The Bradley Method®

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Roberto Caldeyro-Barcia, MD

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- The Fatal Monitor
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- “A Useless Pile of Microchips”

Victor Berman, MD at B.I.R.T.H.S.

SNEAK PREVIEW

Panel Attempts to Rescue Fetal Heart Rate Monitoring

Early discussions reveal few conclusions.

BY BRUCE JANCIN
Rocky Mountain Bureau Chief

SAN FRANCISCO — When 18 of the nation's leading experts on electronic fetal heart rate monitoring gathered under National Institutes of Health auspices to figure out if monitoring can be salvaged from its current state of disarray, they didn't initially agree on much.

There was broad agreement, however, on one critical point. Fetal heart rate variability is extremely predictive of good outcome in terms of absence of deep central asphyxia, Dr. Julian T. Parer said at a meeting on

"There is universal acceptance in North America that fetal heart rate variability is the single most important predictor of a vigorous baby. It doesn't predict pH as well as it predicts fetal vigor, but I put it to you that fetal vigor is the thing we most want to see. We want to see a kicking baby, and we don't particularly care what the blood gas machine shows," said Dr. Parer, chairman of the NIH Committee on Electronic Fetal Monitoring: Research Guidelines for Interpretation.

Essentially, if normal fetal heart rate variability is present, it really doesn't matter what

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The Bradley Method®

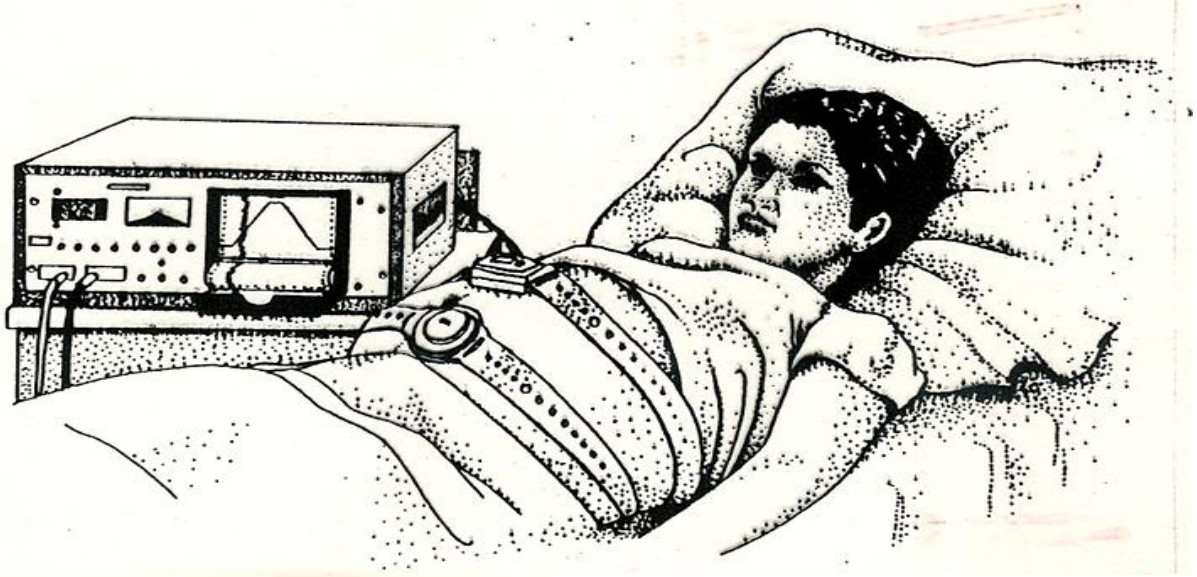
- The History
- The Hardware
- The Diagnostic Mythology
- The Politics

The Bradley Method®

- History
- Human Monitoring
- Crude Acoustic Devices
- Stylized Acoustic Devices
- Electronic-related Devices EFM

