Intact neurological survival after emergency Caesarean delivery for pathological fetal heart rate tracings at term- is it time to rethink 'fetal distress' interpretation of cardiotocography in South African cerebral palsy lawsuits?

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Abstract

Objective:

The aim of this descriptive study was to critically review the CTG tracings that informed the decision to do an urgent Caesarean delivery (CD) in cases where there was a good neonatal outcome.

Method:

This was an observational cross-sectional study using data collected from records at Tygerberg Academic Hospital reviewing women >36 weeks gestation who delivered by emergency caesarean section with the indication of “fetal distress” or “pathological CTG” and had normal neonatal outcomes.

Results:

The mean time from decision to do a CS to the delivery of the baby was 113 minutes and the mean time from the removal of the CTG from the patient (or the last CTG available to review in the folder) to the start of surgery was 46 minutes. The mean duration of abnormal tracings (from diagnosis to recovery or last CTG taken if there was ongoing abnormal CTG) was 72 minutes, ranging from 30 to 355 minutes. Eighty percent of women still had pathological changes on the CTG at the time of transport to theatre.

Conclusion:

This audit showed that in most babies with pathological CTG tracings, neither prolonged periods of abnormal tracing nor delays in delivery necessarily leads to a bad outcome. In litigation cases for term hypoxic brain injury, there are other underlying conditions of the fetus and mother that needs to be considered and not only a focus on CTG interpretation and management, before negligence is inferred.

Introduction

Approximately 3500 caesarean deliveries (CD) are done at Tygerberg Academic Hospital (TAH) each year – of these 63% are emergencies (decision for urgent delivery taken during the intrapartum period) and the majority of these are performed for pathological cardiotocographic tracings, so called “fetal distress”. In this group, only a small number of neonates have poor outcomes or require admission to neonatal care.

Electronic fetal monitoring (EFM) has become the most commonly performed obstetric procedure in the world being implemented in more than 85% of labours in both low and high-risk pregnancies. (1) Its initial purpose and promise were to reduce the incidence of cerebral palsy, mental retardation, and perinatal mortality but EFM was quickly adopted into widespread use without large randomised trials and with very little supporting evidence for its efficacy and reliability. (2)

The fetal heart rate (FHR) patterns that may suggest inadequate fetal oxygenation include changes in the baseline heart rate; the baseline variability and recurrent decelerations. According to the National Institute of Child Health and Human Development (NICHD) in the USA, the deceleration area is the most predictive FHR pattern for acidaemia and (combined with tachycardia) for significant risk of morbidity. (3)

The FHR patterns associated with fetal asphyxia included absent and minimal baseline variability (most specific but only identified in 17% of cases of asphyxia) and late and prolonged decelerations. The estimated positive predictive value

range from 18.1% to 2.6%, and the negative predictive value range from 98.3% to 99.5%. (4) EFM has a very high false-positive rate for predicting fetal asphyxia and poor neurological outcome. (5)

The fallibility, varied interpretation, and poor sensitivity of EFM also lead to an increase in the numbers of operative vaginal deliveries, fewer spontaneous vaginal births, and more caesarean deliveries for abnormal FHR patterns or suspected acidosis. (6,7) Various international clinical societies and colleges have developed definitions and diagnostic criteria for fetal and neonatal outcomes e.g hypoxic-ischaemic encephalopathy (HIE), fetal distress (FD), perinatal asphyxia or “non-reassuring” fetal status. These varied definitions have resulted in difficulty establishing an exact correlation between asphyxia and HIE –insults may be acute, chronic or subacute hypoxia. Consequently, the timing of insult is difficult to determine, and a cardiotocographic (CTG) trace can be misleading as chronic hypoxia may lead to stillbirth or intrauterine fetal demise regardless of the intervention. On the other hand, acute and subacute changes may occur in the perinatal period – up to 48 hours before labour and delivery. In reality, there may be significant overlap in these conditions. (8)

The exact etiopathology of cerebral palsy (CP) is difficult to establish in most cases, especially with regards to timing but it has been largely established that only 10-20% of cases can be linked to intrapartum events – thus only 10-20% would be prevented by action taken upon suggestive findings on EFM. CP is likely predominantly caused by prenatal factors and is therefore not preventable by the response to intrapartum FHR patterns. (9) It is also important to note that babies

that are encephalopathic at birth do not necessarily result in children affected by CP. (8) Hypoxic insults to the fetus may be chronic – e.g placental insufficiency, infection, genetic abnormalities, or exposure to toxins; or acute or subacute when many factors may contribute. Chronic hypoxia may result in intra-uterine fetal death (IUFD) or stillbirth regardless of the intervention based on CTG findings, in fact exposing the mother to increased risk of morbidity and mortality through unnecessary operative procedures (instrumental delivery or CD to expedite delivery). Subacute and acute asphyxia can lead to stillbirth, intrauterine or neonatal death, or neonatal encephalopathy. (8,10)

With the American College of Obstetrics and Gynaecology (ACOG) guidelines on fetal heart rate tracings, the criteria used has a low reliability, low sensitivity, and high specificity in the prediction of acidaemia. With the criteria of the International Federation of Gynaecology and Obstetrics (FIGO) and National Institute for Health and Care Excellence (NICE) guidelines, there is higher reliability, a trend towards higher sensitivity, and lower specificity in the prediction of acidaemia. (11–13)

Risk factors such as prolonged spontaneous rupture of membranes (SROM), prematurity, intrauterine growth restriction (IUGR), infection or the presence of meconium-stained liquor, the use of oxytocin for failure to the progress of labour, and the presence of a uterine scar need to be considered whilst interpreting the CTG trace. In addition, a critical analysis of the CTG trace needs to be made to differentiate between a fetus that is compensating well with the ongoing stress of labour from one that is unable to compensate or has begun the process of

decompensation. Fetal blood sampling (FBS), analysis of the fetal ECG using STAN, fetal pulse oximetry, and fetal scalp blood lactate levels have been evaluated with variable success rates. (14–16, 17, 18)

A Cochrane systematic review on CTG has concluded that the use of FBS does not reduce caesarean section rates or any pre-specified neonatal outcomes. (19) Fetal blood sampling is rarely used in the United States; it has been replaced by observation of the fetal heart rate variability over time, as well as fetal stimulation testing. (20) FBS has largely fallen into disuse with the HIV pandemic and risk for transmission of HIV to the fetus. FBS is no longer recommend in the 2022 NICE guideline. (21)

Despite the above limitations, interpretation and management of CTG tracings are often criticized in obstetric malpractice cases. (22) In South Africa (SA), as in the rest of the world, “failure to diagnose and treat fetal asphyxia” is the most common claim in obstetrical malpractice litigation. (23) As examples from recent SA birth injury claims:

- MEC for Health and Social Development, Gauteng v MM on behalf of OM Case no 697/2020) where ‘the trial revolved largely around the correct interpretation of the CTG tracings during the critical period’ before birth.(24)
- X[....] v Member of the Executive Council for Health, Western Cape (5088/2017) [2021] ZAWCHC 200; where it was argued that ‘there were late decelerations in the fetal heart rate and that, in association with the

plaintiff's contractions in active labour, these were the most likely cause of the hypoxia'(25).

- K v MEC for Health, Eastern Cape (3180/2014) [2018] ZAECGHC 21 where 'they failed to react promptly and appropriately to the CTG tracing showing a combination of reduced variability and late deceleration' (26)

And for a delay between diagnosis of an abnormal CTG and surgery

- M obo M v Member of the Executive Council for Health (43421A/2013) [2015] ZAGPPHC 784 'the operation started more than an hour after the decision was taken let alone performed within the hour. This is negligent because the fetus was experiencing tachycardia and for this reason the decision was taken to perform an emergency C-section; time was of the essence. This lack of urgency caused further damage to the fetus'(27)

The characteristics of fetal monitoring in term infants with moderate to severe neonatal encephalopathy after birth at Tygerberg Hospital were recently described by Adams et al. (28) The main avoidable factors were a delay in access to theatre (waiting time on average 1 hour and 40 minutes from decision to incision) and failure to recognise or react to abnormal CTG tracings in 36% of cases. The purpose of this current study was to scrutinise term Caesareans deliveries indicated by severe fetal compromise on CTG, but where the pattern was recognised in time and the outcome was normal (5 minute Apgar score >5 and uneventful neonatal course with discharge to the mother after birth). The aim was to describe CTG tracings (as classified by the NICE criteria) and the same modifiable factors as in the Adams study to try and determine why the outcome was different (normal) in these cases.

