STAN – ST Waveform Analysis Combined With Cardiotocography for Fetal Monitoring During Childbirth

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Summary and Conclusions

TECHNOLOGY AND TARGET GROUP The aim of fetal monitoring during childbirth is to prevent oxygen deficiency that is severe enough to result in fetal death or long-term damage to the nervous system. Cardiotocography (CTG) is the most common method used for electronic fetal monitoring during childbirth. It registers the heart rate of the child and contractions of the uterus. Cardiotocography can be influenced by factors other than oxygen deficiency in the fetus, which potentially can lead to unnecessary intervention. When needed, testing blood from the child's scalp can provide additional information if CTG readings are abnormal. Blood testing offers greater certainty for ruling out whether or not oxygen deficiency is the reason behind an abnormal CTG. At times, however, it may be technically difficult to perform such a test. Furthermore, it provides only an on-the-spot account. Since the situation can change quickly, there may be a need to repeat the test. STAN combines CTG with ST waveform analysis, ie, analysis of that part of the fetal ECG called the ST segment, which changes if the fetus experiences hypoxia (oxygen deficiency). Hence, STAN technology uses CTG to identify a high-risk group. The method is intended for fetal monitoring during childbirth when it has been determined that continuous monitoring via a scalp electrode is necessary to obtain satisfactory information. This applies to an estimated 20 percent of all deliveries. In contrast to testing scalp blood, STAN continuously monitors the fetus. However, the method is not free from sources of error. For example, even without oxygen deficiency, fetal heart malformations and infections may result in abnormal readings.

PRIMARY QUESTION Can STAN offer better and more cost-effective fetal monitoring by detecting signs of impending oxygen deficiency earlier in the fetus and thereby reduce the number of injured children and/or operative deliveries (Caesarian section, vacuum device, forceps)?

PATIENT BENEFIT Three randomized controlled trials were identified that compared STAN against CTG alone. A synthesis of results from these studies showed that continuous fetal monitoring with STAN resulted in a lower percentage of children with brain dysfunction (encephalopathy). Likewise, the rate of operative vaginal deliveries (vacuum device or forceps) was reduced. However, there was no difference in the percentage of Caesarian sections, or in the percentage of children born with metabolic acidosis resulting from oxygen deficiency. There are no long-term followups showing whether or not these findings are of importance as regards the future health of the child. Clearly, some elements of risk are associated with STAN. For example, the manual for interpretation and intervention, which is used to appraise the results, has certain deficiencies that might lead to management that is too non-interventional. There is also a risk that deviations in the ST analysis might not appear if recording is started too late in the course of oxygen deficiency, after the resources of the fetus have been exhausted.

ETHICAL ASPECTS Injury to the child as a result of oxygen deficiency during labor is rare. When it does occur, however, it is often severe and can cause life-long disability. Therefore, if possible, injury should be avoided by using monitoring methods with high diagnostic reliability. Compared to CTG alone, STAN involves less subjective judgement. Hence, the method should contribute toward reducing the number of misjudgements. It is, however, important to be aware of the potential risk created by a false sense of security.

ECONOMIC ASPECTS The cost for STAN equipment is around 280 000 Swedish kronor (SEK), about double that for CTG equipment. Also, STAN requires substantially more education and training for midwives and obstetricians. No studies addressing the cost effectiveness of the method have been identified.

SBU's appraisal of the evidence

There is limited scientific evidence showing that the method can lead to a lower percentage of children with encephalopathy (brain dysfunction) and a reduced rate of operative vaginal deliveries (Evidence grade 3)*. Further scientific studies are needed to clarify the effects and the cost effectiveness of the method. The manual for interpretation and intervention reveals certain deficiencies that might lead to management that is too noninterventional. Continued utilization and diffusion of the method requires extensive education and training and also systematic followup of long-term effects.

Criteria for Evidence Grading SBU's Conclusions, see page 2

Criteria for Evidence Grading SBU's Conclusions

Evidence Grade 1 – Strong Scientific Evidence. The conclusion is corroborated by at least two independent studies with high quality and internal validity, or a good systematic overview.

Evidence Grade 2 – Moderately Strong Scientific Evidence. The conclusion is corroborated by one study with high quality and internal validity, and at least two studies with medium quality and internal validity.

Evidence Grade 3 – Limited Scientific Evidence. The conclusion is corroborated by at least two studies with medium quality and internal validity.

Insufficient Scientific Evidence. No conclusions can be drawn when there are not any studies that meet the criteria for quality and internal validity.

Contradictory Scientific Evidence. No conclusions can be drawn when there are studies with the same quality and internal validity whose findings contradict each other.

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The complete report is available only in Swedish.