Review Article

When Intra-partum Electronic Fetal Monitoring becomes Court Business

George Gregory Buttigieg

Introduction to the subject of intra-partum electronic monitoring

Sadly but inevitably, the clinical fruit of all scientific research, like the profile of the Roman god Janus, presents us with two faces - one is patient benefit while the other is medico-legal vulnerability. As part of defensive medicine, there are situations where malpractice risk is minimised by actual elimination of certain high-risk procedures e.g. in the case of some neurosurgical[1] operations. Intra-partum electronic fetal monitoring (IPEFM) is the commonest obstetric procedure in the developed world,[2] producing valuable information of fetal well being as co-related to maternal uterine activity with a scope of guarding fetal well-being in labour. It is a prime example of the therapeutic/ legal liability duality which haunts modern Medicine.

The rationale of the use of IPEFM is based on the fact that labour is the shortest but most dangerous trip ever undertaken by man. Every uterine contraction – indispensable for the mechanical process of exteriorisation of the fetus – is associated with a diminution of blood flow to the feto-placental cardiovascular unit. The resulting challenge may not be handled well by the unborn infant resulting in the complex known as fetal distress (the use of this term is being increasingly challenged by the American College of Obstetricians and Gynaecologists – on grounds considered very debatable in this author's opinion. The term is still used by the Royal College of Obstetricians and Gynaecologists of London. It can still be used –and without any apologies). This is especially likely but certainly not limited to[3] the scenario where the patient enters the obstetric arena with an 'ab initio' poorly functioning placenta.

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Short history

It is instructive to take a short look at the present form of IPEFM. Clinically available in the 1960s, IIPEFM in the form of Cardiotocography (CTG) quickly substituted[4] the old fashioned Intermittent Auscultation (IA) method of direct fetal stethoscope listening to the fetal heart [Normally done at regular intervals by the midwife using a Pinard stethoscope (one of many types)]. Clinical widespread cardiotocography commenced by 1966 when Hammacher developed a suitable recording system, which was freely available for routine use in 1968.[5] Caldeyro-Barcia [Roberto Caldeyro-Barcia (26 September 1921 – 2 November 1996), nominated for a Nobel Prize for his work on Feto-Maternal Medicine] was not only a great contributor to the discipline through his work on uterine physiology and patho-physiology but also coined the original nomenclature which he himself found unsatisfactory on further evaluation and stopped using by the 1970s. By that time, CTG monitoring was used in 84% of all U.S. births, regardless of whether the primary caregiver was a physician or a midwife.[6] Intrapartum CTG use is now universally entrenched in spite of any varying albeit methodology of interpretation (one unit may use computerised analysis, another may combine with ST analysis of the fetal ECG STAN etc.). Hospitals and physicians have billed and been collectively paid many millions of dollars for the use of CTGs since its universal acceptance in the 1960s.[7] IPFM in the form of a permanent CTG tracing strip has also proved to be manna from Heaven in the hands of lawyers instituting action in cases with undesired end result where a child suffers hypoxic intrapartum damage.

Clinical and legal equivocity

In spite of evidence demonstrating limited neonatal benefit, the medico - legal climate often pressurises obstetricians to integrate continuous IPEFM in the form of CTG as surveillance into their care of the pregnant labouring patient,[8] even if the various Colleges such the American College and the U.K's Royal College of Obstetricians and Gynaecologists have published specific guidelines as to when to implement such monitoring. The medico-legal aspect of IPEFM itself is rendered extremely complex firstly because of the applicability of legal principles to a phenomenon which by medico-legal standards has somewhat of the properties of "shifting sands". This

fascinating aspect cannot be dwelt on in any depth here but suffice it to quote here the high observer subjectivity of interpretation of CTG tracings. Another reason adding to the complexity of IPEFM in the Courtroom is a corollary of the "shifting sands" aspect and that is that to the plague of subjectivity one must add the scientific controversy[9] which surrounds the subject. Among these we find the already referred to poor inter and intra-observer reliability,[10] high false positive rate of up to 60%,[11] the unquestioned contribution to an increased Caesarean Section rate[12] as well as its failure to deliver the much expected pregnancy outcome improved as compared to |IA.[12]

Diminishing the medico-legal risk

The scope of this article is to attract clinical attention to a few of the innumerable, salient points which come into their own once IPEFM enetering the legal arena.