Methods

This was an observational cross-sectional study using data from the labour ward theatre register and clinical data from patient folders.

Setting and study population

All women >36 weeks gestation who delivered by emergency caesarean section between 1 January and 31st August 2019 with the indication of “fetal distress” or “pathological CTG” and had normal neonatal outcomes were included. The aim was to identify 100 consecutive cases with prolonged (>30 minutes) of pathological CTG changes and then analyse the modifiable factors.

Definitions:

- Pathological CTG: A CTG tracing with two non-reassuring (NICE 2022 ‘amber’) or one abnormal feature (NICE 2022 ‘red’) according to the NICE criteria. In cases of late or variable decelerations with concerning characteristics, a CTG lasting more than 30 minutes. In cases with absent or decreased variability (less than 5bpm), a CTG running for at least 50 minutes. Decelerations were classified as repetitive if they occurred with >50% of the contractions.
- Normal outcome: Babies with a 5-minute APGAR score more than 5, normal umbilical cord blood gas (if indicated) and no signs of neonatal encephalopathy. Babies lodged with their mother with standard post-delivery nursing care, with no interventions needed from neonatology. Babies discharged to home in good condition with the mother. No subsequent hospital admission in the first six weeks of life.

- Modifiable factors: All factors that could potentially have contributed to a good (or bad) outcome was audited from the folder including decision-to-delivery time, delays in starting intra-partum resuscitation, injudicious use of oxytocin or other uterotonic drugs, neonatal resuscitation, acute intra-partum events, the underlying maternal or fetal condition, periods of inadequate (or no) fetal monitoring, and the interval between the last documented CTG and start of theatre.
- Intrapartum resuscitation (IPR): Local hospital protocol dictates a change in position, 200ml intravenous fluid bolus, cessation of any uterotonic drugs and (if no contra-indications exist) a bolus intravenous dose of 250µg salbutamol to suppress contractions; with review after 30 minutes. This is based on the evidence from a systematic review on IPR. (29)

Local Tygerberg growth charts (Theron et al) were used to correlate birth weight with gestational age. (30,31)

Tygerberg Academic Hospital is a secondary and tertiary level referral hospital serving eight midwife obstetric units and three district hospitals with primary level care in the eastern half of the greater Cape Town Metropole. The annual number of deliveries are about 8000. There are only high-risk (specialist and subspecialist referrals) deliveries at TAH, as all the low or intermediate risk women are delivered at the referral units.

The following were exclusion criteria:

- Multiple pregnancies

- Pregnancies with known antenatal fetal compromise (e.g. growth restriction or congenital anomalies)
- Neonates who required extensive resuscitation at birth or admission for neonatal asphyxia or other birth injuries.
- CTG that, on review by both authors, did not met the criteria of a pathological CTG (and had a good outcome).
- Missing case notes
- Acute intra-partum events (e.g. cord prolapse, abruptio, uterine rupture)- so called category 1 CS in the NICE CS guideline. (32)

Data was obtained from labour ward and theatre registers and clinical case notes. As it was a retrospective review, no informed consent was needed. The study protocol was approved by the local Health Ethics Committee and the CEO of the hospital gave permission to conduct the study and distribute the results. Data captured included age, gravidity, parity, body mass index, method of determination of estimated date of delivery (EDD), date and gestational age at first ultrasound, previous modes of delivery, current co-morbidities, date of delivery, gestational age at delivery, CTG trace abnormalities, time from decision to delivery, whether intrapartum resuscitation was performed, Apgar scores, and umbilical cord blood gas if available. The clinical notes and decisions regarding management were also recorded.

The CTG tracings were classified by both authors working independently at first and then discussion to reach consensus on areas where there was disagreement.

Results

Three hundred and fifty folders (identified from the theatre register as “CS for fetal distress”) were reviewed to obtain 100 consecutive cases that met the inclusion criteria. Data were available for all 100 women. The demographic detail is given in Table 1. The folders that were excluded either did not meet the inclusion criteria or the authors did not agree with the findings of a pathological CTG (did not meet the NICE criteria).

Table 1

	Mean	Median	Range minimum	Range Maximum
Gestational Age	275 days (39w2d)	276 days (39w3d)	259 (37w0d)	296 (42w2d)
Maternal age	25	25	18	45
Gravidity		2	1	9
Parity		1	0	4

Gestational age was calculated using early ultrasound (<24 weeks) where available. Eighty percent of women booked early enough to have accurate gestational age available. For the rest, the gestation was calculated by the best means available (usually a later ultrasound correlated with dates). Seven women had some form of mild incongruity noted on ultrasound, as shown in Table 2.

Table 2

Anomaly	**Number of women**
Splenic calcifications	1
Anhydramnios	1
T21 2:1 risk	1

Breech at term	1
Mild pyelectasis	1
Multifibroid uterus	2

All patients were referred for high risk care during the antenatal intrapartum period. The most frequent reason for referral to the labour ward was late onset pre-eclampsia (49 cases). Planned induction of labour was mostly for gestational diabetes (24 cases) or a previous fetal death or adverse outcome (18 cases).

Labour was induced in 55 cases. A combination of prostaglandin (oral misoprostol) and/or mechanical (catheter bulb) was used in 26 women. Oxytocin was used in 29 as the primary means of induction. Artificial rupture of membranes was needed in 31 cases.

The CTG tracing where the diagnosis of fetal distress was made, was reviewed by both authors, and correlated with the clinical notes in the folder. Agreement that the CTG was pathological (NICE 2017, amended 2022)(21) was unanimous in 100% of the cases. Tracings were described at two time points: at the first diagnosis of pathological changes, including the period during and after intra-partum resuscitation up to where the decision for CS was made; and again, for the last 30 minutes before removal of the CTG to take the patient to theatre.

For 28 women, pathological changes were documented prior to the onset of labour. Diagnosis during the latent stage of labour was done in 40 cases and 27 women were already in active labour at the time that CTG changes were

diagnosed. The remaining five cases were detected during the second stage of labour. Only two (of these five) had a simultaneous diagnosis of cephalo-pelvic disproportion.

Junior doctors were the primary decision makers for 34 of the cases. A further 45 were diagnosed and managed at registrar level and for 21 there were specialist input in analysis of the CTG tracings.

Evidence of intrapartum resuscitation was documented in 71 cases. In a further 20 women, the diagnosis was made before the onset of labour and IPR was not deemed necessary by the managing clinicians. Of the remaining 9 cases who did not receive IPR (or no documentation was done), IPR was indicated on retrospective author review, and this could be regarded as a violation of hospital protocol. For these 9 cases, the decision to delivery interval (average 53 minutes) was the same as the last CTG to delivery interval (average 51 minutes) indicating that the first diagnosis of pathological CTG was very close to delivery.

The contraction pattern (only external transducers are used) at the time of diagnosis was normal in 35 CTGs where there were otherwise pathological changes. For a further 30 women, contractions were documented as normal in the folder, but the tocographic tracing was difficult to evaluate due to poor tracing of the contraction pattern. Of the remaining 14 women who were in labour at the time of diagnosis, the contraction pattern was abnormal. Hypertonus (contractions lasting >2 minutes) were present in 10 of them and tachysystole

(more than 5 contractions per 10 minutes) in 4 women. Twelve of the 14 (85%) received intra-partum resuscitation.

