Library* 2006, Issue 4), MEDLINE (1966 to November 2006), CINAHL (1982 to November 2006) and EMBASE (1974 to November 2006) using the search strategies given in [Appendix 1](#).

We did not apply any language restrictions.

Data collection and analysis

The methods of the review were developed in light of the advice contained in the Cochrane Handbook for Systematic Reviews of Interventions ([Higgins 2005](#)).

Study identification

All randomised and quasi-randomised trials involving a comparison of biophysical profile with a) no fetal monitoring and b) any other form of antenatal fetal monitoring. A full text copy of each potentially eligible trial identified by the search strategy was independently assessed for inclusion by Joan Lalor (JGL) and Bukola Fawole (BF). There were no disagreements regarding eligibility for inclusion that needed to be resolved by discussion with Declan Devane. We did encounter problems with missing information, resulting in two studies being classified as 'Study awaiting assessment'. We attempted to contact the authors, but were unsuccessful.

Quality assessment of included studies

Two review authors (JGL and BF) independently assessed the quality of all included trials, namely selection and attrition bias. With regard to performance bias, due to the modus operandi of the biophysical profile (BPP) when compared with antenatal cardiotocograph (CTG) and other forms of assessment of fetal wellbeing, it is unlikely that clinicians or women will have been blinded to the intervention. Therefore, lack of blinding was not considered to undermine the validity of the studies.

Selection bias

We allocated studies a grade on the basis of allocation concealment as per criteria outlined in [Higgins 2005](#), i.e. (A) adequate, (B) unclear for trials where randomisation is not clearly described or prone to bias (e.g. open card, coin toss), (C) for quasi-randomised designs such as alternate allocation and use of record numbers.

Attrition bias

Due to inadequacies in reporting how losses of participants (e.g. withdrawals, dropouts, protocol deviations) were handled, the review authors were cautious about implicit accounts of follow up. Given that study reports on attrition after allocation have not been found to be consistently related to bias, we did not exclude studies on the basis of attrition. Studies were, however, graded for completeness of follow up using the following criteria. For completeness of follow up:

(A) less than 3% of participants excluded;

(B) 3% to 9.9% of participants excluded;

(C) 10% to 19.9% of participants excluded;

(D) more than 20% of participants excluded.

Data extraction

Two review authors (JGL and BF) independently extracted the data using data extraction forms designed specifically for the review, the fields of which had been agreed by all review authors. We extracted data by allocated intervention, irrespective of compliance with allocated intervention, in order to allow an 'intention-to-treat' analysis. Women who were randomised, and then either excluded or lost to follow up, were assumed to have no event in the main analysis, and denominators were altered to reflect when this occurred. Study eligibility was re-confirmed at the time of data extraction. Two review authors (JGL and BF) independently entered data onto the Review Manager (RevMan 2003) computer programme, independently checked them for accuracy and analysed them using RevMan 2003.

Data analysis

We performed statistical analysis with RevMan 2003. We reported dichotomous (or binary) outcomes using the 'relative risk' summary statistic and their 95% confidence intervals. We reported continuous data using the standard mean differences (due to non-normal distribution) and their 95% confidence intervals. We used a fixed-effect model of meta-analysis for summarising the results of studies in the absence of substantial heterogeneity between trials (measured using the I^2 statistic). The statistic is more robust than the Chi-squared test, as it is less affected by the number of trials in the analysis (Higgins 2005). I^2 values of 30% to 50% suggest mild heterogeneity and more than 50% implies substantial heterogeneity (Higgins 2005).

Sensitivity analysis

We performed sensitivity analysis based on quality, comparing high-quality trials (allocation concealment and attrition classified as 'A' (adequate, less than 3%)) with trials of lower quality for two outcomes: caesarean section and Apgar score, as data were available in a usable format for these outcomes from each trial.

