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The impact of the introduction of intrapartum fetal ECG ST segment analysis. A population study

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Abstract

Introduction: ST segment analysis (STAN) of the fetal electrocardiogram was introduced as an adjunct to cardiotocography for intrapartum fetal monitoring 30 years ago. We examined the impact of the introduction of STAN on changes in the occurrence of fetal and neonatal deaths, Apgar scores of <7 at 5 min, intrapartum cesarean sections, and instrumental vaginal deliveries while controlling for time- and hospitalspecific trends and maternal risk factors.

Material and Methods: Data were retrieved from the Medical Birth Registry of Norway from 1985 to 2014. Individual data were linked to the Education Registry and the Central Person Registry. The study sample included 1 132022 singleton births with a gestational age of 36 weeks or beyond. Information about the year of STAN introduction was collected from every birth unit in Norway using a questionnaire. Our data structure consisted of a hospital-year panel. We applied a linear probability model with hospital-fixed effects and with adjustment for potentially confounding factors. The prevalence of the outcomes before and after the introduction of STAN were compared within each birth unit.

Results: In total, 23 birth units, representing 76% of all births in Norway, had introduced the STAN technology. During the study period, stillbirths declined from 2.6 to 1.9 per 1000 births, neonatal deaths declined from 1.7 to 0.7 per 1000 live births, babies with Apgar score <7 at 5 min after birth increased from 7.4 to 9.5 per 1000 births, intrapartum cesarean sections increased from 6.4% to 9.5%, and instrumental vaginal deliveries increased from 7.8% to 10.9%. Our analyses found that the introduction of STAN was not associated with the decline in proportion of stillbirths (p = 0.76) and neonatal deaths (p = 0.76) or with the increase in intrapartum cesarean sections (p = 0.92) and instrumental vaginal deliveries (p = 0.78). However, it was associated with the increased occurrence of Apgar score <7 at 5 min (p = 0.01).

Conclusions: There is no evidence that the introduction of STAN contributed to changes in the rates of stillbirths, neonatal deaths, intrapartum cesarean sections, or

Abbreviations: CTG, CardiotocographySTANST waveform analysis.

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instrumental vaginal deliveries. There was an association between the introduction of STAN and a small increase in neonates with low Apgar scores.

KEYWORDS

Apgar score, CTG, fetal death, fetal electrocardiogram, intrapartum fetal monitoring, national registry study, neonatal death, ST waveform analysis

1 | INTRODUCTION

The aim of fetal monitoring is to identify fetuses at increased risk of acute or long-term injury due to asphyxia to enable timely interventions to prevent such injuries. Continuous electronic fetal monitoring using cardiotocography (CTG) was introduced in the 1960s to detect signs of fetal asphyxia during labor and soon became widely used in clinical practice. The use of CTG has been associated with an increase in instrumental vaginal deliveries and cesarean sections and with a decrease in neonatal seizures after prolonged labor. However, the use of CTG has not been associated with long-term outcomes such as cerebral palsy in the child.¹⁻³ Nor has CTG been proven to affect perinatal or neonatal mortality.^{1,4}

As the CTG method has limitations, such as low specificity, a high false-positive rate, and high interrater variability, a method with greater diagnostic accuracy was needed to identify truly hypoxic fetuses.¹ ST segment analysis (STAN) of the fetal electrocardiogram (ECG) was introduced to clinical practice in the 1990s, as an adjunct test to CTG, to increase the specificity for detection of fetal hypoxia.⁵ During oxygen deficiency, anaerobic metabolism will cause changes in the ST segment of the fetal ECG. STAN is intended for use in attempted vaginal deliveries, with a singleton fetus, after 36 weeks' gestation, and after rupture of membranes since a fetal scalp electrode is necessary for the monitoring.

The effect of the STAN method, compared with CTG alone, has been evaluated in seven randomized controlled trials,⁶⁻¹² of which six have been included in three meta-analyses.¹³⁻¹⁵ The metaanalyses included more than 26000 women and their neonates and concluded that STAN did not improve perinatal outcomes, such as the occurrence of Apgar score <7 at 5 min, encephalopathy, neonatal seizures, or admission to neonatal intensive care units (NICUs). Nor did cesarean section rates decrease, but there was a decrease in instrumental vaginal deliveries in women allocated to STAN monitoring.¹³⁻¹⁵

Despite the results from the three meta-analyses, $^{13-15}$ there is no consensus about whether or not the STAN method should be used. $^{16-18}$

It has been argued that learning how to use the STAN method takes some time and that beneficial effects were therefore missed in previous trials.^{19,20}

As randomized controlled trials do not reflect real life, but the effect of an intervention under the best possible circumstances, evidence is also needed of the effects of the STAN method at a population level.¹⁸

Key message

There is no evidence that the introduction of ST segment analysis (STAN) contributed to changes in the rates of stillbirths, neonatal deaths, intrapartum cesarean sections, or instrumental vaginal deliveries. There was an association between the introduction of STAN and a small increase in neonates with low Apgar scores.