The main pathological changes at the time of diagnosis are shown in Table 3:

Table 3

NICE classification at the time of diagnosis	**Number of cases**
Repetitive late decelerations for >30 minutes	47
Repetitive variable decelerations with any concerning characteristics for >30 minutes	20
Acute bradycardia, or a single prolonged deceleration lasting 3 minutes or more	8
Variability <5bpm lasting more than 50 minutes (and not attributed to drugs) with normal baseline and no decelerations	5
Variability <5bpm lasting more than 50 minutes (and not attributed to drugs) with tachycardia and no decelerations	8
Variability <5bpm lasting more than 50 minutes (and not attributed to drugs) with normal baseline but with late decelerations	2
Variability <5bpm lasting more than 50 minutes (and not attributed to drugs) with tachycardia and late decelerations	6
Fetal tachycardia >160bpm (persistent) with late decelerations but normal variability	4

Examples of CTG tracings made at the time of first recognition/diagnosis is shown in Figures 1 to 7.

Figure 1. Acute bradycardia (a single prolonged deceleration lasting 3 minutes or more)

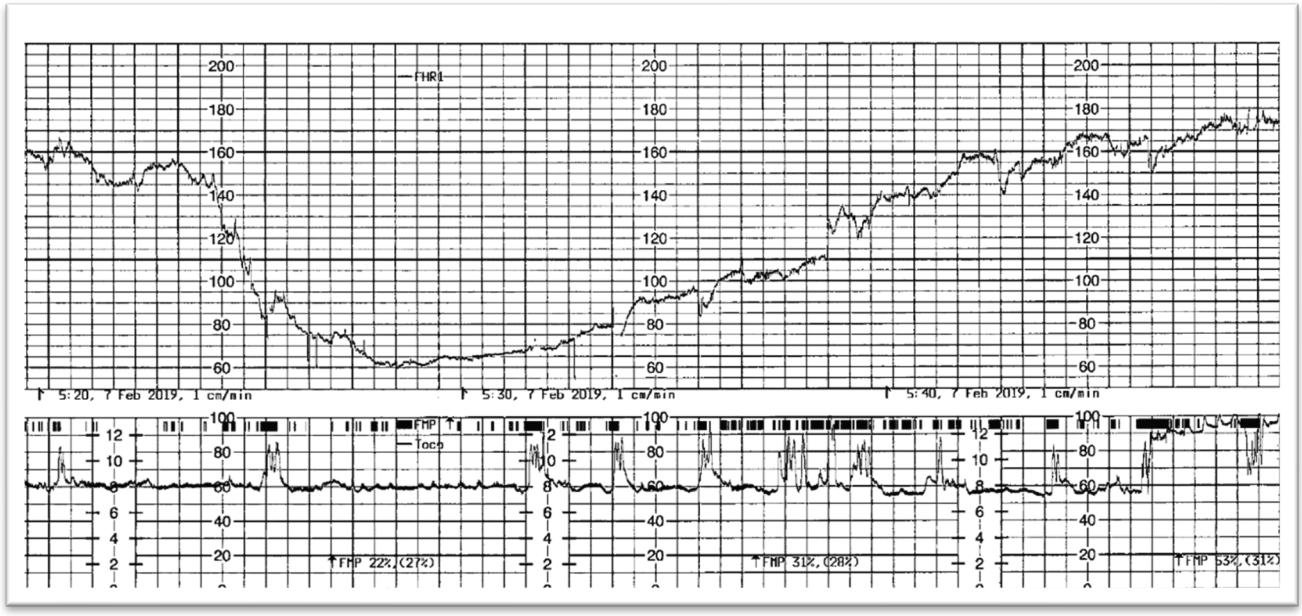


Figure 2a. Hypertonus (a contraction lasting two minutes or longer)

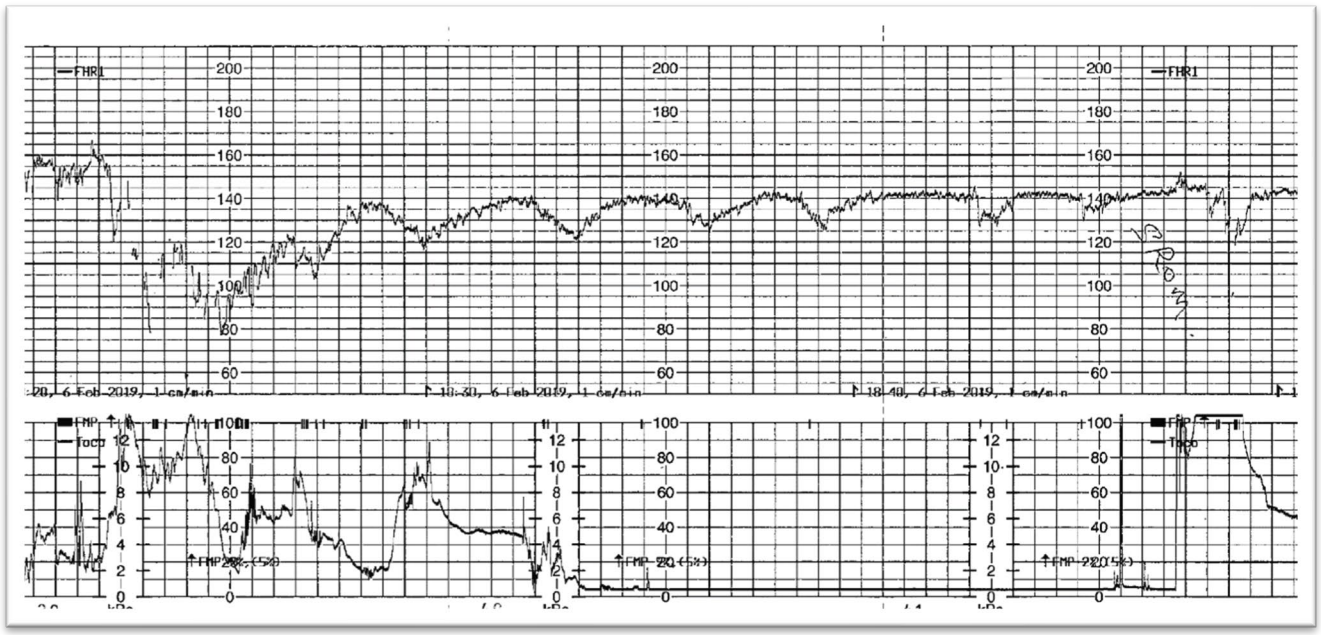


Figure 2b. Hypertonic contractions with repetitive decelerations in the fetal heart rate