RESULTS

Description of studies

Our search strategy identified 498 citations corresponding to 73 studies for potential inclusion. We excluded 55 studies during the initial screening and assessed 17 studies on the basis of their full text paper (or abstract) based on the inclusion and exclusion criteria indicated above. Of those, we excluded 10 studies from the review (see 'Characteristics of excluded studies'). We encountered difficulties with missing information in two studies. There was insufficient information on the trial design and attrition rates in the Lien 1994 study, and on the trial design and event rates in the Petrovic 1998 study. Efforts to contact the authors were unsuccessful; consequently these studies remain classified as 'Studies awaiting assessment'. (Three reports are awaiting assessment.) Five trials met the inclusion criteria for this review (see 'Characteristics of included studies' table). Four studies, with 2829 participating women, compared biophysical profile (BPP) with cardiotocograph (CTG) (Lewis 1999; Manning 1984; Nageotte 1994; Platt 1985) and one trial (Alfirevic 1995), with 145 participating women, compared complex BPP (a modified biophysical profile (MBPP) comprising computerised CTG, AFI and assessment of fetal breathing, tone and gross body movements) with CTG and amniotic fluid assessment using SDP technique. Pregnancies were managed

on the basis of normal or abnormal test results (without reference to the test performed) in the Manning 1984, Lewis 1999 and Alfirevic 1995 trials. Blinding was either not reported or not done in the Nageotte 1994 and Platt 1985 trials. Although not all trials reported the gestational age range of included pregnancies, it is of interest to note that the majority of included pregnancies were at or close to term (36.2 to greater than 42 weeks in the Manning 1984; Platt 1985; Nageotte 1994; Alfirevic 1995 trials ($n = 2829$)), whereas the mean gestational age in the Lewis 1999 trial ($n = 135$) was 24.2 weeks. (There are three trial reports in Studies awaiting classification to be assessed.)

Outcomes of interest to the fetus

Four studies provided data on perinatal deaths (Alfirevic 1995; Manning 1984; Nageotte 1994; Platt 1985) and all included trials provided data on the five-minute Apgar score after birth. Data for several neonatal outcomes were available from one study only, i.e. admission to the neonatal unit (Alfirevic 1995), birthweight less than the 10th centile (Platt 1985), and the presence of intra-amniotic infection (Lewis 1999).

Outcomes of interest to the mother

The data for induction of labour were available from one trial (Alfirevic 1995) and outcome data for caesarean section were available in four studies (Alfirevic 1995; Lewis 1999; Nageotte 1994; Platt 1985).

Where an outcome is not listed in the comparison section, no data were available in a usable format from any study for that *a priori* defined outcome.

Risk of bias in included studies

Five trials met our inclusion criteria. Two trials included in the review ran the risk of biased allocation through the use of coin flip (Manning 1984) or unblinded alternate allocation (Platt 1985). There was a significant and unexplained imbalance in the numbers of randomised participants in the Platt 1985 trial (279 in the experimental group compared with 373 in the control group). For one trial, it is unclear as to whether there was adequate concealment of allocation (Nageotte 1994).

An 'intention-to-treat analysis' was used in four of the five trials (Alfirevic 1995; Lewis 1999; Manning 1984; Nageotte 1994). The original report by Platt 1985 included only women who delivered within seven days of a test (76% in the experimental group and 74% in the control group). Additional unpublished data on the other women recruited in this trial were supplied by Dr Platt.

In the Lewis 1999 trial, women were randomly allocated to receive a daily biophysical profile (BPP) or a daily cardiotocograph (CTG). The last test score obtained before the mother gave birth was used in evaluating the effectiveness of the BPP and the CTG for predicting infectious complications for the mother or fetus. However, abnormal results in the CTG group led to further evaluation with a biophysical profile. In two trials (Manning 1984; Platt 1985), the BPP was performed on all women, but where a woman had been allocated to the control group, then CTG results alone were disclosed to clinicians. There was no attempt to conceal allocation from participants after randomisation in the Nageotte 1994 and Alfirevic 1995 trials. Group allocation was concealed from managing physicians in the Platt 1985 trial, as results were reported

as either normal, suspicious or abnormal, whereas all test results were reviewed by a member of the fetal medicine faculty in the [Lewis 1999](#) trial.