Non-Invasive

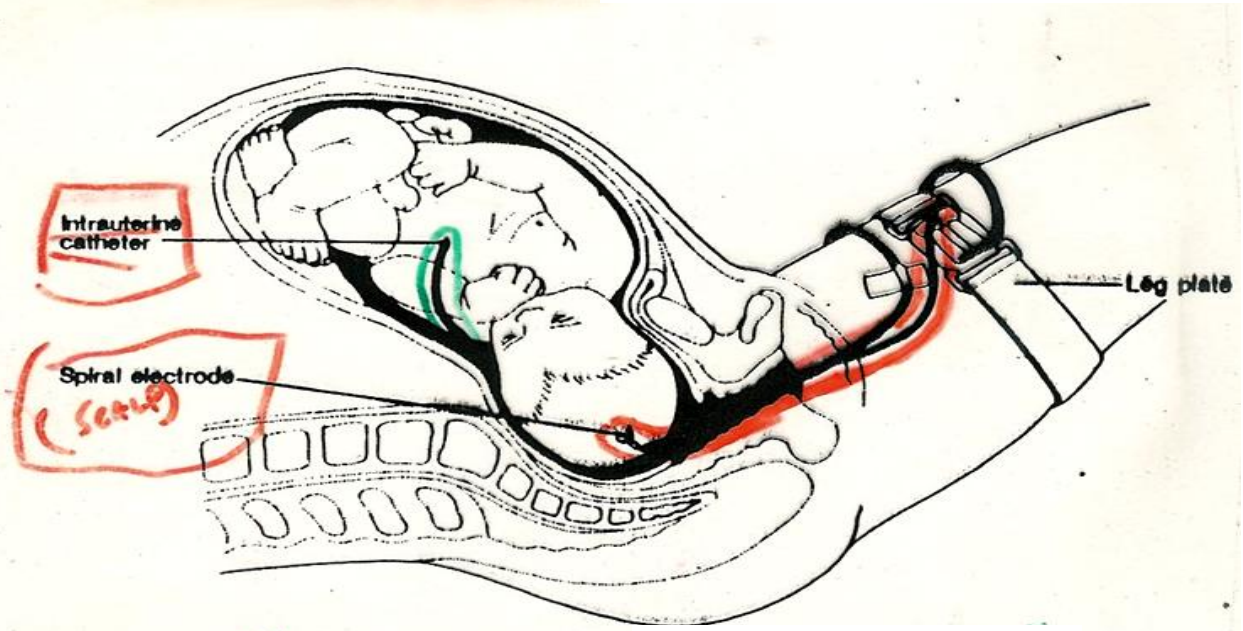
Fetal Monitoring



External fetal monitor

Invasive

Fetal Monitoring



Internal fetal monitor

PEEL DOWN

LIFE ♥ TRACE

Fetal Monitoring Spiral Electr
Single Helix
Reorder Number FSE 1000

Sterile and Disposable

CONTRAINDICATIONS: The spiral electrode should not be applied: to the fetal face, fontanels or genitalia. Do not apply when placenta previa is present; when genital infection (e.g., herpes, Group B streptococcus, gonorrhea) or maternal acquired immune deficiency syndrome (AIDS) exists; when mother is a confirmed carrier of hemophilia and the fetus is either affected or of unknown status; or when not possible to identify fetal presenting part where application is being considered.

WARNING: The fetal electrode tip is designed to penetrate the epidermis of the fetus; therefore, trauma, hemorrhage and/or infection can occur. The electrode should be used with strict adherence to aseptic technique. Amniotic membranes must be ruptured prior to attaching the spiral electrode.

Remove from package and release the wires from between the **Drive** and **Guide Tubes.**

1. Check the proper

CONTRAINDICATIONS: The spiral electrode should not be applied: to the fetal face, fontanels or genitalia. Do not apply when placenta previa is present; when genital infection (e.g., herpes, Group B streptococcus, gonorrhea) or maternal acquired immune deficiency syndrome (AIDS) exists; when mother is a confirmed carrier of hemophilia and the fetus is either affected or of unknown status; or when not possible to identify fetal presenting part where application is being considered.

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Necrotizing Fasciitis of the Scalp in a Newborn

Cecile Davey, MBBS, DM, and Aideen M. Moore, MD, FRCPC

BACKGROUND: Fetal scalp electrode monitoring is usually without complications, but on rare occasions it can serve as a portal of entry for organisms colonizing the maternal genital tract.

CASE: We present a case of neonatal necrotizing fasciitis of the scalp that was associated with intrapartum fetal scalp electrode monitoring. Skin cultures grew Group A *Streptococcus* M11 T nontypeable serotype, an unusual cause of neonatal necrotizing fasciitis. The neonate's mother had a concurrent perineal infection and the same Group A streptococcal serotype was cultured from maternal blood and vaginal swabs.

CONCLUSION: This case highlights the emergence of life-threatening Group A *Streptococcus* causing invasive disease in both infants and mothers and the need for careful monitoring of neonates who have had intrapartum electrode monitoring.

(Obstet Gynecol 2006;107:461–3)

Necrotizing fasciitis also referred to as "flesh-eating bacteria disease" is an acute, rapidly progressive, potentially fatal infection of the superficial and deep fascia and subcutaneous tissue.[1–3] Necrotizing fasciitis, although rare in children (0.018 per 100,000 children per year), is even rare in neonates, occurring mostly in term infants wit an equal gender distribution and a mortality rate high as 60%.[1,2] The paucity of cutaneous findin early in the course makes a high index of suspici necessary for a prompt diagnosis.[2] Marked tis edema, rapid progression of inflammation, signs of septic shock are the clinical diagnc clues.[2] Frozen section analysis, polymerase c reaction assay, ultrasonography, computed to raphy, and magnetic resonance imaging are usef diagnostic tools, but the definitive diagnosis is usually made at surgery.[2] Complications include septic shock, disseminated intravascular coagulation, multiorgan failure, and death.[2]

Neonatal necrotizing fasciitis is frequently polymicrobial, *Staphylococcus aureus*, *Escherichia coli*, *Enterococcus*, *Clostridium* spp, and *Bacteroides* spp being the predominant organisms isolated.[2] However, Group A *Streptococcus* (*S pyogenes*) has been associated in necrotizing fasciitis secondary to omphalitis, circumcision, and abdominal surgery.[4]

CASE

A term female infant weighing 3,560 g was born by vacuum-assisted vaginal delivery for poor maternal effort to a 34-year-old primigravida after 4 hours of ruptured m nes, with intrapartum fetal scalp monitoring. The la ced with no difficulty, because of fetal ta ther sustained second-degree peri- n complained of a sore throat a noted 7 hours after ived 3 doses of