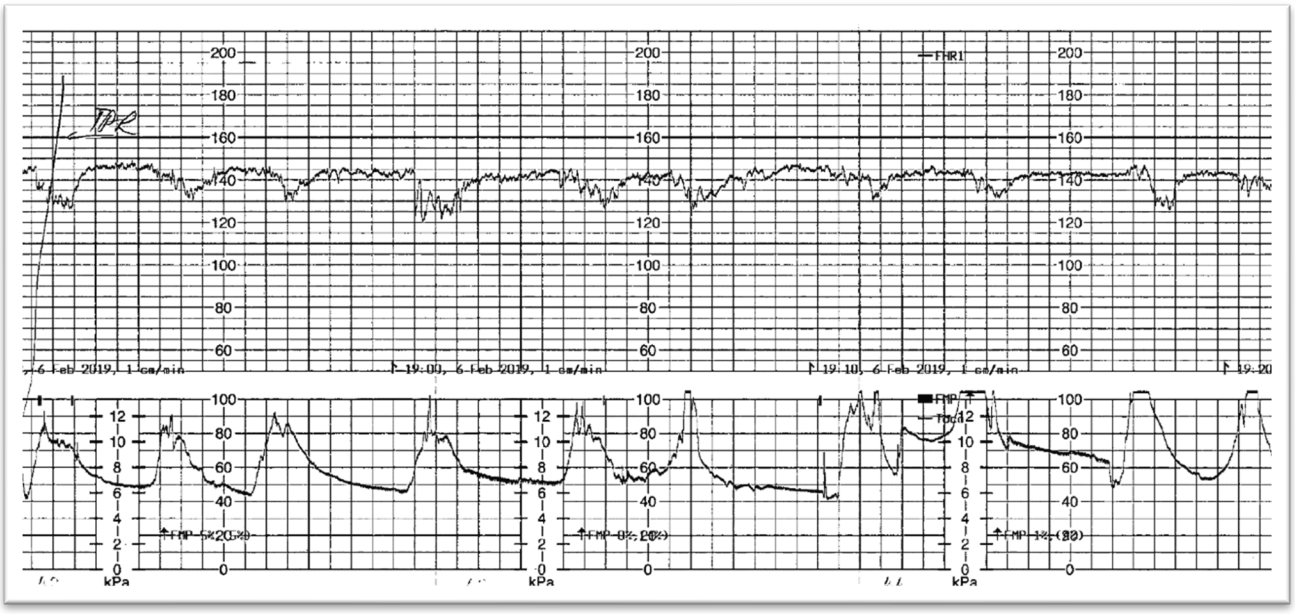


Figure 3. Variability <5bpm with repetitive late decelerations

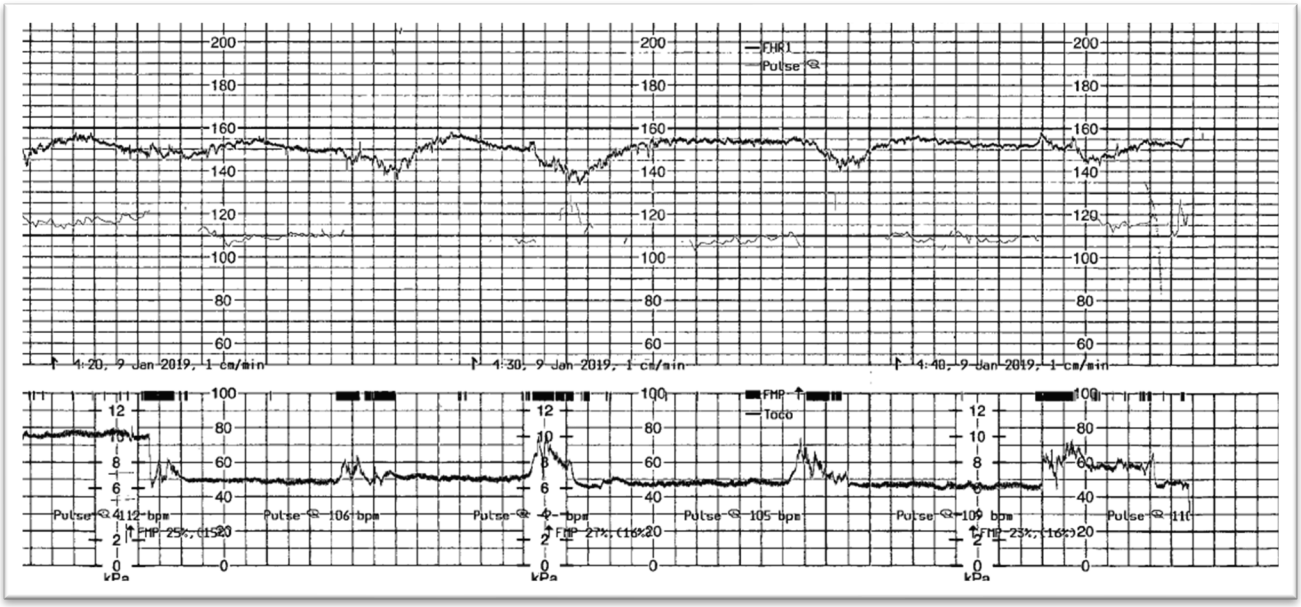


Figure 4. Decreased variability lasting longer than 50 minutes (only 30 minutes shown in example)

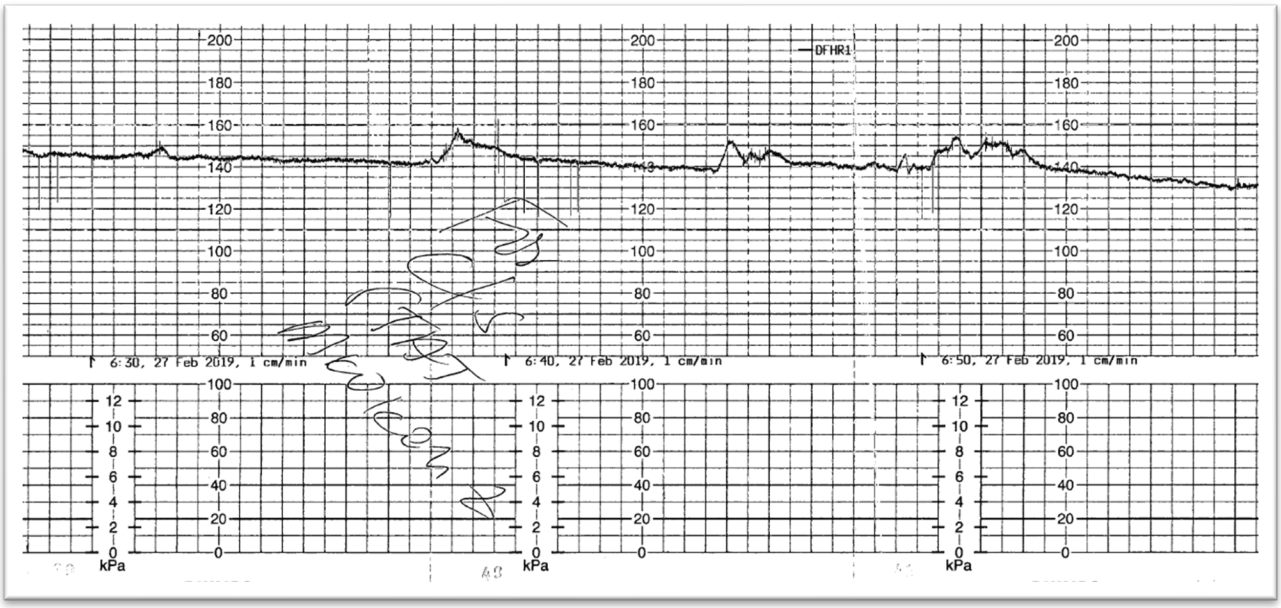


Figure 5. Repetitive variable decelerations with concerning features

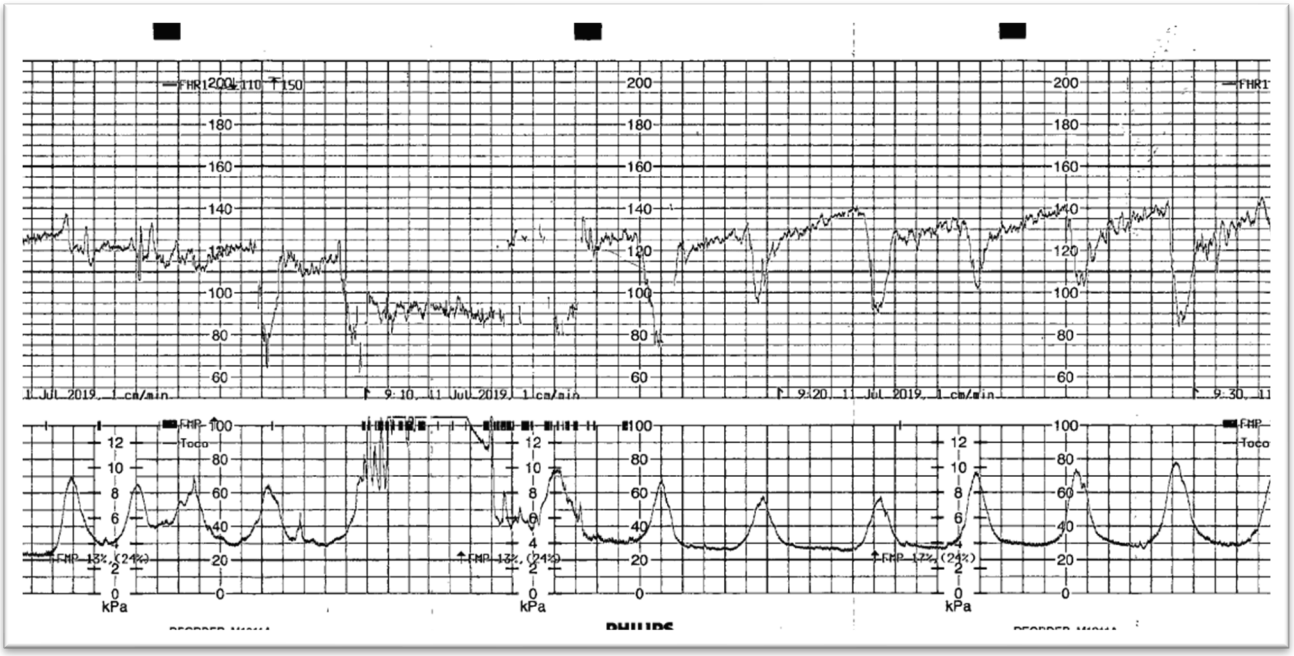


Figure 6. Severe bradycardia lasting 10 minutes with a return to baseline after salbutamol resuscitation.