Effects of interventions

(1) Biophysical profile (BPP) versus conventional monitoring

Five randomised trials have been included in this review with 2974 participating women. When the biophysical profile (BPP) is compared with conventional fetal monitoring (cardiotocograph (CTG) or modified biophysical profile (amniotic fluid assessment and CTG)), we found no significant differences between the groups in perinatal deaths in infants (including those with congenital malformations) (relative risk (RR) 1.33, 95% confidence interval (CI) 0.60 to 2.98, $n = 2839$, four trials), Apgar score less than seven at five minutes (RR 1.27, 95% CI 0.85 to 1.92, $n = 2974$, five trials) and overall incidence of caesarean section (RR 1.18, 95% CI 0.90 to 1.54, $n = 2239$, four trials).

The following *a priori* defined outcomes were reported in individual trials and consequently, comparable data were not available for meta-analysis; however, we found no differences between the groups for incidence of admission to the neonatal intensive care unit (NICU) (RR 0.20, 95% CI 0.01 to 4.15, $n = 145$, $P = 0.30$), presence of meconium at birth (RR 1.45, 95% CI 0.79 to 2.64, $n = 145$, $P = 0.23$) ([Alfirevic 1995](#)) and birthweight less than 10th centile (RR 0.71, 95% CI 0.32 to 1.56, $n = 652$, $P = 0.39$) ([Platt 1985](#)).

There were significant differences between the groups (favouring conventional monitoring) in length of stay for the neonate in the NICU (SMD 0.20 95% CI 0.09 to 0.30, $n = 1442$, two trials). However, the data are skewed due to the length of stay associated with prematurity in the [Lewis 1999](#) trial and are therefore unreliable. Women in the BPP group were also more likely to have labour induced (RR 1.45, 95% CI 1.04 to 2.03, $n = 145$, one trial, $P = 0.03$), in particular for an abnormal BPP test result (RR 2.58, 95% CI 1.39 to 4.78, $n = 145$, $P = 0.003$). The [Lewis 1999](#) trial ($n = 135$) found that neither the BPP nor daily CTG demonstrated good sensitivity for predicting infectious complications following preterm prelabour rupture of membranes.

No reported data were available for analysis for the following outcomes: acidemia, transient tachypnoea of the newborn, hypoxic ischaemic encephalopathy, multi-organ compromise, cognitive impairment or disability, incidence of antenatal admissions, incidence of fetal blood sampling, and length of postnatal hospital stay.

Sensitivity analysis (high-quality trials)

There was no significant difference in Apgar scores less than seven at five minutes between the groups (outcome 02.01, RR 1.37, 95% CI 0.63 to 3.01, $n = 280$, two trials). However, it would appear that the risk of having a caesarean section was influenced by the quality of the trials (outcome 02.02). In the two high-quality trials ([Alfirevic 1995](#); [Lewis 1999](#)) the caesarean section rate in the BPP group was higher than women who had a CTG or CTG and MBPP (RR) 1.60, 95% CI 1.05 to 2.44, $n = 280$, interaction test $P = 0.03$.

DISCUSSION

The main reason for the introduction of the biophysical profile (BPP) into clinical practice was the belief that it would identify

fetuses at increased risk of poor outcomes in pregnancies with identified obstetric risk factors. Available evidence from the randomised trials included here does not support the use of BPP as a test of fetal wellbeing in high-risk pregnancies. However, the findings should be considered, taking cognisance of the fact that the total number of women included in this meta-analysis remains small at 2974, and some of the studies carry a high risk of bias (large imbalance in the numbers of women in each group in the [Platt 1985](#) trial, randomisation using a coin flip in [Manning 1984](#) trial). The overall incidence of adverse outcomes was low (perinatal deaths = 0.81%, Apgar score at or below seven at five minutes = 2.9%); thus additional evidence is required to support the value of the test in high-risk pregnancies. In order to derive any meaningful conclusions about the impact of the BPP on perinatal mortality, in excess of 10,000 women would need to be studied. It is also important to note that, although the BPP is used in clinical practice to assess fetal wellbeing at premature gestations, most trials, with the exception of [Lewis 1999](#) ($n = 135$), included participants with pregnancies of 36 weeks' gestation or more. Furthermore, the impact of the BPP at premature gestations, on intervention rates, length of hospitalisation, serious short-term and long-term neonatal morbidity and parental satisfaction requires further evaluation.