We therefore examined the impact of the introduction of the STAN method on changes in the occurrence of fetal and neonatal deaths, Apgar scores <7 at 5 min, intrapartum cesarean sections, and instrumental vaginal deliveries. We also examined whether a learning curve affected neonatal outcomes.

2 | MATERIAL AND METHODS

We performed a population study using data from all the birth units in Norway that have introduced the STAN technology. Data were retrieved from the Medical Birth Registry of Norway for the period 1985 to 2014. Midwives and consultants are required to report all births to the Medical Birth Registry.

Individual data from the Medical Birth Registry were linked to the Norwegian Education Registry to obtain information about the attained level of maternal education at delivery²¹ and to the Central Person Registry to gain information about each mother's country of birth.

Information about the introduction of STAN was collected by means of a questionnaire emailed in May 2016 to the head of every birth unit in Norway. We asked them to answer the following questions: Does your birth unit use the STAN method (yes/no)? If yes, in what year was the STAN method introduced? All 46 birth units answered the questionnaire.

We performed separate data analyses for the following main outcomes: stillbirth (baby born without signs of life), neonatal death (death of a live-born baby within the first 28 days of life), and Apgar score <7 at 5 min after the birth. The Apgar score is a standardized assessment of infant vitality after birth, which comprises a sum score of five components: skin color, heart rate, reflexes, muscle tone, and respiration, each of which is given the score 0.1 or 2, and a score \geq 7 at 5 min after birth is considered normal.²² An Apgar score <7 at 5 min is associated with an increased risk of neonatal death and neurologic disability, although the absolute risks are low.²³ We also assessed the effect of the introduction of STAN on the maternal endpoints intrapartum cesarean section (cesarean section performed after the onset of an intended vaginal delivery) and instrumental vaginal delivery (vacuum or forceps delivery). Each outcome was coded as "no" or "yes."

2.1 | Data analysis

Our data structure consisted of a hospital-year panel. We applied a linear probability model in the estimation.²⁴ The treatment group comprised women with a gestational length of 36 weeks or more who delivered after STAN had been introduced. The control group comprised women who delivered in the same maternity ward prior to the introduction of STAN.

We ran three different models for each primary outcome measure. In the first model, we included the following maternal risk factors of adverse pregnancy outcome: age, number of previous births, level of education (below upper secondary, upper secondary, higher), previous cesarean section, previous birth of a stillborn baby, immigrant status (country of birth), and whether she had a chronic disease (asthma, diabetes, epilepsy, heart disease, chronic hypertension, chronic kidney failure, rheumatoid arthritis, preeclampsia, bleeding during pregnancy). We also included year of delivery to adjust for any changes that may have occurred during our observation period, and we included hospital-fixed effects. Fixed effects were included to control for timeinvariant heterogeneity between hospitals, for example differences in the guality of obstetric care. In the second model, we extended the first model to also include hospital-specific trends, to consider whether time trends could have different effects in different hospitals. In the third model, we used the second model but excluded the maternal risk factors. The analyses were restricted to the period 1985-2014, as STAN was first introduced in 1990. The analyses regarding intrapartum cesarean section were restricted to 1989-2014 as the Medical Birth Registry of Norway did not differentiate between elective and emergency cesarean sections before 1989. Our regression model is described in detail in Appendix S1.

For the primary endpoints, we repeated the analyses including only women with intended vaginal deliveries, excluding women who delivered by elective cesarean sections. To assess whether a learning curve affects the effect of the STAN technology, we assessed the results after learning curves of 1, 2, and 3 years after the introduction.