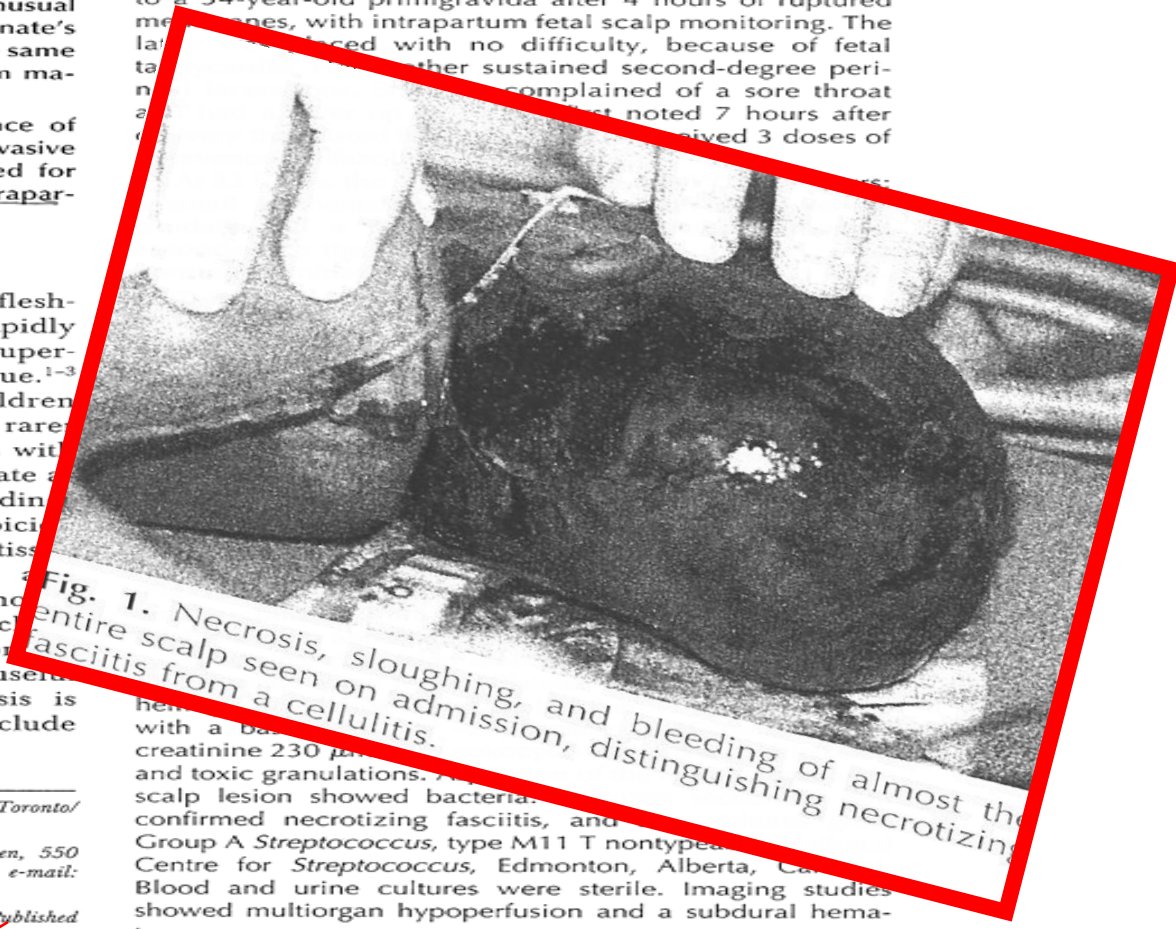

Fig. 1. Necrosis, sloughing, and bleeding of almost the entire scalp seen on admission, distinguishing necrotizing fasciitis from a cellulitis.

he with a ba creatinine 230 μ and toxic granulations. A scalp lesion showed bacteria confirmed necrotizing fasciitis, and Group A *Streptococcus*, type M11 T nontypea Centre for *Streptococcus*, Edmonton, Alberta, C Blood and urine cultures were sterile. Imaging studies showed multiorgan hypoperfusion and a subdural hematoma.

Her scalp was débrided 3 times in the first 72 hours of

From the Department of Perinatal-Neonatal Medicine, University of Toronto/Hospital for Sick Children, Toronto, Ontario, Canada.

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ISSN: 0029-7844/06

Fetal Heart Rate --- FHR
Fetal Heart Tones --- FHT

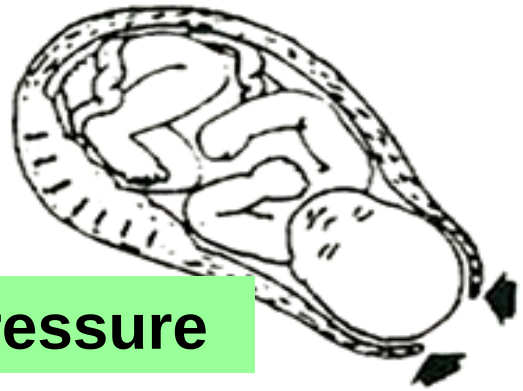
Auscultation = To diagnose by listening

(Auscultare = To listen to)