The use of correct nomenclature

Shakespeare's oft quoted dictum in Romeo and Juliet ("*a rose by any other name would smell as sweet*") would not hold much water in the subject at hand. It is annoying at best, misleading at worst and open to challenge in Court at any stage to refer to a CTG strip using the old Caldeyro Barcia classification (such as using 'Type I dips' or 'Type II dips.) Sometimes, ironically the ante-deluvian term 'dips' is actually mish-mashed with the correct term 'decelerations' *in the same sentence*. These are not airy-fairy changes of nomenclature but reflect genuine physiological principles which are scientifically challengable in Court. Other terms such as 'beat to beat' variation rather than 'variability' reflect knowledge pertaining to the older CTG machines and though not quite as misleading as 'dips', still render medico-legally vulnerable through lack of updated knowledge. While good obstetric practice demands the use of the most recent, standardized, quantitative nomenclature to interpret intra-partum CTG, to minimise miscommunication, propagate consistent, evidence-based responses to CTG patterns, and systematize research terminology[13] the standards of Court litigation demand no less precision.

With this mind it is disconcerting to hear the Court itself delivering a scientifically challengeable statement (as late as 2009) in *Whiston v London Strategic Health Authority*:

It is said that if the CTG had still been available the court would be able to tell when it was discontinued and whether there were Type II dips and, if so, for how long (i e whether they were continuous).[14]

One wonders at the possible sequelae at a Court of Appeal if the very momenclature employed was outdated, for appeals have been won or lost on much weaker technical points. The Court has a firm "commitment to mainstream science, so that we could avoid inconsistent verdicts in mass tort litigation".[15]

By contrast, it is a veritable pleasure to read the clear and scientifically correct exposé in *Smith v West Yorkshire Health Authority (t/a Leeds Health Authority).* The Judge speaks of 'baseline variability', 'decelerations and correctly refers to the reassurance generally elicited by accelerations with uterine contractions or movements. In reverse to the fit adult, accelerations of the fetal heart rate during the challenge of a maternal uterine contraction or a fetal movement, are a reassuring indicator of fetal well-being.

Baseline variability describes the changes in the baseline of the FHR. Such changes occur slowly unless there is an acute accident. Accelerations are the increases in the FHR and they are a positive and reassuring sign if they occur as a response to uterine contractions or movements in which case they are seen occasionally. They may not occur regularly but they should be seen occasionally. Decelerations are reductions in the FHR of more than 15 beats per minute from the baseline rate, while accelerations are increases in the FHR of more than 15 beats per minute.[16]

No serious case can be put forward either by plaintiff or defendant unless correct information on current nomenclature and guidelines is provided by correct expert advice. A good example comes across in *Brodie McCoy v East Midlands Strategic Health Authority*, (reference being made in this case to an antenatal and not intrapartum CTG tracing) where defence was not only well versed with the 1987 FIGO Guidelines for CTG interpretation but intelligently and justifiably attacked one of its Achilles tendons :

...reference was made to the 1987 FIGO Guidelines for interpreting CTG traces. Mr Porter pointed out that there was an apparent internal inconsistency in the FIGO classification of decelerations in antepartum CTGs, as these state that the "absence of decelerations except for sporadic, mild decelerations of very short duration" is consistent with a normal fetal heart pattern; but "sporadic decelerations of any type unless severe" are part of the definition of "suspicious" fetal heart patterns. Thus in cases such as this, where decelerations are difficult to identify, it is not obvious whether a CTG should be classified as normal or "suspicious".[17]

The case was dismissed 0n the grounds that neither did the plaintiff prove breach of duty through care below what is expected – although neither did the defendant prove that such care was delivered.