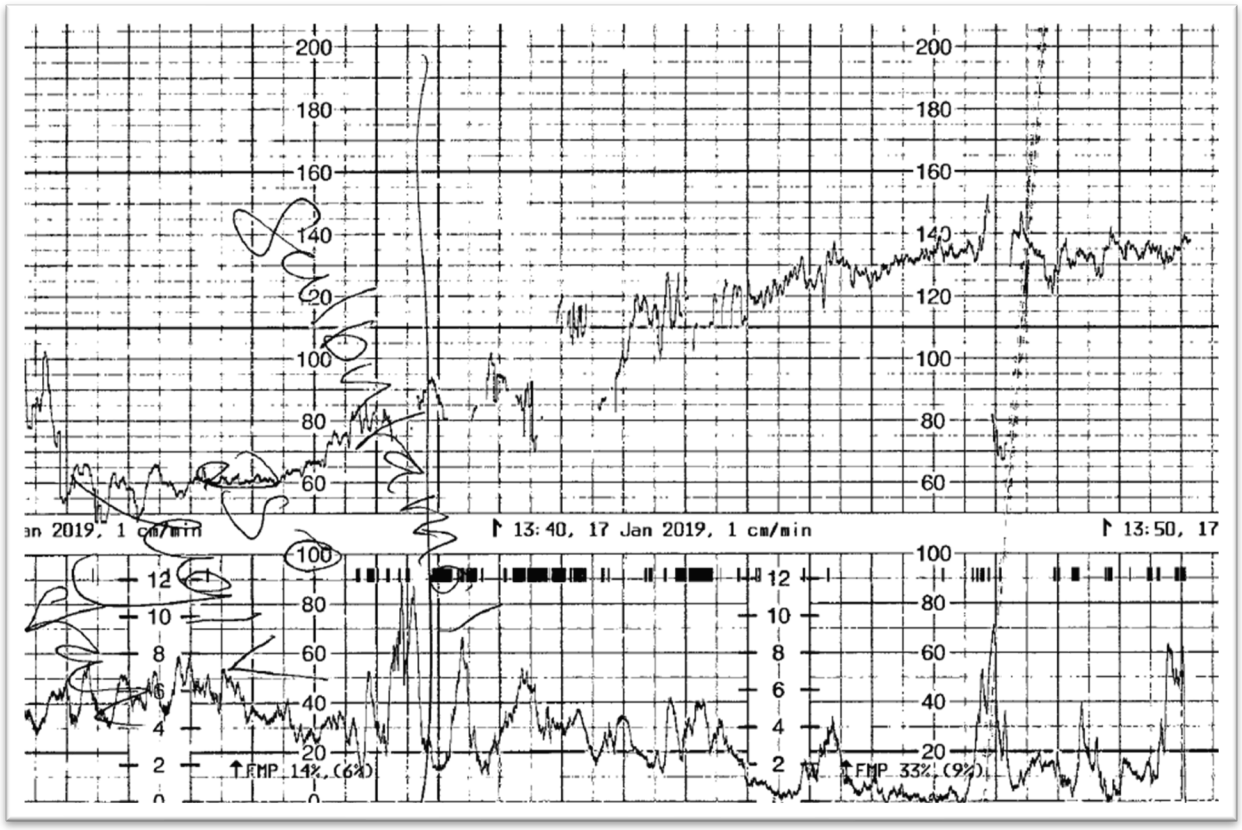
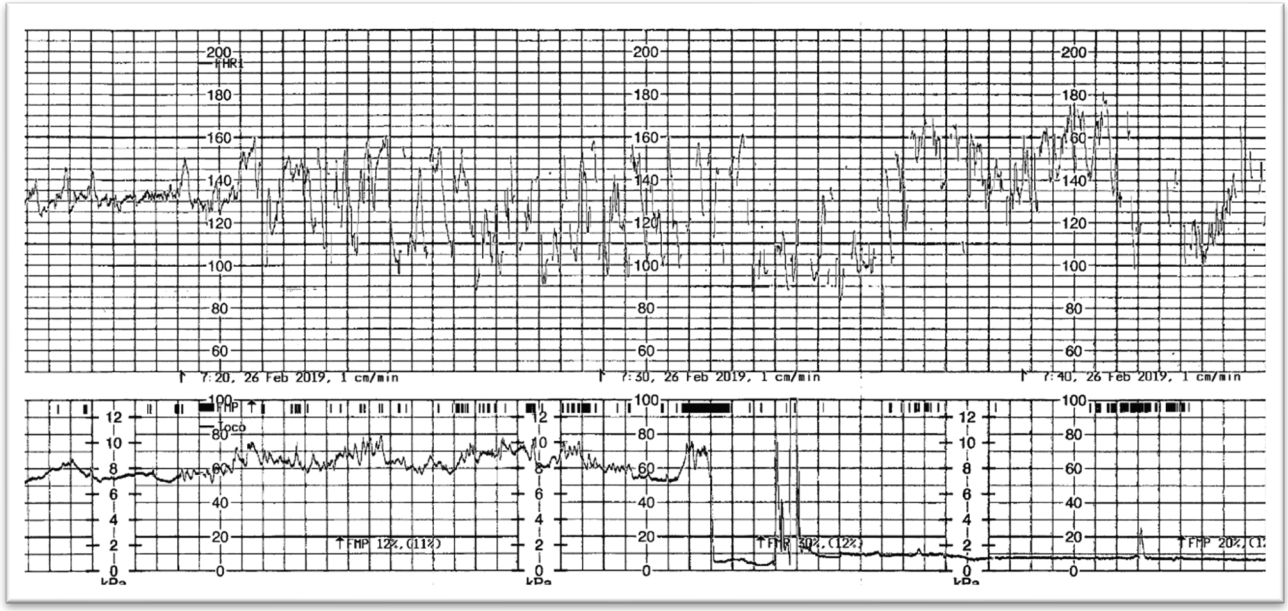


Figure 7. Variability of more than 25 beats a minute for more than 10 minutes.



The mean time from decision to do a CS to the delivery of the baby was 113 minutes. This ranged from 5 to 430 minutes. The mean time from the removal of the CTG from the patient (or the last CTG available to review in the folder) to the start of surgery was 46 minutes, and this ranged from a few minutes to 215 minutes. The mean duration of abnormal tracings (from diagnosis to recovery or last CTG taken if there was ongoing abnormal CTG) was 72 minutes, ranging from 30 to 355 minutes.

Eighty percent of women still had pathological changes on the CTG at the time of transport to theatre. This is shown in Table 4.

Table 4

NICE classification for the last 30 minutes of CTG before surgery	**Number of cases**
Normal	16
Suspicious	4
Pathological	80

Examples of CTGs taken during the last 30 minutes before transport for surgery are shown in Figure 8-11.

Figure 8. Severe bradycardia prior to delivery. The baby was born 55 minutes later with no further CTG tracing during that time. The diagnosis of fetal distress was made 40 minutes prior to this tracing.