The increase in the rate of induction of labour observed in the small trial by [Alfirevic and Walkinshaw \(Alfirevic 1995\)](#) highlights the need for careful evaluation of the impact of different fetal monitoring policies on a much wider range of relevant outcomes. The observed increase in this outcome in this study was thought by the authors to be caused by the difference in the type of test used to assess amniotic fluid volume in two groups (amniotic fluid index in the BPP group (experimental) and maximum pool depth in the MBPP group (control)) rather than by the BPP itself. The amniotic fluid index was more frequently abnormal than maximum pool depth leading to increased intervention in the BPP group.

It is regrettable that since the introduction of the BPP in the 1980s, and following reports of observational studies of tens of thousands of pregnancies, less than 3000 women have been enrolled into randomised trials.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence from randomised trials to support the biophysical profile (BPP) as a test of fetal wellbeing in high-risk pregnancies. Although the number of participating women was relatively small ($n = 280$), combined data from the two high-quality trials [Alfirevic 1995](#) and [Lewis 1999](#) suggest an increase in the risk of caesarean section in the BPP group. In addition, the increase in the rate of induction of labour in the [Alfirevic 1995](#) trial highlights the need for careful evaluation of the impact of the BPP on a wide range of relevant maternal and neonatal outcomes. However, additional data are required to reach any definite conclusion about the benefit or otherwise of the BPP in high-risk pregnancies, as the total number of women included in this meta-analysis remains small at 2964. Consequently, careful evaluation of the impact of the BPP on intervention rates, in premature gestations, on serious short-term and long-term neonatal morbidity is required.

[Note: The three citations in the awaiting classification section of the review may alter the conclusions of the review once assessed.]

Implications for research

The implications for future research are considerable. Further randomised trials of the BPP in pregnancy are long overdue. Researchers are urged to evaluate and report outcomes on interventions, length of hospitalisation, serious neonatal morbidity and parents' satisfaction. In view of an increase in induction of labour associated with a variation in the method of estimating amniotic fluid volume in the [Alfirevic 1995](#) trial, a systematic review of the effectiveness of the various methods of assessing amniotic fluid volume is recommended. This should also include the impact that measurement technique has on obstetric interventions, such as caesarean section and induction of labour, and on infant outcomes such as Apgar score, acidosis and admission to NICU.

ACKNOWLEDGEMENTS

The review authors would like to acknowledge the support of Mrs Sonja Henderson, Review Group Co-ordinator, and Ms Lynn Hampson, Trials Search Co-ordinator, in the preparation of this review. We are grateful to Dr Lawrence D Platt who provided additional unpublished information and to Dr Michael Nageotte for responding to queries.

As part of the pre-publication editorial process, this review has been commented on by two peers (an editor and referee who is external to the editorial team), one or more members of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Alfirevic 1995

Methods	Randomisation: consecutively-numbered, sealed, opaque envelopes.
Participants	145 women with uncomplicated singleton post-term pregnancies (= or > 42 weeks); 72 women were randomised to BPP and 73 to simple monitoring.
Interventions	Complex (BPP) versus simple fetal monitoring (CTG and amniotic fluid measurement) twice weekly. Experimental group: complex BPP: FM, FT, FBM and computerised CTG instead of standard CTG, amniotic fluid assessment using AFI technique Control group: CTG and ultrasound measurement of the maximum pool depth twice weekly. If monitoring was normal, labour was induced at 43 weeks. Abnormal monitoring was an indication for induction of labour as soon as possible.
Outcomes	Induction of labour. Induction of labour for abnormal fetal assessment result. Caesarean section. Caesarean section for fetal distress. Apgar < 7 after 5 minutes. Admission to neonatal intensive care unit. Perinatal death.

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Alfirevic 1995 (Continued)

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	A - Adequate

Lewis 1999

Methods	Randomisation: random-number tables.
Participants	135 women with preterm (< or = 34 weeks) rupture of membranes.
Interventions	BPP versus CTG (non-stress test). Experimental group: BPP after 24-hour observational period. Control group: Daily CTG - if results were abnormal a BPP was performed.
Outcomes	Caesarean section. Intra-amniotic infection. Apgar < 7 after 5 minutes. Neonatal pneumonitis. Sepsis. Presumed sepsis.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	A - Adequate