Correct CTG interpretation

It is a sad fact that there *are* obstetricians in training, or otherwise, who cannot interpret a CTG

tracing correctly. A ghastly indictment of one such obstetrician can be found in *Azzam v General Medical Council.*

The expert evidence, which was accepted by the appellant, was that if he had not made an error in the assessment of a cardiograph (CTG) reading, it was likely that the child would have been delivered successfully. In October 2007, a Fitness to Practise Panel (the panel) of the respondent General Medical Council (GMC) found that the appellant had not interpreted or recognised signs of fetal distress as shown by the CTG trace…. The panel's conclusion was that the appellant's assessment of the CTG scan had been inappropriate, inadequate and irresponsible, not in the best interests of the mother and below the standards which could reasonably have been expected of a competent obstetrician.[18]

Again, the defendant in *Simms v Birmingham Health Authority,* may have opted for euphemistic language but he had botched up his management with disastrous results:

"With hindsight I consider it showed some reduced variability and was thus abnormal. This reduced variability warrants continued observation but it does not warrant Caesarean section, unless other significant abnormalities develop."[19]

We speak of a serious and significant problem. In a series of 3600 deliveries at the Middlesex Northwick Park Hospital (UK) between 1996 and 2000, 22% of the management care problems were directly attributed to CTG misinterpretation.[20] More than 1 in 5 of serious mismanagements resulting from CTG misinterpretation in this serious were preventable. This preventability is stressed by Hove et al.,[21] who showed that all hypoxic brain injuries are potentially avoidable using established obstetric practice to avoid CTG misinterpretation - this in turn demands adequate CTG education and training. Such CTG misinterpretation with resultant fetal hypoxemia and/or academia ("birth asphyxia") in the unborn (the term 'fetal distress' has been lately reviewed with dislike by the American College of Obstetricians and Gynaecologists is still used and accepted by others, such as the Royal College of Obstetricians and Gynaecologists of London,) comes at a massive cost. In 2011 "birth asphyxia" comprised 50% of the UK NHS litigation costs,[22] and in the 2000-2010 decade, the same NHS forked out £3.1 billion for maternity medico-legal claims (the highest of any speciality) mostly involving cerebral palsy and CTG misinterpretation.[23]

The UK's National Health Service Litigation Authority's (NHSLA) emphasises that there is still need for improvement in general CTG education and has made formal attendance at CTG courses as a mandatory requirement to receive Clinical Negligence Scheme for Trusts (CNST) discounts.[24]

The interpretation of a baby's heart rate tracings requires special knowledge and experience. Quite often subtle changes in the CTG as early warning signs of asphyxia can only be interpreted by experienced doctors and junior doctors need to be supported and educated to acquire this skill. It is therefore crucial to have experienced obstetricians (consultants) working in labour ward during the out-of-hours period.[25]

Numerous reports have repeatedly recommend regular in-service education programmes, as part of the cure of the problem. Though all experts on whichever side should state the truth according to their conscience, IPEFM may allow a wider swing of opinion due to its inter-observer variance – one of the difficulties of the subject.

The Truth and nothing but…and on anticipating the unexpected.

All scientific Court statements ought to be assumed to come under the scrutiny of 'opposing' experts. Though all experts on whichever side should state the truth according to their conscience, IPEFM may allow a wider swing of opinion due to its inter-observer variance – one of the difficulties of the subject. This applies to obstetric defendant as well as Court appointed obstetric expert. One must avoid the fatal 'faut pas' of imagining that one is talking down to laymen just because there is no visible expert on site. In *Smith v West Yorkshire Health Authority,* Judge Silber J speaks with impressive authority when he demolishes an expert opinion on the fetal baseline heart-rate of an intrapartum CTG :

The fallacy of Mr Hare's contention is that he apparently regards the peaks as being the baseline. A much more realistic approach is that adopted by Mr Mackenzie of submitting that the baseline is 130 bpm, which is close to a little below the rate to which the fetal heart rate returned on a substantial number of occasions during the period in question and that rate also takes into account the peaks and the troughs of the FHR during that period. My reading of the trace is that the baseline would have been a little higher than Mr Mackenzie's figure and would in the 130-140 bpm region, but it certainly was not 160 bpm. As I will explain later when I turn to the causation issue in paras 227-230, I consider that Mr Mackenzie's estimates of the baseline are much more accurate than those of Mr Hare.