Fetal Heart Rates for Near-Term Fetuses

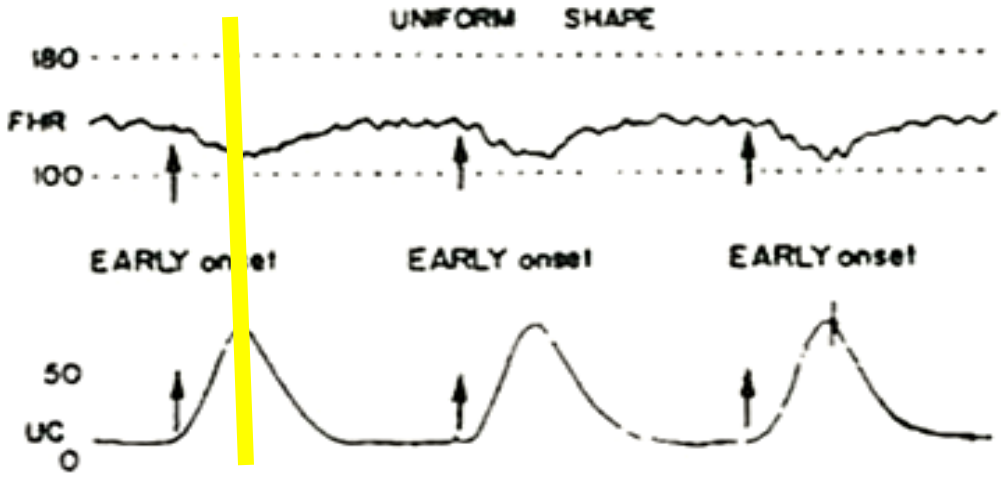
Average Baseline FHR	**100-160 BPM**
Tachycardia	**161-up BPM**
Bradycardia	**Below 100 BPM**

Source: ACOG Technical Bulletin #132



Pressure

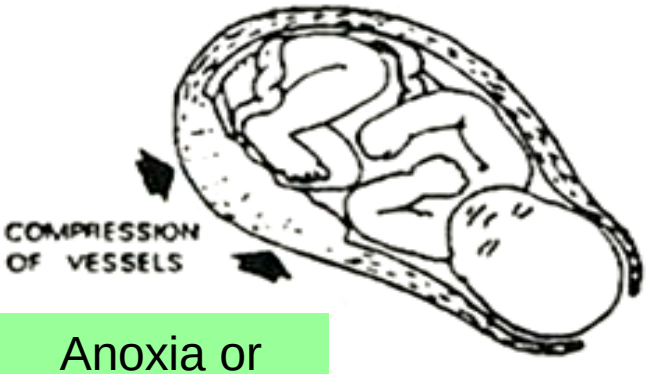
HEAD COMPRESSION



EARLY DECELERATION (HC)

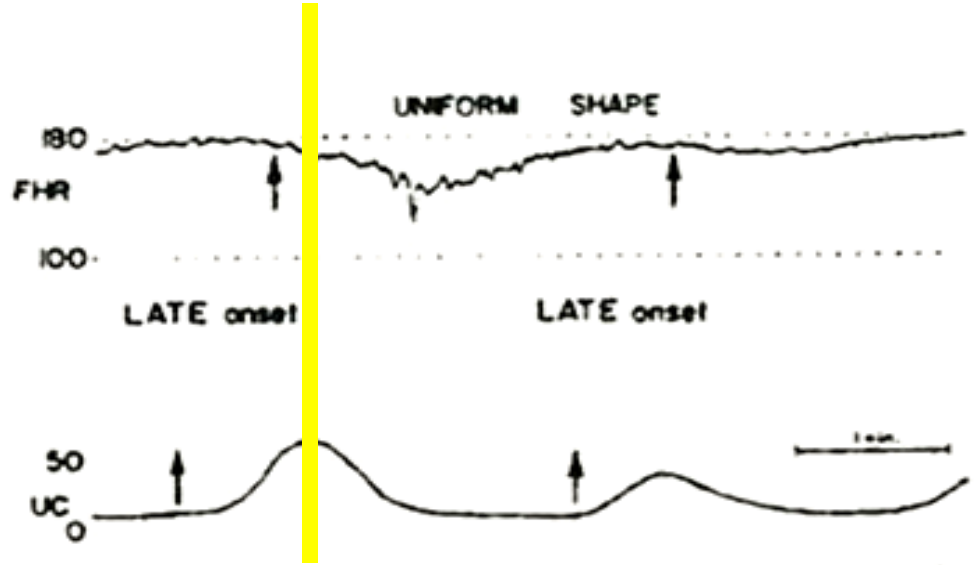
Fig. 3-9

Type one dip



Anoxia or Hypoxia

UTEROPLACENTAL INSUFFICIENCY



LATE DECELERATION (UPI)