2.2 | Setting for intrapartum services in Norway

Health services are financed through taxes, and all maternity health care is free of charge. Except for a few independent midwives assisting homebirths, intrapartum care is provided in public hospitals and health centers. Obstetricians, midwives, and other staff members receive fixed salaries. Intrapartum care is organized at three levels: (1) highly specialized birth units providing advanced obstetric, anesthetic, and pediatric services, and with NICUs; (2) birth units in smaller hospitals, with obstetric and anesthetic services; and (3) midwifery-led units that provide care for low-risk women only. Midwives attend all births, are the main caregivers in low-risk labors, assist spontaneous vaginal deliveries, and are present at instrumental deliveries. In high-risk women, and when there are complications, an obstetrician will be responsible and perform operative deliveries. Norwegian guidelines for intrapartum fetal monitoring recommend intermittent auscultation for low-risk women and continuous CTG for women with risk factors for adverse neonatal outcomes. STAN or fetal blood sampling (lactate or pH from the fetal scalp) are recommended as adjuncts to CTG monitoring.²⁵

Approximately 57000 births take place annually in Norway, in 46 birth units, of which 17 are at level 1, 22 at level 2, and 7 at level 3. Women are screened for risk status upon admission and throughout labor. Risk status is not registered systematically. Two studies, from a level 1 and a level 2 unit, reported that 26% and 36% of all women were low risk upon admission and remained so throughout labor.^{26,27}

2.3 | Ethical approval

The study was approved on 3 October 2012 by the Norwegian Regional Committee for Medical and Health Research Ethics with registration number 2012/1433.

3 | RESULTS

Our source population included all 1 778864 births in Norway from 1985 to 2014. We included all singleton births at gestational age 36 weeks or beyond in units where STAN had been introduced: a total of 1 132022 births (Figure 1).

STAN was first taken into use in 1990, in two hospitals. By 2014, 23 of the 46 birth units had introduced STAN, covering 76% of all births in Norway (Table S1).

3.1 | Fetal and neonatal deaths

During the period 1985–2014, in our study sample, the proportion of stillbirths reduced from 2.6 to 1.9 per 1000 births, and neonatal deaths (within the first 28 days of life) reduced from 1.7 to 0.7 per 1000 live births. Our analyses investigated whether the introduction of STAN influenced the occurrence of fetal or neonatal deaths among babies born with a gestational age of 36 weeks or beyond. In the three different models, the regression coefficients of introducing STAN were between 0.0048 and –0.00002 and far from statistically significant at conventional levels (*p*-values 0.76–0.95 for fetal deaths and 0.69–0.76 for neonatal deaths) (Table 1). This means that the introduction of STAN had no impact on the reductions in stillbirth



FIGURE 1 Enrolment to study and models for analyses. STAN = ST segment analysis

and neonatal death rates observed through the study period. We also performed data analyses with the exclusion of all women who delivered by elective cesarean section and were therefore not exposed to intrapartum fetal monitoring. Such exclusion did not alter the estimates substantially (Table 2).

3.2 | Apgar score <7 at 5 min after birth

During the study period, the proportion of babies with Apgar score <7 at 5 min after birth increased from 7.4 to 9.5 per 1000 births in our study sample. Our analyses showed that the introduction of STAN was associated with an increase in the proportion of infants with Apgar scores <7 at 5 min after birth (Table 1). In the three different models, the regression coefficients were in the range 0.0010-0.0013 (*p*-values 0.09-0.075) (Table 1).

When women who delivered by elective cesarean sections were excluded from the analyses, the regression coefficient was

0.0012–0.0015 (*p*-values 0.005–0.085) (Table 2). Calculated using this proportion, our results imply that the use of STAN contributed 12%–17% of the increase in babies born with a 5-min Apgar score <7 in our study sample. In absolute numbers, it means that the introduction of STAN resulted in in one more baby with an Apgar score <7 at 5 min per 3–4000 births.

3.3 | Intrapartum cesarean sections and instrumental vaginal deliveries

During the study period, the proportion of intrapartum cesarean sections increased from 6.4% to 9.5% in our study sample (1989–2014). The proportion of instrumental vaginal deliveries increased from 7.8% to 10.9%. The introduction of STAN did not contribute to the increase in the occurrence of either intrapartum cesarean sections (*p*-values 0.51–0.92) or instrumental vaginal deliveries (*p*-values 0.24–0.78) (Table 3).