Any opinion, even if expressed *before* a case reaches Court, may come back to haunt. In *Gossland v East of England Strategic Health Authority* :

Mr Johnson agreed in cross-examination that he had been "putting it too high" when stating in his written report that before his delivery Omar showed all the features of a seriously sick baby; and he agreed that by some standards, including Beard and Finnegan's Foetal Heart Patterns and their Interpretation, 1974 at

28, Omar did not present a complicated tachycardia. He agreed that when describing the foetal heart beat as "severely abnormal" at 21.40 he was using "hyperbole".[26]

Hyperbole on one side and a doctor's career on the other! Furthermore, the same "expert" obstetrician provides us with yet another rich lesson:

... he had not anticipated that the Defendant would contest the case.[26]

In other words this expert is saying that he feels free with his opinion but once in Court he would execute better circumspection.

Furthermore the truth of the facts must be recorded legibly in the case file not omitting date, and time. A Court statement such as the following is a terrible indictment of carelessness:

On being recalled on 30 October, she accepted that it (the CTG tracing strip) should definitely have been dated and timed.[27]

Ensuring interpretability of CTG strip tracing.

It is crucial that CTG documentation should be of adequate quality for visual interpretation.[28]

Producing "miles" of por quality CTG strip tracing reflects either a *persistent* lack of interest in the patient or, equally condemning, long periods of absence from the bedside.

An example of this is clearly found in *Popple v Birmingham Women's NHS Foundation Trust (2011)*

When the judge came to deal with this, which he did in sub-paragraph (d) of paragraph 63 of his judgment (page 54), he said that he was quite satisfied that CTG does not reliably exclude a foetal bradycardia. He went on to repeat the view of the claimant's experts in their supplementary joint memorandum that all the obstetric experts have emphasised extreme difficulty in reliably interpreting the CTG traces due to poor quality and the obstetric experts in their meeting record that the CTG is uninterpretable from 14.21 onwards.[29]

To Sample or NOT to sample

Fetal blood sampling has been relegated to second division for so long and in so many units that the question seems to have now jumped from "is this CTG amanifestation of true fetal distress?" to "Should I section on this tracing or not?" This is both understandable as well as puzzling to those of us, mature enough to remember crouching on our knees in labour ward, struggling to obtain a fetal blood sample through amnioscopes – only to repeat the procedure within the hour. This by-passing of FBS seems NOT to have penetrated Court mentality:

In particular, it was submitted to the Lord Ordinary on behalf of the pursuer that at any of four points in the course of the labour on 1 October 1999, namely at 0810 hrs, 1230 hrs, 1345 hrs and 1600 hrs approximately, the CTG trace showed features which no competent obstetrician exercising reasonable care would have interpreted otherwise than as requiring the taking of a foetal blood sample, which failing, the carrying out of a caesarean section.[30]

This Court statement come in 2013 and it still equates fetal blod sampling with a "competent obstetrician". The purpose of sampling (a fetal blood sample is obtained from the scalp using a small bladed long handled knife passed through an amnioscope manoeuvred through the maternal cervix) is to measure the fetal pH, in stuations where IPEFM is abnormal and *may* be indicative of hypoxia. Besides the preponderance of habit veering to *non* performance of sampling in deference to a Caesarean Section, one needs to add the fact that existing evidence disproves intrapartum FBS as a gold standard of proving or excluding fetal hypoxia (Mahendru et al. 2011).[31] Incidentally the same authors further discount scalp lactate, pulse oximetry, fetal ECG waveform analysis, and central haemodynamics in labouring rhesus monkeys as providing such a gold standard.[31] Neither is omission of FBS likely to be challenged medico-legally in cases where with a fine neonatal outcome after a caesarean section. However this excludes the exceptionally litiginous patient challenging the omission as part of the grounds for a claim of an unnecessary caesarean or a caesarean section were severe complications supervene. Such a potential medico-legal scenario is similar to performing intra-partum EFM in a case where such monitoring is not formally indicated by most guidelines. As far back as 2008, Wiberg-Itzel et al.,[32] found no significant differences in rate of acidaemia at birth after the use of lactate analysis or pH analysis of fetal scalp blood samples (pH≥ 7.25 being considered normal, 7.21–7.24 as borderline and ≤ 7.20 as abnormal.) However, when all is said and done, in the section on determining hypoxia during labour, the NICE guidelines[33] *still* advise FBS (evidence level 1b) in the presence of a pathological FHR trace unless there is clear evidence of fetal compromise, such as a prolonged deceleration exceeding three minutes. In fact, the same guidelines recommend repeating the sampling after 1 hour if the result is normal but the FHR tracing remains pathological. Although little has been published as yet on the actual use of guidelines in litigation,[34] as matters stand, present Court opinion tends to be based on *witness* testimony in court regarding *what is done* rather than what *ought to be done*.[35] Non adherence to clinical guidelines does not automatically imply an adverse outcome for the defendant,[36] although the legal importance of guidelines is bound to increase.[36] In *Ludwig (by her mother & litigation friend Della Louise*