Fig. 3-10

Type two dip

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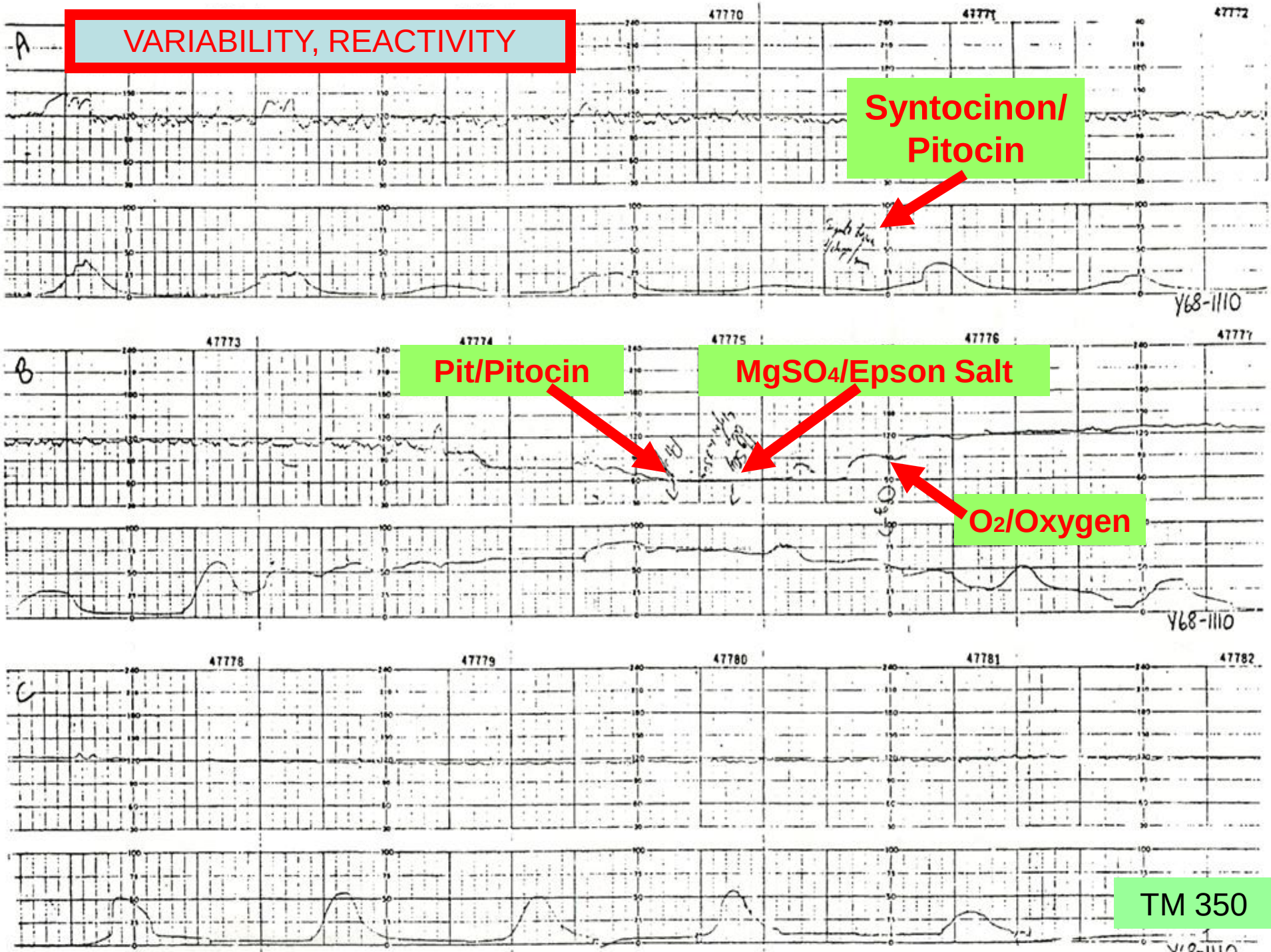
VARIABILITY, REACTIVITY



Fetal heart rate monitoring: Is it salvageable?

Julian T. Parer, MD, PhD, and Tekoa King, CNM, MPH

San Francisco, California

Fetal heart rate monitoring was introduced in the 1960s. After a number of randomized controlled trials in the mid 1980s, doubt arose regarding the efficacy of fetal heart rate monitoring in improving fetal outcome. The potential reasons why fetal heart rate monitoring has not been shown to be efficacious are (1) use of an outcome measure that is not related to variant fetal heart rate monitoring patterns, (2) lack of standardized interpretation of fetal heart rate patterns, (3) disagreement regarding algorithms for intervention of specific fetal heart rate patterns, and (4) the inability to demonstrate the reliability, validity, and ability of fetal heart rate monitoring to allow timely intervention. A recent National Institutes of Health committee proposed detailed, quantitative, standardized definitions of fetal heart rate patterns, which can serve as a basis for determining whether fetal heart rate monitoring is reliable and valid. In this article we examine reasons why fetal heart rate monitoring did not live up to its original expectations and why the randomized controlled trials did not demonstrate efficacy, and we make suggestions for determining whether electronic fetal heart rate monitoring should be abandoned. (Am J Obstet Gynecol 2000;182:982-7.)

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FETAL MONITORS RIDICULED

An editorial in the March 1, 1990 issue of the New England Journal of Medicine (a general medical journal... rather than an obstetrical journal) put yet another nail in the coffin of electronic fetal monitoring. Doctors in other fields of medicine have traditionally held low opinions of obstetricians, anyway... but this time obstetrics has given it's critics some new and powerful ammunition.