Manning 1984

Methods	Randomisation: coin flip.
Participants	735 high-risk women referred with the diagnosis other than suspected IUGR, ie hypertension (27%), post-term (22%), diabetes (15%), previous stillbirth (7%), decreased fetal movements (4%), antepartum haemorrhage (4%), premature labour (3%), Rh disease (1%). 360 women were assigned to a non-stress test and 375 to a BPP. Mean gestational age 36.2 weeks.
Interventions	BPP versus CTG (non-stress test). Experimental group: full BPP reported weekly (diabetics and post-term twice weekly). Control group: full BPP concealed. CTG reported weekly (diabetics and post-term twice weekly).
Outcomes	Perinatal deaths (> 500 gr, > 20 weeks' gestation, < 28 days of neonatal life). Apgar < 7 after 5 minutes.

Notes

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Manning 1984 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	C - Inadequate

Nageotte 1994

Methods	Randomisation: not stated.
Participants	1307 women referred for antepartum fetal surveillance who had abnormal 'modified' BPP (CTG with sound stimulation and the amniotic fluid index); 628 were randomised to a contraction stress test and 679 to a BPP. Insulin-dependent women were excluded. Mean gestational age 40.1 weeks.
Interventions	All women were monitored with twice weekly MBPP (CTG and amniotic fluid assessment using AFI technique). Women with abnormal results were randomised into backup BPP or contraction stress test. Experimental group: full BPP as a back-up test. Control group: contraction stress test as a back-up test.
Outcomes	Perinatal death. Caesarean section for fetal distress within first 2 hours of labour.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Platt 1985

Methods	Quasi-randomisation using sequential numbers (even/odd).
Participants	642 women with high-risk pregnancies, ie post-term (41%), IUGR (13%), diabetes (12%), decreased fetal movements (7%), hypertension (12%), previous stillbirth (3%). 279 women were randomised to a BPP and 373 to the control group. Mean gestational age 39 weeks.
Interventions	BPP versus CTG (non-stress test). Experimental group: BPP twice weekly. Control group: CTG and ultrasound measurement of the maximum pool depth twice weekly. If monitoring was normal, labour was induced at 43 weeks. Abnormal monitoring was an indication for induction of labour as soon as possible.
Outcomes	Perinatal death (> 500 gr, < 28 day of life). Intrapartum fetal distress (persistent late decelerations, bradycardia or serial fetal scalp sampling with pH < 7.20, or both). Apgar < 7 after 5 minutes Birthweight below 10th centile.

Platt 1985 (Continued)

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	C - Inadequate

AFI: amniotic fluid index

BPP: biophysical profile

CTG: cardiotocography

FBM: fetal breathing movements

FM: fetal movements

FT: fetal tone

IUGR: intrauterine growth retardation

MBPP: modified biophysical profile

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Chauhan 2004	This randomised study compared (i) MBPP (CTG and sonographic estimation of amniotic fluid) or (ii) determination of the presence or absence of a 2x1-cm single deepest pocket.
Habek 2001	Non-randomised trial; included pregnant women with a singleton pregnancy in the 28th to 42nd week of gestation with clinically and ultrasonically verified fetal growth retardation and evaluation of the variables of the BPP for prediction of perinatal outcome.
Jamal 2005	This randomised trial did not include antenatal CTG. 2 randomised groups received (i) BPP or (ii) MBPP.
James 2001	This randomised study of low-risk women (287 days' gestation) compared (i) induction of labour with (ii) antenatal monitoring (daily fetal movement counting and BPP alternate days).
Kamel 1999	This non-randomised trial included 2 groups of high-risk women comparing (i) BPP and fetal acoustic stimulation and (ii) BPP and antenatal CTG.
Magann 2003	This randomised study compared (i) AFI or (ii) the SDP technique to estimate the adequacy of amniotic fluid volume during a BPP along with the other components of the test in predicting an adverse pregnancy outcome. Conclusion: the AFI offers no advantage in the detection of adverse outcomes to the SDP when assessed with the other components of the BPP.
Ott 1998	Does not meet the criteria for this review.
Tongsong 1999	Non-randomised trial; compared 2 groups (i) antenatal CTG with (ii) the rapid BPP which includes estimation of the AFI and SPFM to predict intrapartum fetal distress in high-risk pregnancies.
Tyrrell 1990	This randomised study of high-risk women compared 2 groups (i) routine BPP with (ii) umbilical and uteroplacental artery doppler velocity waveforms for obstetric intervention rates and short-term neonatal morbidity.

