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COMMENTARY

# Journal Watch

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## ST waveform analysis versus cardiotocography alone for intrapartum fetal monitoring: a systematic review and meta-analysis of randomized controlled trials. Blix et al. Acta Obstet Gynecol Scand. 2016 Jan; 95(1):16–27

The purpose of ST waveform analysis (STAN) during intrapartum monitoring is to promptly identify fetal asphyxia, reducing the incidence of both metabolic acidosis at birth and consequent unnecessary operative deliveries, in comparison with traditional cardiotocography (CTG). The latter has low specificity and high incidence of false positives that caused an increase in the rate of cesarean section.

The aim of this meta-analysis was to quantify the efficacy of the STAN method used in combination with conventional CTG, compared to isolated CTG analysis. Six original randomized, controlled trials (RCTs) were selected, overall accounting for 26,554 women and their babies. The selection criteria consisted of women in labor, $\geq$36 weeks of gestation, singleton pregnancy, cephalic presentation, and continuous fetal monitoring during labor. The comparison considered CTG plus STAN versus CTG alone. Primary and secondary maternal and fetal outcomes were finally analyzed.

Only a minority of assessed outcomes reached statistical significance and some of them had low statistical power due to their low incidence, even lower than 1 %. No significant difference was noted in the rate of cesarean section (RR 0.93; 95 % CI 0.78–1.12), operative vaginal delivery for fetal distress (RR 0.87; 95 % CI 0.74–1.03) and Apgar score <7 after 5 min (RR 0.95; 95 % CI 0.73–1.25). The difference between the two groups was also not statistically significant either for newborn seizures (OR 0.58, 95 % CI 0.18–1.90) or death (OR 1.79, 95 % CI 0.69–4.64). The number of observed events (seizures or deaths) was too small for decisive conclusions. The incidence of metabolic acidosis was lower in the STAN group (RR 0.64; 95 % CI 0.46–1.88) than in women monitored with CTG alone. An opposite pattern was seen for the Apgar score $< 4$ after 5 min (OR 2.63; 95 % CI 1.16–5.96), occurring more frequently with STAN. Assisted vaginal delivery for all indicators was slightly but significantly less common with STAN, but its clinical relevance is restricted by the small effect size. Only fetal blood sampling was performed less frequently in the STAN group. No significant differences were shown on any of the other outcomes.

The data demonstrated a reduction in metabolic acidosis and all operative deliveries, but not in the number of operative deliveries for fetal distress. The authors argue that metabolic acidosis is a surrogate endpoint which should be interpreted with caution and the authors discourage excessive emphasis on it. In fact, only 22 % of neonates with encephalopathy, seizures or death had $pH < 7$, while 75 % of them had $pH > 7$. The authors argue that hospitals not using STAN should not introduce it, but those that are already using it may continue, as no evidences demonstrate it causes harm. In conclusion, the controversy surrounding the use of STAN refuses to go away. The superiority of STAN over CTG is seen only for surrogate outcomes, and the effect size is small. Not using STAN should not be considered suboptimal care.

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## Induction of labour versus expectant management for large-for-date fetuses: a randomized controlled trial. Boulvain M et al. Lancet. 2015; 385:2600–05

Macrosomia is a risk factor for shoulder dystocia as well as for operative vaginal delivery and cesarean sections. Subjecting women carrying a fetus thought to be macrosomic to elective cesarean section does not seem a reasonable strategy, as too many elective procedures would be needed in order to avoid one permanent brachial plexus injury. The alternative might be to induce labor, before the fetal growth reaches a risky threshold. The potential concerns are that induction may increase the rate of cesarean section or might also lead to higher mortality and morbidity of the newborn. This was an RCT comparing elective induction of labor (IOL) to conservative management for presumed fetal macrosomia.

This study tested the following hypotheses:

1. It is possible to predict macrosomia prenatally with reasonable accuracy.
2. Elective delivery by induction of labor at term would reduce the prevalence of shoulder dystocia.
3. Elective induction of labor would not increase the rate of cesarean delivery or perinatal morbidity as compared to those women managed conservatively.

The study was a multicenter, randomized controlled trial, including 822 women. Women with estimated fetal weight (EFW) >95th centile near term were eligible for inclusion. Women with previous cesarean delivery, neonatal trauma or shoulder dystocia were excluded. Four hundred seven women were included in the IOL group and 411 in the expectant management one.

In the IOL group, labor was induced between 37 + 0 and 38 + 6 weeks, within 3 days after randomization. Prostaglandine E2 or misoprostol were used in women with unfavourable cervix, eventually followed by oxytocin if labor did not start after the administration of the cervix ripening agents. In the expectant management group, pregnancies continued until spontaneous labor or until induction of labor was considered necessary, according to local protocols.

The composite primary outcome included significant shoulder dystocia (defined as difficult shoulder delivery, not resolved by McRoberts' manoeuvre), delay between head and shoulders delivery greater than 60s, clavicle fracture, brachial plexus injury, intracranial hemorrhage and death. The secondary outcomes consisted of several maternal and neonatal morbidities.

