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STAN AT 12; A CRITICAL ANALYSIS!!

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ABSTRACT
The purpose of this critical analysis was to review the usefulness of STAN in intrapartum surveillance. This review was based on a survey of the relevant literature including review articles during the decade from 2011 to 2021. We perused several data bases including CINAHL, PubMed, and Cochrane, using search terms like intrapartum surveillance, Intrapartum foetal hypoxia, Detection of intrapartum Hypoxic ischaemic encephalopathy and STAN. More than 100 articles were recovered among which were six review articles. The scope of the paper included a deliberate effort to identify any published literature on STAN in the decade from 2011 to 2021. We were desirous of knowing whether STAN has had a significant or any impact on neonatal outcome and whether STAN was fit for purpose, we were also curious in understanding the cellular based physiology which would lend credence to the way it is thought to function. Results: We found that neither the National Institute of Health and Clinical Excellence (NICE) nor the Royal College of Obstetricians and Gynaecologists recommended its use. Further search of the literature allowed us to conclude that the evidence supporting its usefulness is weak. So, whereas STAN involves increased mechanisation, is invasive and cannot function independently; has led us to believe that its usefulness if any is limited. We believe, therefore that STAN as a monitoring tool should be archived as and should be allowed no place in the clinical space of the British labour ward.

In 2019, the infant mortality rate in England and Wales was 3.7 deaths per 1,000 live births. While this corresponds to a general decline since 1980, over the past five years the infant mortality rate has remained static. In 2019, the neonatal mortality rate (aged under 28days) was 2.8 deaths per 1000 live births.

Doubtlessly intrapartum care has contributed to the numbers, and there remains a driving force in the research designed to optimise intrapartum care. Emerging from this research are a variety of newer tools focussed on improving foetal surveillance and hopefully outcome during labour and delivery; One such tool is the ST segment analysis or STAN on a foetal Electrocardiogram which should be used in conjunction with its traditional cousin, The Cardiotocogram (CTG).

The role of CTG monitoring, the most widely used type of electronic foetal monitoring in labour over the past sixty years; is to enable the detection of foetal hypoxia before it can cause long term neurological damage to the foetus. Unfortunately, as reflected in the relative static infant mortality rates over the past five years, though necessary, the CTG is inadequate in reducing both infant morbidity and infant mortality. STAN, upon its introduction with much fanfare was heralded as the great hope to put a dent in these numbers but sadly despite being in use for more than twelve years in the UK, STAN has not quite lived up to the desired expectations. The hope of every prospective mother as well as any Obstetrician is essentially the same, the delivery of the baby in the best possible condition. Granted, arguably among the most dangerous journey mankind will ever make, is the journey through the birth canal.

We are fully aware that among the most physiological stressors that the foetus faces during labour is in the second stage of labour. We have employed the available tools of CTG and FBS to inform appropriate management. CTG though having a high sensitivity has a very poor specificity and positive predictive value for intrapartum hypoxic injury. The positive predictive value for metabolic acidosis is only about 30%. We, therefore, remain in search of more tools which will more appropriately inform management leading to the arrival of a baby from the birth canal in its best possible physiological condition. Is STAN, that long awaited tool? Neither the National Institute of Health and Clinical Excellence (NICE) nor the Royal College of Obstetricians and Gynaecologist (RCOG) believe it is.

Unfortunately, despite being in vogue for more than 12 years in the United Kingdom, STAN has not been sanctioned for use by either NICE or the RCOG.

WHAT IS STAN

Simply put it refers to the analysis of the QRS Complex and ST segment in a foetal ECG. STAN combines the standard CTG monitoring with simultaneous assessment of the foetal ECG.

A normal ECG complex consists of a p-wave which reflects atrial contraction, a QRS complex which reflects ventricular contraction and a T-wave which represents ventricular repolarisation. Basic electro physics tells us that these waves are all related to a change in electrical conductivity in the heart muscle. Hypoxia is associated with changes in electrical conductivity and alterations in these wave forms. The normal ST waveform is horizontal or upward sloping, and the T-wave has a constant amplitude. The QRS Complex, the ST segment and the T-wave are analysed in STAN. The software is reputed to detect subtle changes in the ST waveform, that may predict myocardial hypoxia. STAN's proponents posit that CTG has a high false positive rate of intrapartum hypoxic injury and has a positive predictive value for metabolic acidosis of only approximately 30%. STAN by monitoring the changes in the electrophysiology of the vital organ, the heart, It would hopefully be able to predict with accuracy when the electrophysiological changes at the cellular level in this vital organ could present the foetus with a severe challenge.