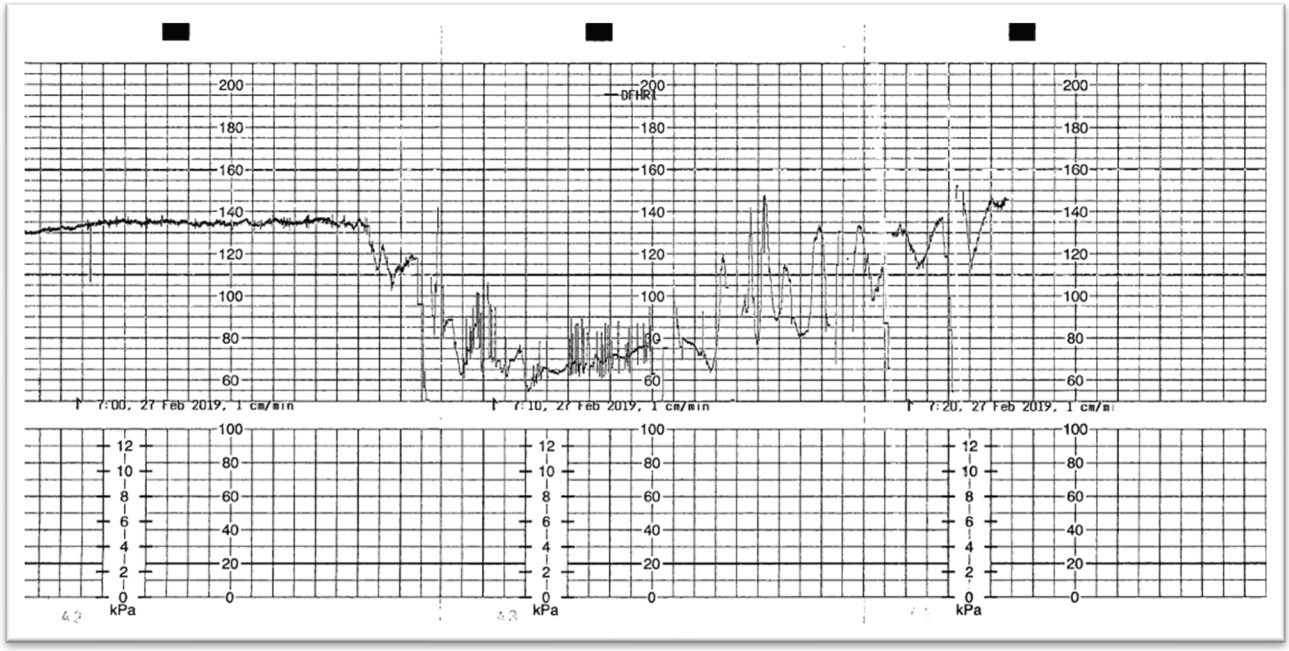


Figure 9. Recurrent late decelerations with baseline variability of <5bpm. The baby was born 35 minutes later with no tracing in the interim.

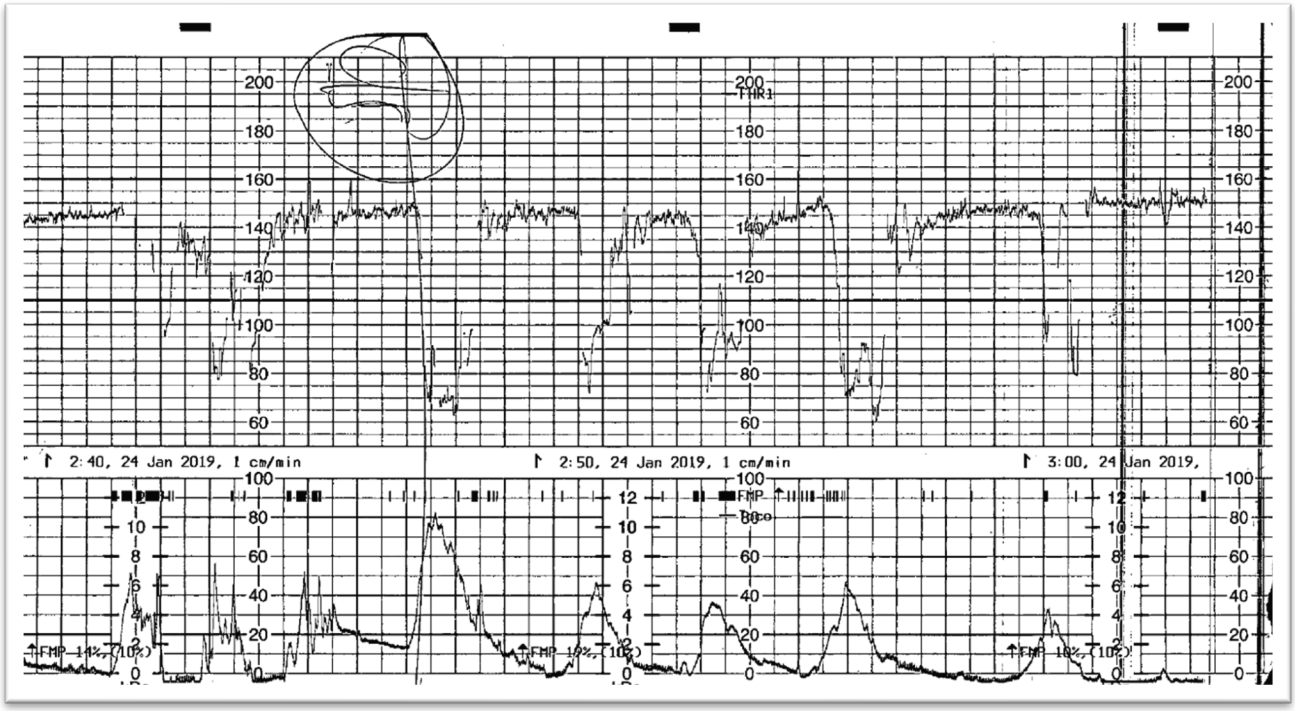


Figure 10. A change in baseline, variability <5bpm with recurrent decelerations. The baby was born 30 minutes later with no further tracing up to birth. The first diagnosis of a pathological CTG was made 110 minutes earlier.