Using put-down words such as "loyalists" and "zealots" and referring to an "electronic fetal monitoring camp" The NEJM wondered, for all to see, why nobody did scientific tests of efficacy BEFORE using a potentially harmful gadget.

This same line of questioning could and should be applied to almost every existing obstetrical device, test or intervention... as well as to obstetrics itself. The history of obstetrics is a sad and sordid affair, and fetal monitors will go the way of un-washed hands, ether, DES, thalidomide, weight restriction, diuretics, leeches, and all the rest.

Bradley®advocates have often been attacked with similar put-downs... it is refreshing to see a little balance sneak into medical thought... but, is anyone really listening??

Jay Hathaway, AAHCC

INTRAPARTUM FETAL MONITORING — A DISAPPOINTING STORY

INTRAPARTUM electronic fetal-heart-rate monitoring was introduced in the United States in the early 1970s after studies supported the existence of a correlation between patterns of fetal heart rate and signs of fetal hypoxia — specifically, intrapartum fetal death, fetal blood pH, and Apgar scores.[1,2] The common perception was that with this objective technique, evidence of fetal hypoxia would appear in a timely fashion, allowing the clinician to intervene and thus protect the fetus from the ravages of continued intrauterine oxygen deprivation. It was believed then that the intrapartum period was an especially treacherous time for the fetus, when most hypoxic injury occurred, accounting for the correlation between intrapartum events and subsequent neurologic damage.

During the early and middle 1970s, there were numerous reports indicating that electronically monitored fetuses did much better than those undergoing periodic auscultation during birth. These nonrandomized retrospective reports even indicated that among electronically monitored fetuses at high risk there were fewer intrapartum deaths and better outcomes than among fetuses at low risk who were monitored by auscultation.

The first prospective, randomized trial of intrapartum electronic fetal monitoring, by Haverkamp et al., was reported in 1976.[3] It showed no benefit of electronic fetal monitoring as compared with auscultation when the monitoring was performed at 15-minute intervals in the first stage of labor and 5-minute intervals in the second stage. There was a higher rate of cesarean birth in the electronic-fetal-monitoring group. A follow-up study by the same investigators showed that pH sampling of fetal scalp blood lowered the excess rate of cesarean births in the electronic-fetal-monitoring group.[4] A subsequent study of the children involved in the studies of Haverkamp et al. failed to show any long-term benefits of electronic fetal monitoring.[5] Critics were quick to point out that the number of infants was small and that with larger numbers the benefits of electronic fetal monitoring were likely to become evident.[6]

Since then, there have been six prospective, randomized trials of electronic fetal monitoring in a total of 17,510 fetuses born at term. None of these studies found decreases in the rates of intrapartum death, low Apgar scores, or fetal acidosis (see references cited by Shy et al.[7]). The study from Dublin did find more seizures in the auscultation group, but long-term follow-up failed to demonstrate any difference in neurologic outcome.

At this point, many loyalists suggested that if there was to be a benefit from electronic fetal monitoring, it would certainly be demonstrated in a randomized trial in premature infants. In 1987 Luthy et al. studied 246 women whose infants weighed between 700 and 1750 g, and this study too failed to show any difference in immediate outcome between the infants monitored electronically and those monitored with auscultation.[8]

The article by Shy et al.[7] in this issue of the *Journal* among their electronically monitored patients was higher than that reported by others, especially in infants weighing under 1750 g. Since the protocol prescribed intervention only when the fetal-heart-rate pattern was ominous, with a fetal blood pH below 7.20, there may have been longer-lasting abnormal fetal-heart-rate patterns and a higher incidence of cerebral palsy in the electronic-fetal-monitoring group than in the auscultation group, in which it was not necessary to wait for documentation of low fetal pH.

Many who had been zealots in the electronic-fetal-monitoring camp could not explain how a technique that clearly detected fetal hypoxia caused by uteroplacental insufficiency and umbilical-cord compression apparently did not lead to beneficial intervention. There are several possible explanations. First, could most hypoxic damage occur before the onset of labor, providing intrapartum electronic fetal monitoring with a correlation with hypoxia but no benefit from intervention? Second, could hypoxic injury occur so rapidly that even though electronic fetal monitoring gives a warning, it is not soon enough? Finally, could it be that fetuses destined to be neurologically abnormal will have hypoxia secondarily, thus accounting for the correlation but negating the value of intervention?

Clearly, the hoped-for benefit from intrapartum electronic fetal monitoring has not been realized. It is unfortunate that randomized, controlled trials were not carried out before this form of technology became universally applied. Before we discard the electronic fetal monitor, however, we must realize that the randomized trials all had dedicated nurses assigned to the auscultation group, a circumstance that is not always possible in a busy clinical setting. A study comparing either auscultation or electronic fetal monitoring with no fetal surveillance has not been performed, and until it has, it would seem prudent to follow the recommendation of the American College of Obstetricians and Gynecologists. They advise that patients at high risk have either continuous electronic fetal monitoring or intermittent auscultation every 15 minutes in the first stage of labor and every 5 minutes in the second stage. Although there are no data to support the use of auscultation every 30 minutes in the first stage of labor and every 15 minutes in the second stage, this is their recommendation for low-risk patients.