| Primary endpoints | Fetal deaths | | | Neonatal dea | :hs 0–28 days | | Apgar score < | .7 at 5 min | |
|---|---|---|--|-------------------------------------|--|---|--------------------|-------------|---------|
| Regression model | Model 1 | Model 2 | Model 3 | Model 1 | Model 2 | Model 3 | Model 1 | Model 2 | Model 3 |
| Regression coefficient ^a | -0.00001 | -0.00004 | -0.00002 | 0.00005 | 0.00004 | 0.00005 | 0.00105 | 0.00129 | 0.00135 |
| Standard error | 0.00011 | 0.00011 | 0.00012 | 0.00012 | 0.00012 | 0.00012 | 0.00056 | 0.00046 | 0.00047 |
| <i>p</i> -value | 0.95 | 0.76 | 0.90 | 0.69 | 0.76 | 0.71 | 0.075 | 0.010 | 0.009 |
| Model specification | | | | | | | | | |
| Maternal risk factors included | Yes | Yes | No | Yes | Yes | No | Yes | Yes | No |
| Linear trend (year of birth) | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Hospital fixed effect | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Hospital fixed effect $	imes$ linear trend | No | Yes | Yes | No | Yes | Yes | No | Yes | Yes |
| No. of deaths ^b | 2224 | 2224 | 2324 | 1054 | 1054 | 1093 | | | |
| No. of live-born with Apgar score <7 at 5 min ^b | | | | | | | 9242 | 9242 | 9662 |
| Total no. of births ^c | 1 091 390 | 1 091 390 | 1 132 022 | 1089166 | 1 089 166 | 1 129 698 | 1085970 | 1085970 | 1126418 |
| ^a Regression coefficients with standard error: ^b The numbers are lower in Models 1 and 2 b ^c Total number of births for fetal deaths inclu | s clustered at the h ecause Model 3 do des all live-born an | iospital level. es not adjust for m d stillborn babies; | laternal risk factor total number for n | s and thereby incleonated deaths ar | udes more womer id Apgar score incl | ו and babies in the udes live-born bab | analyses. vies. | | |

TABLE 1 Neonatal endpoints: Fetal deaths, neonatal deaths, and Apgar scores <7 at 5 min after birth

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| Primary endpoints | Fetal deaths | | | Neonatal deat | hs U-Z8 days | | Apgar score | at 5 min</th <th></th> | |
|---|---|--------------------------------------|--------------------|-------------------|--------------|----------|-------------|------------------------|---------|
| Regression model | Model 1 | Model 2 | Model 3 | Model 1 | Model 2 | Model 3 | Model 1 | Model 2 | Model 3 |
| Regression coefficient ^b | -0.00006 | -0.00010 | -0.00008 | -0.00003 | -0.00003 | -0.00002 | 0.00126 | 0.00146 | 0.00153 |
| Standard error | 0.00011 | 0.00015 | 0.00015 | 0.00011 | 0.00013 | 0.00013 | 0.00070 | 0.00049 | 0.00048 |
| <i>p</i> -value | 0.59 | 0.52 | 0.58 | 0.79 | 0.79 | 0.85 | 0.085 | 0.007 | 0.005 |
| Model specification | | | | | | | | | |
| Maternal risk factors included | Yes | Yes | No | Yes | Yes | No | Yes | Yes | No |
| Linear trend (year of birth) | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Hospital fixed effect | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Hospital fixed effect $	imes$ linear trend | No | Yes | Yes | No | Yes | Yes | No | Yes | Yes |
| No. of deaths ^c | 1900 | 1900 | 1997 | 775 | 775 | 809 | | | |
| No. of live-born with Apgar score <7 at 5 min ^c | | | | | | | 8196 | 8196 | 8590 |
| Total no. of births ^d | 923110 | 923110 | 960045 | 921210 | 921210 | 958048 | 919231 | 919231 | 956008 |
| Before 1989, the Medical Birth Registry of I Regression coefficients with standard error | Norway did not di s clustered at the | ferentiate betwee hospital level. | n elective and eme | rgency cesarean s | ections. | | | | |

^cThe numbers are lower in Models 1 and 2 because Model 3 does not adjust for maternal risk factors and thereby includes more women and babies in the analyses.

^dTotal number of births for fetal deaths includes all live-born and stillborn babies; total number for neonatal deaths and Apgar score includes live-born babies.

6

3.4 | Learning curve

Staff may need time to learn how to use the technology. If this is the case, any effects of the introduction of STAN will not occur until a period after its introduction. In Table 4, we present estimates for the effects of STAN 1, 2, and 3 years after its introduction. There were no delayed effects on the occurrence of fetal or neonatal deaths. STAN increased the occurrence of babies born with Apgar score <7 at 5 min from 2 years after its introduction (*p*-values 0.013–0.016) (Table 4).