A significant reduction in the primary composite outcome was reported in the intervention group [8 events (2 %), compared to 25 events (6 %)] with expectant management (RR 0.32–95 % CI 0.15–0.71), with a risk reduction of 4 % (95 % CI 1.4–6.8), [number of patients needed to treat—25 (95 %; CI 15–70)]. No cases of brachial plexus injuries, intracranial hemorrhage or death occurred. No significant difference in the rate of cesarean section (28 % in the IOL group and 32 % in the expectant management group, RR 0.80, 95 % CI 0.58–1.12) operative vaginal delivery (13 and 17 % respectively, RR 0.89, 95 % CI 0.72–1.09), and anal sphincter tears (2 vs. 1 %). The probability of spontaneous vaginal delivery was higher in the IOL group (59 % compared to 52 %, RR 1.14, 95 % CI 1.01–1.29). A similar pattern was seen for post-partum hemorrhage, occurring in 3 % of IOL and in 5 % with expectant management. Secondary outcome was almost identical. Finally, 9 % of neonates from the IOL group experienced bilirubin concentration higher than 250 mmol/L, in comparison to 12 % of those in the expectant management, although phototherapy was never required.

The findings suggest a significantly lower risk of shoulder dystocia and bone fracture and a higher chance of spontaneous vaginal delivery in women carrying large for gestational age fetuses, undergoing to IOL between 37 and 39 weeks of gestation.

This result differs from previous RCTs, reporting no significant benefit from induction of labor for reducing shoulder dystocia. In previous RCTs, the sample size was small, the inclusion criteria particularly restrictive, and IOL was performed around 40 weeks, when the weight difference between induction and expectant group would not be large. In the light of this study, it would be difficult to not agree for elective induction of labor at 37–38 weeks if the fetus is thought to be too big. Not only is the risk of shoulder dystocia reduced, but the rate of spontaneous vaginal birth is significantly higher.

## Immediate delivery compared with expectant management after preterm pre-labour rupture of the membranes close to term (pPROMT trial): a randomised controlled trial. Morris JM et al. Lancet. 2015 Nov 9; pii:S0140-6736(15)00724-2

Immediate induction of labor or conservative management up to 72–96 h is equally effective for term pre-labor rupture of membranes In the absence of infection or maternal or fetal compromise, expectant management is recommended in moderate to severe preterm (23–34 weeks) prelabor rupture of membranes (pPROM). However when the rupture occurs between 34 and 37 weeks of gestation, the optimum management is not clear. Both American College of Obstetricians and Gynecologists (ACOG) and Royal College of Obstetricians and Gynaecologists (RCOG)

recommend delivery for all cases of ruptured membranes after 34 week, although this statement is based on limited and inconsistent scientific evidences.

The aim of the study was to compare immediate delivery to expectant management in case of pPROM close to term. The study is a randomized controlled trial, taking place in 65 centers and gathering data from 1835 women. Women carrying a singleton pregnancy with confirmed rupture of membranes between 34 and 36 + 6 weeks were eligible. Exclusion criteria were established labor, chorioamnionitis, meconium staining and any contraindication to continuing the pregnancy. Approximately, 40 % of participants had received antenatal steroids and 86 % had received antibiotics in the previous 24 h. 923 were assigned to immediate delivery and 912 to the expectant management group (control group). Elective delivery was scheduled within 24 h for the intervention group. Women awaited onset of labor in the control group. Labor induction was arranged if they did not go in labor till 37 weeks. It was arranged earlier if the attending physician felt that induction of labor was mandated on clinical grounds.

The primary outcome was the presence of definite or probable neonatal sepsis. Adjudicators of primary outcomes were masked to treatment allocation. Secondary infant outcomes consisted of a composite neonatal morbidity and mortality indicator, respiratory distress syndrome, perinatal mortality, pneumonia, mechanical ventilation, duration of stay in a neonatal intensive-care unit (NICU), and others. Secondary maternal outcomes were also recorded. Mode of delivery was governed by O-obstetric indications. Antibiotic therapy, hospitalization as well as laboratory testing were chosen according to local protocols.

Definite and probable sepsis occurred in 2 and 3 %, respectively in experimental and control group (RR 0.8 %–95 % CI 0.5–1.3). Women in expectant management were more likely to deliver following spontaneous onset of labor and at a later gestational age. No significant difference was noted in the composite neonatal morbidity and mortality indicator (8 and 7 %). Newborns in the immediate delivery group had lower birthweight, higher incidence of respiratory distress syndrome (8 % compared to 5 % in babies expectantly managed, RR 1.6, 95 % CI 1.1–2.3), mechanical ventilation (12 % against 9 %, RR 1.4–95 % CI 1.0–1.8) and longer stay in special care baby unit (4.0 and 2.0 days respectively, $p < 0.0001$). There were six deaths in total, equally distributed in both groups, with no significant differences in terms of causes (sudden infant death syndrome, congenital abnormality and acute suppurative chorioamnionitis in the experimental group and sudden infant death syndrome (SIDS), congenital abnormalities and unknown cause in the control group). Antepartum hemorrhage and intrapartum fever were less common in the immediate delivery group than in the expectant management group. However, immediate delivery group had a higher incidence of cesarean section (26 % compared to 19 % with conservative management). All other secondary neonatal and maternal outcomes were no different. The findings demonstrate that expectant management is a better option when rupture of membranes occurs in singleton pregnancies between 34 + 0 and 36 + 6 weeks of gestation, provided there are no contraindications for continuing with the pregnancy. There is no significant risk of harm to the newborn. The benefits are higher birthweight, reduced respiratory distress and lower risk of cesarean delivery. Immediate delivery did not lead to any considerable reduction in the incidence of neonatal sepsis, but increased neonatal complications. On this basis the authors recommend expectant management for pPROM between 34 + 0 and 36 + 6 weeks gestation. Careful monitoring of fever and other sign and symptoms of infection, chorioamnionitis and antepartum hemorrhage is required.