AFI: amniotic fluid index

BPP: biophysical profile

CTG: cardiotocograph

MBPP: modified biophysical profile

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SDP: single deepest pool

SPFM: sound provoked fetal movement

DATA AND ANALYSES

Comparison 1. Biophysical profile versus conventional fetal monitoring (CTG)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Perinatal deaths including major malformations	4	2839	Risk Ratio (M-H, Fixed, 95% CI)	1.33 [0.60, 2.98]
2 Apgar score < 7 at or after 5 minutes (all infants included)	5	2974	Risk Ratio (M-H, Fixed, 95% CI)	1.27 [0.85, 1.92]
3 Admission to neonatal intensive care unit	1	145	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.01, 4.15]
4 Length of stay in neonatal intensive care unit	2	1442	Std. Mean Difference (IV, Fixed, 95% CI)	0.20 [0.09, 0.30]
5 Birthweight < 10th centile	1	652	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.32, 1.56]
6 Meconium	1	145	Risk Ratio (M-H, Fixed, 95% CI)	1.45 [0.79, 2.64]
7 Respiratory distress syndrome	1	135	Risk Ratio (M-H, Fixed, 95% CI)	1.72 [0.97, 3.04]
8 Induction for abnormal fetal assessment (biophysical profile or cardiotocograph)	1	145	Risk Ratio (M-H, Fixed, 95% CI)	2.58 [1.39, 4.78]
9 Caesarean section	4	2239	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.90, 1.54]
10 Caesarean section for fetal distress	2	1452	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.83, 1.68]
11 Caesarean section for intra-partum fetal distress	2	1959	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.74, 1.42]
12 Induction of labour	1	145	Risk Ratio (M-H, Fixed, 95% CI)	1.45 [1.04, 2.03]

Analysis 1.1. Comparison 1 Biophysical profile versus conventional fetal monitoring (CTG), Outcome 1 Perinatal deaths including major malformations.

Study or subgroup	BPP n/N	CTG n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Alfirevic 1995	1/72	0/73		4.84%	3.04[0.13,73.44]
Manning 1984	4/375	4/360		39.77%	0.96[0.24,3.81]
Nageotte 1994	5/679	3/628		30.37%	1.54[0.37,6.42]
Platt 1985	3/279	3/373		25.02%	1.34[0.27,6.57]
			Favours BPP 0.01 0.1 1 10 100 Favours CTG

Analysis 1.2. Comparison 1 Biophysical profile versus conventional fetal monitoring (CTG), Outcome 2 Apgar score < 7 at or after 5 minutes (all infants included).

Analysis 1.3. Comparison 1 Biophysical profile versus conventional fetal monitoring (CTG), Outcome 3 Admission to neonatal intensive care unit.

Analysis 1.4. Comparison 1 Biophysical profile versus conventional fetal monitoring (CTG), Outcome 4 Length of stay in neonatal intensive care unit.

Analysis 1.5. Comparison 1 Biophysical profile versus conventional fetal monitoring (CTG), Outcome 5 Birthweight < 10th centile.

Analysis 1.6. Comparison 1 Biophysical profile versus conventional fetal monitoring (CTG), Outcome 6 Meconium.

Analysis 1.7. Comparison 1 Biophysical profile versus conventional fetal monitoring (CTG), Outcome 7 Respiratory distress syndrome.

Analysis 1.8. Comparison 1 Biophysical profile versus conventional fetal monitoring (CTG), Outcome 8 Induction for abnormal fetal assessment (biophysical profile or cardiotocograph).

Analysis 1.9. Comparison 1 Biophysical profile versus conventional fetal monitoring (CTG), Outcome 9 Caesarean section.

Analysis 1.10. Comparison 1 Biophysical profile versus conventional fetal monitoring (CTG), Outcome 10 Caesarean section for fetal distress.

Analysis 1.11. Comparison 1 Biophysical profile versus conventional fetal monitoring (CTG), Outcome 11 Caesarean section for intrapartum fetal distress.