4 | DISCUSSION

This large population study found no evidence that the introduction of STAN in Norway contributed to changes in the rates of fetal deaths, neonatal deaths, intrapartum cesarean sections, or instrumental vaginal deliveries. There was an association between the introduction of STAN and a small increase in babies born with Apgar score <7 at 5 min after birth.

STAN is an adjunct to CTG, and the use and interpretation of CTG is a crucial part of the STAN method. In our study, we compared the outcomes of labor in the periods when CTG was used alone with outcomes in the period when STAN was used in conjunction with CTG.

A meta-analysis comparing the effects of STAN adjunct to CTG vs CTG alone found twice as many cases of perinatal death among deliveries monitored by STAN plus CTG compared with CTG alone.¹³ The numbers were small, and the difference was not statistically significant.¹³ We are not aware of any previous study that has reported

changes at a population level in the occurrence of stillbirths or neonatal deaths after the introduction of STAN.¹⁸

In the present population study, we did not find that the introduction of STAN had any effect on the occurrence of intrapartum cesarean sections. This is in line with results from previous randomized controlled trials comparing CTG plus STAN with CTG alone.¹²⁻¹⁵ However, meta-analyses of six randomized controlled trials suggested that women randomized to fetal monitoring with STAN plus CTG had a reduced risk of instrumental vaginal delivery compared with women randomized to CTG alone.¹³⁻¹⁵

We found that the introduction of STAN increased the occurrence of Apgar score <7 at 5 min after birth. Despite reaching statistical significance,²⁸ the clinical impact is probably limited for Norway as it implies an increase of about 14–21 babies per year with a lower Apgar score. Three meta-analyses including six randomized trials comparing STAN vs CTG alone reported no differences between the groups in the occurrence of Apgar score <7 at 5 min after birth.¹³⁻¹⁵ An observational study reported a decrease in babies with neonatal encephalopathy after the introduction of STAN²⁰ but no change in the proportion of babies with a low Apgar score at birth.²⁰ A review concluded that there was a consistent association between low 5min Apgar scores <7 and neurological disabilities.²³ However, the absolute risks were low, and the majority of children born with a low Apgar score did not develop any disabilities.²³

The STAN method was introduced to increase the specificity for detection of fetal hypoxia as compared with CTG alone. Any increase in the specificity of a diagnostic instrument may decrease its sensitivity, and some pregnancies with true fetal hypoxia may not have been diagnosed as such using the STAN method. Hence, the lower sensitivity for fetal hypoxia using STAN compared with CTG

| Secondary endpoints | Intrapartum cesa | arean sections | | Instrumental vag | inal deliveries | |
|---|------------------|----------------|-----------|------------------|-----------------|-----------|
| Regression model | Model 1 | Model 2 | Model 3 | Model 1 | Model 2 | Model 3 |
| Regression coefficient ^a | -0.00244 | -0.00031 | -0.00129 | -0.00731 | 0.00098 | 0.00269 |
| Standard error | 0.00363 | 0.00318 | 0.00353 | 0.00602 | 0.00357 | 0.00376 |
| p-value | 0.51 | 0.92 | 0.72 | 0.24 | 0.78 | 0.48 |
| Model specification | | | | | | |
| Maternal risk factors included | Yes | Yes | No | Yes | Yes | No |
| Linear trend (year of birth) | Yes | Yes | Yes | Yes | Yes | Yes |
| Hospital fixed effect | Yes | Yes | Yes | Yes | Yes | Yes |
| Hospital fixed effect $	imes$ linear trend | No | Yes | Yes | No | Yes | Yes |
| No. of intrapartum cesarean sections ^b | 72250 | 72250 | 76907 | | | |
| No. of instrumental vaginal deliveries ^b | | | | 85057 | 85057 | 89307 |
| Total no. of births ^c | 968792 | 968792 | 1 009 754 | 968792 | 968792 | 1 009 754 |

TABLE 3 Maternal endpoints: Intrapartum cesarean sections and instrumental vaginal deliveries

^aRegression coefficients with standard errors clustered at the hospital level.

^bThe numbers are lower in Models 1 and 2 because Model 3 does not adjust for maternal risk factors and thereby includes more women in the analyses.