This issue poses a medical–legal dilemma, since frequently such practice standards may not have been met for fetal surveillance. By inference in such cases, there is an implied connection with abnormalities of neurologic development, even in the absence of documented asphyxia during birth. There is a great need for research to determine the cause or causes of adverse neurologic outcomes. Medical liability for substandard intrapartum fetal surveillance should be limited to the rare case in which intrapartum asphyxia is clearly at fault and in which intervention could have been preventive. The story of electronic fetal monitoring also illustrates the need for proper randomized clinical trials before new forms of technology are introduced that may become the standard of practice without clearly demonstrated benefit.

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Long Beach, CA 90801

ROGER FREEMAN, M.D.

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The New England
Journal of Medicine

Volume 334 MARCH 7, 1996 Number 10

UNCERTAIN VALUE OF ELECTRONIC FETAL MONITORING IN PREDICTING CEREBRAL PALSY

KARIN B. NELSON, M.D., JAMES M. DAMBROSIA, PH.D., TRICIA Y. TING, B.S., AND JUDITH K. GRETHER, PH.D.

Abstract *Background.* Electronic monitoring of the fetal heart rate is commonly performed, in part to detect hypoxia during delivery that may result in brain injury. It is not known whether specific abnormalities on electronic fetal monitoring are related to the risk of cerebral palsy.

Methods. Among 155,636 children born from 1983 through 1985 in four California counties, we identified singleton infants with birth weights of at least 2500 g who survived to three years of age and had moderate or severe cerebral palsy. The children with cerebral palsy were compared with randomly selected control children with respect to characteristics noted in the birth records.

Results. Seventy-eight of 95 children with cerebral palsy and 300 of 378 controls underwent intrapartum fetal monitoring. Characteristics found to be associated with an increased risk of cerebral palsy were multiple late decelerations in the heart rate, commonly defined as slowing of the heart rate well after the onset of uterine contractions (odds ratio, 3.9; 95 percent confidence interval, 1.7 to 9.3), and decreased beat-to-beat variability of the heart rate (odds ratio, 2.7; 95 percent confidence interval, 1.1 to 5.8); there was no association between the highest or lowest fetal heart rate recorded for each child and the risk of cerebral palsy. Even after adjustment for other risk factors, the association of abnormalities on fetal monitoring with an increased risk of cerebral palsy persisted (adjusted odds ratio, 2.7; 95 percent confidence interval, 1.4 to 5.4). The 21 children with cerebral palsy who had multiple late decelerations or decreased variability in heart rate on fetal monitoring represented only 0.19 percent of singleton infants with birth weights of 2500 g or more who had these fetal-monitoring findings, for a false positive rate of 99.8 percent.

Conclusions. Specific abnormal findings on electronic monitoring of the fetal heart rate were associated with an increased risk of cerebral palsy. However, the false positive rate was extremely high. Since cesarean section is often performed when such abnormalities are noted and is associated with risk to the mother, our findings arouse concern that, if these indications were widely used, many cesarean sections would be performed without benefit and with the potential for harm. (N Engl J Med 1996; 334:613-8.)

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Medscape
Medical News

Electronic Fetal Monitoring Does Not Improve Outcome

Laurie Barclay, MD

Feb. 6, 2003 — Electronic fetal monitoring does not improve outcome, according to the results of a prospective, randomized trial reported in the Feb. 8 issue of *The Lancet*.

"The findings of this trial demonstrate that a widespread and expensive practice is largely unjustified," lead author Lawrence Impey, from John Radcliffe Hospital in Headington, Oxford, says in a news release.

Admission cardiotocography, or electronic assessment of fetal heartbeat, is widely used to identify fetal distress and other high-risk pregnancies that might benefit from more invasive continuous electronic fetal monitoring.

At the National Maternity Hospital in Dublin, Ireland, 8,580 women admitted to the delivery ward received either admission cardiotocography for 20 minutes or the unit's usual care consisting of intermittent auscultation of the fetal heart beat using a stethoscope. There was no difference between groups in the primary outcome of perinatal death or moderate to severe neonatal morbidity (1.3% in each group; relative risk [RR], 1.01; 95% confidence interval [CI], 0.70 - 1.47).

Although the cardiotocography group had increased use of continued cardiotocography (RR, 1.39; 95% CI, 1.33 - 1.45) and of fetal blood sampling (RR, 1.30; 95% CI, 1.14 - 1.47), there was no difference between groups in the rates of caesarean delivery, instrumental delivery, or episiotomy.

"By concentrating our attention on the pattern of the baby's heart-beat in labor we are seeing only a fraction of the causes of stillbirth and neonatal handicap," Impey says. "We need better research to understand the processes behind these. Only then can we improve things in the years to come, rather than play catch-up by evaluating what we have done in years past."