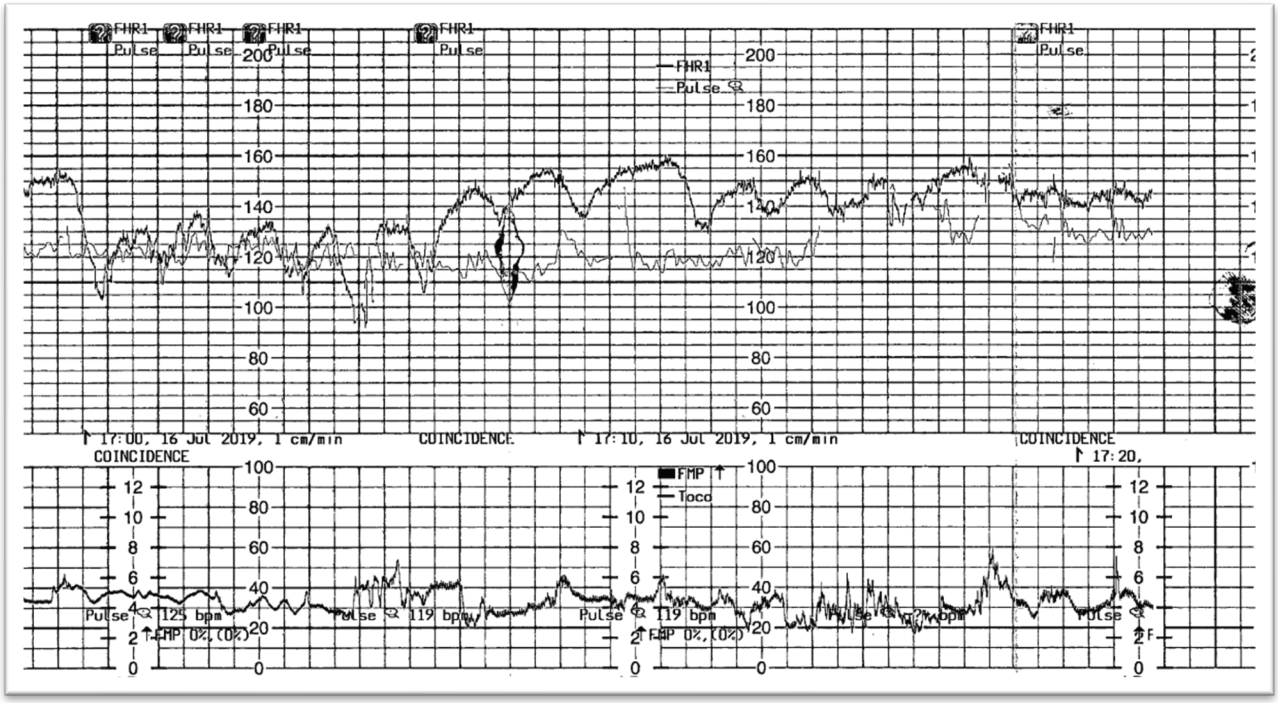
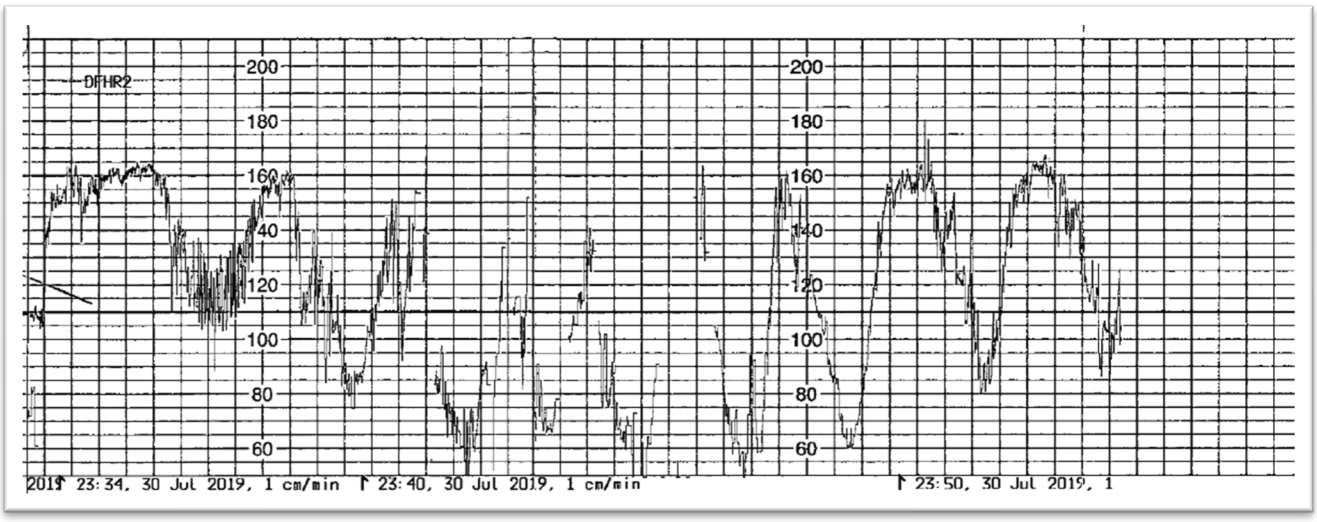


Figure 11. Repetitive, deep decelerations with a baby born 23 minutes later (no further tracings done). The diagnosis of a pathological CTG was done 2 hours prior to this.

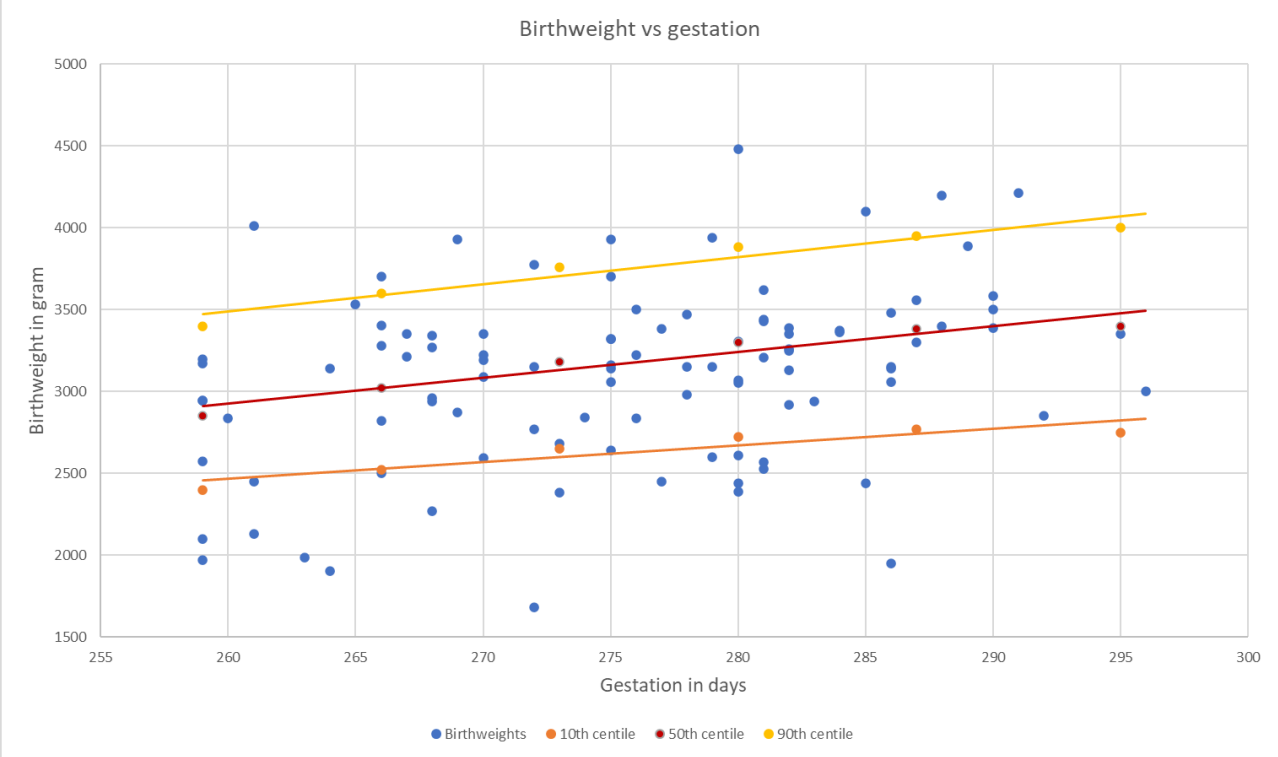


Fetal outcome

For the total group of 100 women, the median 1- and 5-minute APGAR scores was 8 and 9 respectively and all babies were discharged to their mother. The 10-minute APGAR score was 10 for 93 babies, 9 for a further six babies and one baby had a 10 minute score of 7. No baby required more than the routine resuscitative care given at CS birth. There was no subsequent hospital admission in the first six weeks after discharge.

The birthweight correlated with gestational age is given in Figure 12.

Figure 12



The 10th (orange line), 50th (red line) and 90th (yellow line) centiles for Tygerberg hospital is indicated on the graph. There were more than the expected number of small-for-gestational-age (SGA) babies (19% <10th centile). Of the 19 SGA

babies, 73% (14 of the 19) had confirmation of gestational age by early ultrasound.

Significantly more SGA babies (7 of the 19) had a normal CTG prior to delivery than in the appropriately grown and bigger babies (9 of the 81) with a chi-square of 7.5815 and p-value 0.005897. For the 12 SGA babies with pathological CTGs prior to delivery, all had a baseline variability of <5bpm as one of the abnormal CTG features. Their median 5-minute APGAR score of the SGA babies was 9 and all babies were discharged to their mother.

Discussion

This study aimed to describe the CTG patterns in Caesarean deliveries for fetal compromise during labour, but with a completely normal neonatal outcome. The most likely explanations are false positive patterns, where there is no hypoxic insult to the fetus, but the CTG pattern appears abnormal. The other possible explanation is that there was genuine fetal distress, but that intra-partum resuscitation and a quick delivery prevented any hypoxic brain injury. To diminish the risk of possible false positive patterns, an internationally accepted classification system (NICE) was used to describe the changes, by two researchers working independently. Cases were chosen where the pathological changes were dramatically apparent, lasting for at least 30 minutes. And to monitor the possible protective effect of successful IPR and a quick delivery, the decision to delivery time as well as the time from the last CTG to delivery was calculated.