^cIncludes both live-born and stillborn babies.

| Primary endpoints | Fetal deaths | Neonatal deaths ^a | Apgar score <7 at 5 min |
|--|--------------|---------------------------------|----------------------------|
| Time for introduction of STAN | | | |
| The year of introduction | | | |
| Regression coefficients | -0.00014 | -0.00004 | 0.00055 |
| Standard errors ^b | 0.00023 | 0.00017 | 0.00053 |
| <i>p</i> -values | 0.56 | 0.83 | 0.31 |
| One year after introduction | | | |
| Regression coefficients | 0.00018 | -0.00010 | 0.00096 |
| Standard errors ^b | 0.00024 | 0.00024 | 0.00088 |
| p-values | 0.46 | 0.68 | 0.29 |
| Two years after introduction | | | |
| Regression coefficients | -0.00018 | 0.00017 | 0.00230 |
| Standard errors ^b | 0.00027 | 0.00019 | 0.00088 |
| p-values | 0.51 | 0.40 | 0.016 |
| Three or more years after introduction | | | |
| Regression coefficients | 0.00010 | 0.00015 | 0.00142 |
| Standard errors ^b | 0.00017 | 0.00012 | 0.00052 |
| P-values | 0.58 | 0.20 | 0.013 |
| No. of deaths | 2224 | 1054 | |
| No. of babies with Apgar score <7 | | | 9242 |
| Total no. of births | 1 091 390 | 1 089 166 | 1 085 970 |

TABLE 4 Effects of learning curves 1, 2 and 3 or more years after the introduction of STAN

BLIX ET AL.

Abbreviation: STAN, ST segment analysis.

^aWithin 28 days after birth.

^bStandard errors clustered at the hospital level.

alone could possibly explain the increased occurrence of low Apgar scores after the introduction of STAN.

The increase in babies born with an Apgar score <7 at 5 min after birth was seen from 2 years after the introduction of STAN in the present study. Two observational studies found that learning curves after the introduction of STAN probably had an effect on outcomes.^{19,20} After learning curves of 2 and 3 years, respectively, a decrease in babies born with metabolic acidosis in umbilical artery blood was reported.^{19,20} One of the studies also reported a reduction in the proportion of cesarean sections after a 3-year learning curve.19

Our study suggests that the introduction of the STAN method had no effect on the rates of stillbirths or neonatal mortality. We cannot rule out that the STAN method has a beneficial effect in clinical settings where the prevalence of perinatal and neonatal deaths is higher than in our study. Population studies evaluating the introduction of STAN in other countries can provide additional clinical implications.

Our study has several strengths. The dataset is large and includes all deliveries ≥36 gestational weeks in all Norwegian birth units that introduced the STAN technology during the years 1985-2014. It is therefore unlikely that the lack of effect from the introduction of STAN on fetal and neonatal mortality can be explained by lack of statistical power. The study was carried out in a population

where neither the pregnant women nor the caregivers had economic incentives that could influence which type of fetal monitoring the women received. We adjusted for maternal risk factors. Additionally, we included hospital-fixed effects and hospital-specific trends in the estimations to control for non-observable factors within hospitals over time, which could affect the risks of adverse pregnancy outcomes and also be associated with the introduction of STAN. The consistent findings in all models increase the reliability of our results.

Our study has limitations. The information about the year of STAN introduction was based on reports from every birth unit in Norway. However, STAN was introduced several years prior to the reporting, and there is a risk of erroneous reporting. However, it is unlikely that such errors in reporting were also associated with adverse pregnancy outcomes. Unsystematic errors in reporting are likely to cause underestimations rather than overestimations of associations.

Another limitation is that the proportion of women who were monitored with STAN is unknown. In 2017, when the Medical Birth Registry of Norway started to register mode of intrapartum fetal monitoring, 51% of deliveries were monitored with STAN in the units that had introduced the technology,²⁹ but the proportion in the years prior to this remains unknown. A third limitation is that we did not have information about umbilical cord pH values or metabolic acidosis in the neonates.

5 | CONCLUSION

There is no statistical evidence that the introduction of STAN in Norway contributed to changes in the occurrence of stillbirths, neonatal deaths, intrapartum cesarean sections, or instrumental vaginal deliveries. There was an association between the introduction of STAN and a small increase in the occurrence of neonates with Apgar score <7 at 5 min after birth. Thus, our results do not support the use of STAN over CTG alone for fetal monitoring.

CONFLICT OF INTEREST

None.

AUTHOR CONTRIBUTIONS

AE, IS and JG initiated the study. AE collected data on the introduction of STAN from all hospitals in Norway. IS and JG performed the analyses. All authors interpreted the results. EB wrote the first draft of the manuscript, with contributions from all authors. All authors approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

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200



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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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