In the presence of reduced oxygen availability, the cardiac myocytes revert to glycolysis as a means of generating energy. Anaerobic metabolism, like glycolysis leads to less energy production per molecule of glucose than aerobic metabolism and hence the body turns to its stored carbohydrates, glycogen to supplement its energy needs. The resultant breakdown of glycogen leads to a release of potassium ions which is associated with an increase in the height of the T-wave. Cardiac hypoxia and ischaemia can cause ST depression and T-wave inversion. The STAN software is designed to detect these changes. STAN software analyses the average waveform of the foetal ECG signal over 20 consecutive heart beats. It then compares the waveform with the average of each of the subsequent complexes by analysing the ST segment and T wave changes over time and alerts the user to this by signalling a STAN event.

Surely, based on the interpretation of the physiology leading to ECG changes; Should this explanation be the accepted rationale for ST changes in the foetal ECG; One would expect STAN to be all that it promised and thus it was hoped that it would make a significant dent in the incidence of neonatal morbidity, the incidence of hypoxic ischaemic encephalopathy or even intrapartum deaths. STAN's failure to deliver, could therefore mean one of two things; (a) the suggested mechanism by which STAN works is incorrect or (b) the information it relays is unreliable. Surely that the normal ST segment is usually slanted upwards or horizontal and that increased release of potassium ions should lead to taller T-waves, hence leading to an increase in the upward slope of the ST segment versus a downward sloping ST segment and an inverted T-wave in the presence of hypoxia. A closer analysis of the given explanation does not seem to be in harmony with the mechanism at the cellular level. Basic physiology advises us that glycolysis tends to occur in the reduction of oxygen. Once oxygen levels are adequate, the preferred process for energy generation is not Glycolysis, it is aerobic respiration. Glycolysis is energy wasteful and yields a net gain of only 2 molecules of ATP compared to 36 molecules of ATP with aerobic respiration. It seems logical that the cells would tend to prefer to gain more energy, hence aerobic respiration rather than the wasteful process of glycolysis, to lead to a net gain of only 2ATP for every molecule of glucose. It would therefore seem that as a forerunner to glycolysis is a relative depletion in available oxygen. We know that glycogenolysis is increased when potassium is lost from the cell. Potassium depletion leads to to increased breakdown of glycogen and appears to be associated with abdominal obesity in patients. It therefore seems that the physiological association with increased potassium in glycolysis is accurate. If an increase in potassium in the cardiac myocytes lead to a depressed ST segment and an inversion of the T wave which is also going to be more prominent because of the increased potassium levels, then, suffice it to say that the physiology is sound but are the changes in the ST segment and T-wave simply based on this explanation? or are there other factors involved?

In May 2013, the Cochrane review involving five trials which included more than 15,000 women on foetal echocardiogram for foetal monitoring during labour was published. In that review the use of STAN was found to make no significant difference to births by caesarean section (R.R 0.99, 95% CI 0.91-1.08), the rate of severe foetal metabolic acidosis (cord arterial PH less than 7.05 and baseline deficit greater than 12 mmol (R.R 0.78, 95% CI (0.44-1.37) or the number of babies with neonatal encephalopathy (RR).54.95%CI 0.24-1.25).[6] The Cochrane Review did claim that the use of STAN resulted in fewer scalp sampling (FBS) RR 0.89, 99% C.I0.81-0.98).[6] Four other metanalysis came to a similar conclusion as the Cochrane. However, a 6th metanalysis in June 2014, was critical of the five previous metanalysis finding errors in the five previous randomised control trials. After correction of these errors a subsequent review article by sarcco et al in 2014 found that by using STAN, there was a reduction in severe foetal metabolic acidosis RR0.61 95% CI (0.41 – 0.91) as well as a reduction in FBS and operative vaginal deliveries. Interestingly, the lead author is a medical advisor to the company promoting the use of STAN. This obviously raises the issue of a conflict of interest.

STAN EVENTS

STAN should not be used without a Cardiotocographic (CTG) trace. This is the first area where the introduction of STAN to the UK based Obstetrician and Gynaecologist presents a problem. In the UK the CTG is classified based on NICE guidelines and broadly describes a CTG as normal, suspicious or pathological whereas STAN employs a CTG Classification based on FIGO criteria, which talks of normal, intermediary, abnormal or preterminal. Since the lexicon is different there is the inherent risk of failure to diagnose and treat a patient appropriately if the two nomenclatures are used interchangeably.

Changes in the foetal ECG waveforms are detected and displayed as an ST event. The details of the type and magnitude of the ST event are shown in the event log. There are three types of events that can be noted. (a) An episodic T/QRS rise, (b)Baseline T/ QRS rise and (c) Biphasic ST segment.

Episodic T/QRS rise

An episodic T/QRS rise is an increase in the T/QRS ratio that lasts for less than 10 minutes. The crosses at the bottom of the screen will rise steadily before returning to normalcy. This would indicate a brief period during which the foetus used anaerobic respiration but has reverted to the use of aerobic respiration.