It took on average 113 minutes to deliver a baby after the diagnosis of fetal distress and decision to deliver urgently was made. This could take as long as 430 minutes. A delay in accessing theatre when the diagnosis of fetal distress was made, was the main system-related modifiable factor (25/58 or 43% of cases delivered by emergency caesarean section) in the previous study from this same hospital, but where the outcome was HIE. (28) The average decision-to-delivery time in that study was 100 minutes. All the cases in the present study were NICE Category 2 urgency, where the recommendation is to do caesarean birth as soon as possible, and in most situations within 75 minutes of making the decision. (32)

But the current data showed that even a delay of almost two hours can still lead to a normal outcome and should not be the sole modifiable factor quoted when there was an adverse outcome. The reason Category 1 urgency (immediate threat to the life of the mother or baby) was excluded is that an acute intra-partum event is a known cause of hypoxic brain injury.

If the delivery delay is not always contributing to a bad outcome, could timely recognition and resuscitation have been the major reason for a good outcome? Lack of adverse outcomes could reflect that a unit makes decisions at a time before a clinically significant fetal compromise occurs. (33) One would expect this when the CTG recovers completely, and the last minutes or hours of the tracing is completely normal. But in the present study, only 16% of tracings were classified as normal in the last 30 minutes of available tracing and 4% were still suspicious. Despite IPR, 80% of tracings were still pathological by the time the CTG was removed, and the patient transported to theatre.

The use of fetal scalp sampling at the authors' hospitals has been eliminated with the HIV pandemic. The Dublin Trial published in 1989 reviewed over 13 000 children who were monitored electronically intrapartum and where scalp blood sampling was done when indicated. These measures were associated with a 55% reduction in neonatal seizures. They also found that almost 80% of cases found later to have cerebral palsy had not shown any signs of intrapartum asphyxia and would therefore not have had CTG trace abnormalities. This showed that intensive monitoring has little if any, protective effect against cerebral palsy. (5) Currently, there is no supporting evidence to support the re-

introduction of fetal blood sampling at Tygerberg hospital. The NICE review on FBS shows no evidence of an important difference for most neonatal outcomes, with the exception of Apgar score <7 where fetal blood sampling with CTG showed an important harm, compared to CTG alone.(21)

Regarding the absence of CTG tracings during the 'crucial' last minutes before delivery, it is surprising that the average time from removal of the CTG (to transfer the patient on a theatre trolley) to delivery of the baby was 46 minutes. This include surgery preparation time, during which there is no fetal monitoring. But a simultaneous category 1 CS can supersede the patient already on the table, who will be removed and (at this hospital) wait in the theatre recovery room until the theatre is ready, again without continuous fetal monitoring. This is an important deficiency detected by this audit and which will need local intervention. Yet, despite a period (that could be as long as almost 4 hours) of no documentation of monitoring, the outcome was still good. In perinatal mortality reviews, inadequate fetal monitoring is the most common health worker-related avoidable factor quoted for perinatal hypoxia in South African audits. (34)

There is a correlation between the duration of fetal distress and adverse outcome- Berglund et al showed that the longer the CTG was abnormal during labour, the greater was the risk that the infant had a low 5-minute Apgar score. (35) In the Tygerberg audit, pathological patterns persisted for as long as 355 minutes and 80% of women still had pathological CTGs on their way to theatre. So why are some babies resilient to all these insults, and others end up with severe asphyxia? The main difference with the previous (HIE outcome) audit was the

non-recognition of abnormal CTG tracings in the HIE cases, and timely recognition and management in the current study. (28) It is also argued that a fetus who is exposed to prolonged periods of hypoxia due to placental insufficiency will adapt to the suboptimal intrauterine environment and on CTG will show a baseline rate on the upper limit of the normal range, decreased baseline variability, with no accelerations and possibly ongoing shallow decelerations.(36) When there is the added insult of contractions during normal labour, these babies may develop hypoxia much quicker.

Although most of the women in this audit had underlying maternal conditions, most entered labour with an initial normal CTG. Also, known cases of prolonged chronic intra-uterine hypoxia (placental insufficiency) were excluded. Nevertheless, there were 19 (19%) unidentified SGA babies with good outcome (vs 15% SGA babies in the HIE audit).

The role of computerized analysis of CTG tracings has been investigated with the use of interpretation and management algorithms but is not superior to visual analysis in predicting metabolic acidosis or operative interventions. (37)

Despite the variety of fetal monitoring devices that have been developed, no specific approach or design appears to be superior to the CTG, and more investigation in this regard is required. (38) The Fetal Reserve Index (FRI) is a combines 5 quantifiable components of fetal heart tracing but additionally allows for the inclusion of 3 clinical variables creating an 8-point risk index. Studies thus far have shown that FRI can significantly improve the predictive capacity and

allow the identification of pregnancies at increased risk for adverse outcomes earlier than traditional CTG.(39)

Conclusion

A term baby with a pathological CTG tracing in a public sector hospital in South Africa will need intra-partum resuscitation and prompt delivery if the abnormal pattern persists, as there are currently no alternative measures to distinguish the hypoxic fetus from one who is still compensating to the insults of normal labour. This audit showed that in most babies with severe pathological CTG tracings, neither prolonged periods of abnormal tracing nor delays in delivery necessarily leads to a bad outcome. In litigation cases for term hypoxic brain injury, there are other underlying conditions of the fetus and mother that needs to be considered and not only a focus on CTG interpretation and management, before negligence is inferred.

Disclosures

None of the authors declared a financial or non-financial interest.

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Donée van Rooyen

Student number: 23497998
Stellenbosch University

26 January 2023

Sir / Madam,

I wish to submit an original research article entitled "**Intact neurological survival after emergency Caesarean delivery for pathological fetal heart rate tracings at term- is it time to rethink 'fetal distress' interpretation of cardiotocography in South African cerebral palsy lawsuits?**". This is a post graduate project for my MMed study.

I confirm that this work is original and the research was conducted by myself, supervised by Prof GS Gebhardt.

Thank you for your consideration of this manuscript.

Sincerely

Dr Donée van Rooyen

Stellenbosch
UNIVERSITY
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forward together
sonke siya phambili
saam vorentoe

Approval Notice

New Application

23/05/2022

Project ID :23646

HREC Reference No: S22/04/059

Project Title: The Resilient Fetus: Neonatal outcome after Caesarean delivery for fetal distress- a descriptive study of cardiotocographic tracings

Dear Dr D Van Rooyen

The **New Application** received on 06/04/2022 was reviewed and **approved** by members of **Health Research Ethics Committee** via **expedited** review procedures on 23/05/2022.

Please note the following information about your approved research protocol:

Approval Date: 23 May 2022

Expiry Date: 22 May 2023

Please remember to use your Project ID 23646 and Ethics Reference Number S22/04/059 on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review

Translation of the informed consent document(s) to the language(s) applicable to your study participants should now be submitted to the HREC.

Please note you can submit your progress report through the online ethics application process, available at: Links Application Form Direct Link and the application should be submitted to the HREC before the year has expired. Please see *Forms and Instructions* on our HREC website (www.sun.ac.za/healthresearchethics) for guidance on how to submit a progress report.

The HREC will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

Please note that for studies involving the use of questionnaires, the final copy should be uploaded on Infonetica.

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility, permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Please consult the Western Cape Government website for access to the online Health Research Approval Process, see: https://www.westerncape.gov.za/general-publication/health-research-approval-process. Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard HREC forms and instructions, please visit: Forms and Instructions on our HREC website https://applyethics.sun.ac.za/ProjectView/Index/23646

If you have any questions or need further assistance, please contact the HREC office at 021 938 9677.

Yours sincerely,

Melody Shana
Coordinator: Health Research Ethics Committee 1

National Health Research Ethics Council (NHREC) Registration Number:

REC-130408-012 (HREC1)•REC-230208-010 (HREC2)