Analysis 1.12. Comparison 1 Biophysical profile versus conventional fetal monitoring (CTG), Outcome 12 Induction of labour.

Comparison 2. Biophysical profile versus conventional monitoring (CTG) - high-quality trials

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Apgar score < 7 at or after 5 minutes	2	280	Risk Ratio (M-H, Fixed, 95% CI)	1.37 [0.63, 3.01]
2 Caesarean section	2	280	Risk Ratio (M-H, Fixed, 95% CI)	1.60 [1.05, 2.44]

Analysis 2.1. Comparison 2 Biophysical profile versus conventional monitoring (CTG) - high-quality trials, Outcome 1 Apgar score < 7 at or after 5 minutes.

Analysis 2.2. Comparison 2 Biophysical profile versus conventional monitoring (CTG) - high-quality trials, Outcome 2 Caesarean section.

APPENDICES

Appendix 1. Search strategies

MEDLINE

1. biophysical profil\$.af.
2. randomized controlled trial.pt.
3. exp Randomized Controlled Trials/
4. exp Random Allocation/
5. exp Double-Blind Method/
6. exp single-blind method/
7. clinical trial.pt.
8. exp Clinical Trials/
9. (clin\$ adj25 trial\$).tw.
- 10.((singl\$ or doubl\$ or trebl\$ ot tripl\$) adj25 (blind\$ or mask\$)).tw.
- 11.exp Placebos/
- 12.placebo\$.tw.
- 13.random\$.tw.
- 14.exp Research Design/
- 15.comparative study/
- 16.exp Evaluation Studies/
- 17.exp Follow-Up Studies/
- 18.exp Prospective Studies/
- 19.or/ 2-18
- 20.1 and 19

CINAHL

1. exp Clinical Trials/

2. clinical trial.pt.
3. (clinic\$ adj trial\$1).tw.
4. (((singl\$ or doubl\$ or treb\$ or tripl\$) adj blind\$3) or mask\$3).tw.
5. randomi?ed control\$ trial\$.tw.
6. exp Random Assignment/
7. random\$ allocat\$.tw.
8. placebo\$.tw.
9. exp Quantitative Studies/
- 10.random\$ allocat\$.tw.
- 11.exp Placebos/
- 12.or/1-11
- 13.biophysical profil\$.af.
- 14.13 and 12

EMBASE

1. randomization/
2. double blind procedure/
3. crossover procedure/
4. intermethod comparison/
5. single blind procedure/
6. clinical study/
7. controlled study/
8. randomized controlled trial/
9. (clin\$ adj2 trial\$).tw.
- 10.((singl\$ or doubl\$ or treb\$ or tripl\$) adj2 (blind\$ or mask\$)).tw.
- 11.exp clinical trial/
- 12.placebo/
- 13.placebo\$.tw.
- 14.random\$.tw.
- 15.comparison/
- 16.follow up/
- 17.evaluation.mp. and follow up/
- 18."evaluation and follow up"/
- 19.prospective study/
- 20.major clinical study/
- 21.(control\$ or prospectiv\$ or volunteer\$).tw.
- 22.1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or
- 23.17 or 18 or 19 or 20 or 21 or 22
- 24.23 biophysical profil\$.af. and 22

WHAT'S NEW

Date	Event	Description
10 January 2012	Amended	Search updated. One report added to Studies awaiting classification (Jamal 2007)

HISTORY

Protocol first published: Issue 2, 1996

Review first published: Issue 2, 1996

Date	Event	Description
13 May 2009	Amended	Corrected year of publication for Ott 1998.
11 February 2008	Amended	Converted to new review format.
9 November 2007	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

The original review was conceived by ZA.

JL and DD updated the methods section and BF updated the background.

JL and BF extracted and entered the data for analysis independently.

JL ran the analyses and drafted the results; however, all authors contributed to each section of the final review.

DECLARATIONS OF INTEREST

Zarko Alfirevic is the first author of one of the randomised trials included in this review.

SOURCES OF SUPPORT

Internal sources

- The University of Liverpool, UK.

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Fetal Development; *Pregnancy, High-Risk; *Ultrasonography, Prenatal; Fetal Monitoring [*methods]; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Pregnancy