Baseline T/QRS rise

This is described as an increase in the T/QRS ratio that has lasted for more than 10minutes. The crosses at the bottom of the graph rise and remain elevated. This pattern suggests that the foetus is using anaerobic respiration for greater than 10 minutes.

Biphasic ST

This type of event is related to a downward sloping ST segment. In this event, the grade of depression is labelled, 1, 2 or 3 at the bottom of the screen. This grading is based on the location of the ST segment relative to the ECG baseline. In Grade 1 Biphasic events, the ST segment is sloping downwards but the entire segment does not cross the baseline but instead remains above the baseline.

In Grade 2 biphasic events The ST segment which continues to trend downwards, now crosses the ECG baseline, but it is not entirely below the baseline.

In grade 3 biphasic events: the ST segment continues the downward sloping trajectory but unlike a grade2 biphasic event, the entire segment is below the ECG baseline.

These biphasic events suggest that hypoxia is present in the foetus, but the foetus has not yet responded or is incapable of responding to the hypoxic insult.

INTERPRETATION OF STAN EVENTS

The interpretation of a STAN event is inextricably bound to the interpretation of the CTG. Inherent in this requirement, is the view that STAN is not independent of the CTG. Because irrespective of the nature of the STAN event, if the CTG is normal no action is needed. The experts explain this unreliability of a STAN event as being tantamount to an adrenalin surge in the presence of a normal CTG. If the CTG is defined as being pathological, delivery must be expedited irrespective of the type of any STAN event.

The Reanalysis of STAN

Though a bit of kit which enhances the monitoring of foetuses in labour would be greatly welcomed, if it makes a contribution to improved foetal outcome, but despite the claim by the proponents of STAN; many, like us, believe that STAN is not that kit.

It is interesting that our national oversight bodies as the National Institute for Health and Care Excellence (NICE) and the Governing body for Obstetricians and Gynaecologist, the Royal College of Obstetricians and Gynaecologists (RCOG) has failed to recommend or even encourage the use of STAN as a tool to be used in the intrapartum surveillance of babies who may be unable to tolerate Labour or traverse their most dangerous passage; even after being available in the UK for almost 14 years.

Additionally, the Cochrane review of Foetal Electrocardiogram (ECG) for foetal monitoring during labour was published in 2013. It included five trials of STAN involving more than 15,000 women. Between 2012 and 2015, there have been four other meta-analysis of STAN published. The conclusions from these studies were the same, namely the use of STAN was associated with fewer Foetal blood sampling and fewer operative vaginal deliveries but makes no difference in the rate of metabolic acidosis, the very event that STAN was to address. It therefore leads the enquiring mind to wonder about the value of STAN and is it fit for purpose?

Though the physiological explanation appears to be correct, other factors seem to be involved. There are also additional features which questions the value of STAN. Clearly, it lacks the ability to distinguish between normal physiology and pathology, suggesting that a STAN event recorded in the presence of a normal CTG would be due to an adrenal surge. The use of STAN is also ill advised in cases of congenital cardiac abnormality. STAN's supposed focus is the detection of hypoxia in a foetus. It must however be understood that infection can cause severe illnesses in a foetus without the foetus being hypoxic. Additionally, STAN events may also be recorded in the presence of a dead foetus.

The procedure is invasive, requiring the placement of a foetal scalp electrode, the use of which is generally restricted to patients whose monitoring with external transducers may be challenging. Its use would therefore be contraindicated in patients with known blood borne

infections and in patients whose parents have bleeding disorders.

STAN apart from requiring increased hardware is unable to function as a stand-alone monitoring tool. It requires the adjunctive use of the Cardiotocograph (CTG) which gains precedence over whatever STAN may be suggesting. Irrespective of the type of STAN event, in the presence of a normal CTG, that STAN event should be ignored. Thus, using STAN, there is increased use of monitoring hardware which as revealed in the randomised controlled studies mentioned above has negligible impact on neonatal outcome.

Further the amalgamation of STAN which is dependent on the FIGO interpretation of CTG as opposed to the interpretation recommended by both NICE and the RCOG is a recipe for potential disaster and confusion.

Although there is a breech mode function, the inadvertent placement of the foetal scalp electrode on the breech may lead to an inversion of the ECG signal and hence faulty interpretation of a biphasic event.

With a foetal heart rate more than 170 beats per minute, a phenomenon that is occasionally seen in a healthy foetus during labour, the repolarising activity of the ventricle (the T-wave) may occur at the same time as the P-wave of atrial contraction. The morphology of the T-wave will therefore be altered leading to the triggering of a stan event of no significance.

Considering these concerns, we conclude by suggesting that STAN has failed to deliver on its expectations. The continued use of Stan as promoted is not fit for purpose in these United Kingdom and should be relegated to the archives of Obstetrics and Gynaecology. It should not be rolled out for use in the British labour ward clinical space.

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