Lancet. 2003;361:465-70

Electronic Fetal Monitoring as a Public Health Screening Program

The Arithmetic of Failure

David A. Grimes, MD, and Jeffrey F. Peipert, MD, PhD

Electronic fetal monitoring has failed as a public health screening program. Nevertheless, most of the four million low-risk women giv... United States each year continue to under... of this program should ha... had the accepted ... before its introduc... tive predictive val... such as fetal death... is aggravated whe... validity as is the ... Because of low-p... validity, the pos... monitoring for fe... zero. Stated alter... wrong. To avoi... prerequisites for... before the prog...
(Obstet Gynecol

Electronic fetal monitoring has failed as a public health screening program. Nevertheless, most of the four million low-risk women giving birth in the United States each year continue to undergo this screening. The failure of this program should have been anticipated and thus avoided had the accepted principles of screening been considered before its introduction. All screening tests have poor positive predictive value when searching for rare conditions such as fetal death in labor or cerebral palsy. This problem is aggravated when the screening test does not have good validity as is the case with electronic fetal monitoring. Because of low-prevalence target conditions and mediocre validity, the positive predictive value of electronic fetal monitoring for fetal death in labor or cerebral palsy is near zero. Stated alternatively, almost every positive test result is wrong. To avoid such costly errors in the future, the prerequisites for any screening program must be fulfilled before the program is begun.
(Obstet Gynecol 2010;116:1397–1400)

statistically significantly increases instrumental and cesarean deliveries for women but provides no long-term benefits for children.[2] Clinicians, too, have suffered indirectly because of the epidemic of litigation and "expert" testimony that electronic fetal monitoring has ...out fetal heart-rate tracings.[3] Sadly, the fail... ...nitoring could have, and thus avoided. The ...go was viewing elec... ...ric technology for an ...national public health ...his error was com... ...ening principles and ...ive results.[4]

"For a new ... must be ... and until it is ... same rigour ... Electroni... health screen... of electronic ... tent ausculta...

...ge numbers of appar... ...ose at increased risk of ...one among asymptom... ...on those ordering the ...erforming tests on ill ...lse-positive results of ...ns of their perceived ...iagnostic tests and pro... ...morbidity, and waste ...[5] Hence, stringent re... ...re a screening program ...ith electronic fetal mon... ...commentary to the usual ...ring as a screening test in ...n used in women with ...ive of adverse outcomes ...otic fluid), electronic fetal ...ered a diagnostic test.

...Be Done?

...satisfied before launching ...specially on a large scale. ...ortant, and diagnostic and

From FHI, Res... Obstetrics and G... Chapel Hill, N... Department of ... School of Medic...

Corresponding ... Triangle Park,...

Financial Di...
The authors di...

ISSN: 0029-7844/10

ACOG
PRACTICE
BULLETIN

CLINICAL MANAGEMENT GUIDELINES FOR
OBSTETRICIAN–GYNECOLOGISTS
NUMBER 70, DECEMBER 2005

(Replaces Practice Bulletin Number 62, May 2005)

This Practice Bulletin was developed by the ACOG Committee on Practice Bulletins—Obstetrics with the assistance of Suneet P. Chauhan, MD and George A. Macones, MD. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

Intrapartum Fetal Heart Rate Monitoring

In 2002, approximately 3.4 million fetuses (85% of approximately 4 million live births) in the United States were assessed with electronic fetal monitoring (EFM), making it the most common obstetric procedure (1). Despite its widespread use, there is controversy about the efficacy of EFM, interpretation of fetal heart rate (FHR) patterns, reproducibility of its interpretation, and management algorithms for abnormal or nonreassuring patterns. Moreover, there is evidence that the use of EFM increases the rate of cesarean and operative vaginal deliveries. The purpose of this document is to review nomenclature for FHR assessment, review the data on the efficacy of EFM, delineate the strengths and shortcomings of EFM, and describe the management of nonreassuring FHR patterns.

Background

Even though the fetus is efficient at extracting oxygen from the maternal compartment, a complex interplay of antepartum complications, suboptimal uterine perfusion, placental dysfunction, and intrapartum events may be associated with adverse outcome. Known obstetric conditions, such as hypertensive disease, fetal growth restriction, and preterm birth, predispose fetuses to poor out-

Given that the available data do not clearly support EFM over intermittent auscultation, either option is acceptable in a patient without complications. Logisti-

ACOG PRACTICE BULLETIN

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN–GYNECOLOGISTS

NUMBER 106, JULY 2009

Replaces Practice Bulletin Number 70, December 2005

Intrapartum Fetal Heart Rate Monitoring: Nomenclature, Interpretation, and General Management Principles

In the most recent year for which data are available, approximately 3.4 million fetuses (85% of approximately 4 million live births) in the United States were assessed with electronic fetal monitoring (EFM), making it the most common obstetric procedure (1). Despite its widespread use, there is controversy about the efficacy of EFM, interobserver and intraobserver variability, nomenclature, systems for interpretation, and management algorithms. Moreover, there is evidence that the use of EFM increases the rate of cesarean deliveries and operative vaginal deliveries. The purpose of this document is to ra... for fetal heart ra...

ractice Bulletin was developy the ACOG Committee on e Bulletins with the assisf George A. Macones, MD. formation is designed to aid oners in making decisions appropriate obstetric and logic care. These guidelines not be construed as dictating usive course of treatment or ure. Variations in practice e warranted based on the of the individual patient, es, and limitations unique to itution or type of practice.

Given that the available data do not show a clear benefit for the use of EFM over intermittent auscultation, either option is acceptable in a patient without complications.

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A complex interplay of antepartum complications, suboptimal uterine perfusion, placental dysfunction, and intrapartum events can result in adverse neonatal outcome. Known obstetric conditions, such as hypertensive disease, fetal

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Number of Retarded Children?