Ludwig) v Oxford Radcliffe Hospitals NHS Trust and another we find direct reference to the NICE guidelines:

The guidelines continue as follows:

"In cases where the CTG falls into the suspicious category, conservative measures should be used. In cases where the CTG falls into the pathological category, conservative measures should be used and fetal blood sampling be undertaken where appropriate/feasible. In situations where fetal blood sampling is not possible or appropriate then delivery should be expedited".[37]

Hence the answer to this section's title is likely to be "not", but in reality, medico-legally, one is traversing no man's land. This is likely to hold until a clear fool proof formula comes to the fore by which fetal distress is diagnosed, for example by a computerised programme evaluating CTG, ST analysis of the fetal ECG…

Spoliation of Evidence

In any Court case centring on damage from intra-partum asphyxia, the physical availability of the *original* CTG strip is of inestimable importance. If this goes missing (not a rare occurrence)– this is a form of what is termed spoliation of evidence. This is serious business indeed, because however scientifically challengeable, the Court tends to hold that:

the fetal monitoring strips would give fairly conclusive evidence as to the presence or absence of fetal distress, and their loss deprives the plaintiff of the means of proving her medical malpractice claim against the Hospital.[38]

No Court is likely to take the situation lightly. Comments at Court such as

"the fetal heart tracing has been missing since delivery,"[39]

do *not* wash down well with Judge or Jury. In *Martelly v. New York City Health & Hosp. Corp.*,[40] where the CTG tracing was missing, the Court gave the jury instruction to draw the strongest adverse inference against the defendant hospital which had a legal obligation both to safeguard the CTG strip as well as give a reasonable explanation for its disappearance.

Some hospitals legally bind the relevant personnel to preserve such tracings as an intrinsic part of the medical record. One such example comes from New York Hospital[41] where CTG strips must be safely preserved for whichever period is the longest, namely:

6 years from the date of patient discharge from hospital.

3 years after the child reached the age of maturity (18 years).

6 years after the child's death.

The Maltese Health system will eventually have to evaluate this point, either pro-actively or a result of bitter experience. When paper based systems are used, the original paper strip must still be preserved even if a photocopy or microfilm of it exists[42] and furthermore any photocopying must be in toto (special photocopiers must be used and if not available are available at newspaper printers) and *not* in separate segments. Where computerized clinical information systems (CIS) is in operation, various regulations apply in conjunction with advice from respective organisations or Colleges.[43]

Conclusion

Most Court cases centred around IPEFM are often both complex and contentious by nature of the subject . The subjective nature of CTG interpretation as well as the end scope of such subjectivity in a Courtroom are further challenging factors. As is standard in medico-legal litigation the plaintiff must establish that (a) There was a breach of duty by the defendant who delivered care below a reasonably expected standard and (b) It was this substandard care that led to the unsatisfactory final clinical result for which legal redress is being sought. It is not sufficient to prove substandard care but one must go the next step and show that this contributed to the damage in question.[44] With Courtroom CTG cases it is often (but not invariably) the second proviso which may elicit the greatest difficulty, the mechanics of which are beyond the scope of this paper.

There are many relevant aspects not addressed in this short article. However the final emphasis should be and is on the competency of interpretation of the CTGtracing. The UK's National Health Service Litigation Authority's (NHSLA) emphasises that there is still need for improvement in general CTG education and has made formal attendance at CTG courses as a mandatory requirement to receive Clinical Negligence Scheme for Trusts (CNST) discounts.[34]

The interpretation of a baby's heart rate tracings requires special knowledge and experience. Quite often subtle changes in the CTG as early warning signs of asphyxia can only be interpreted by experienced doctors and junior doctors need to be supported and educated to acquire this skill. It is therefore crucial to have experienced obstetricians (consultants) working in labour ward during the out-of-hours period.[45]

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