

Understanding the Decision-Delivery Interval in Cesarean Births

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Avoiding the adverse neonatal effects of perinatal asphyxia has been one of the common indications for cesarean deliveries in current obstetric practice. Expeditious delivery is dependent on decision to perform cesarean delivery and time lines achieved. A decision-delivery interval of 30 minutes, a concept initiated by the American College of Obstetricians and Gynecologists has open to debate as controversy rears about neonatal outcome when this time interval is considered in isolation. Time lines alone are probably not the only criteria to be employed, and may contribute to errors in interpretation by professional regulatory bodies and the society at large. Procedures prior to decision making like trial of labour, fetal scalp sampling and readily available resources for instituting emergent cesarean delivery invariably need to be considered. Though decision to delivery time is an integral component of critical conduct intervals in the acutely compromised fetus, a more pragmatic approach needs to be taken considering potential and known logistical and obstetric factors in line with good obstetric practice.

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Introduction

Since the dawn of cesarean births, operative deliveries have been performed in extreme clinical situations. In 715 B.C., Numa Pompilius codified a Law in the Roman Court by making the procedure as a mandate in advanced pregnancy in the event of maternal demise.^{1,2} In modern obstetrics, on the other end of the spectrum routine cesarean delivery (CD) are offered electively to women for variety of indications; or performed in emergency fetal or maternal complications or both.³ Perimortem cesarean birth is a rarity.

In recent years the rate of non-acute cases of cesarean births has markedly outnumbered emergent cases.² Emergency cesarean deliveries (ECD) are performed,

in most cases to prevent birth asphyxia. Determining perinatal asphyxia is both complex and a crucial issue. Even with the best risk prevention strategies, there are clinical situations that prompt a shortest possible decision delivery interval. Current approaches evolve around critical evaluation so as to adopt and focus relying on the time required to initiate a surgical procedure with birth of a non-hypoxic baby. Though controversial, currently, there is no strict regulation on upper limit of the decision-delivery interval (DDI) that code an acceptable time interval for performance of cesarean delivery.⁴ Previously, the American College of Obstetricians and Gynecologist guidelines suggest that medical facilities providing obstetric care services have the capability to manage delivery of a fetus within 30 minutes of the decision to operate, referred to as “decision- delivery interval”.⁵ The OB Pearls Committee of the American Society of Health Care Risk Management (ASHRM) does not streamline the DDI to a time limit rather addresses based on the institutional capability providing obstetric care.⁶

In this review “cesarean delivery”(CD) is a preferred term to “cesarean section” and will be used in the whole text. The two words “caesarean” and “section” were derived from Latin verbs “caedere” and “seco” respectively, both of which mean “cut” or “incision”. Therefore, it seems superfluous to use the terminology “cesarean section”. In the United Kingdom and other commonwealth countries, the syllable – “caesarean” has retained the “ae”, whereas in the United States it spells “cesarean”; and for simplicity of spelling, the authors will prefer using “cesarean”.

What is decision delivery interval?

The time line between a decision being made and delivery of the baby is referred to as a decision delivery interval. In tandem with this statement, is not synonymous with decision to incision time where the goal of birth of a baby is yet to be achieved. The “30 minute rule” for a DDI takes its origin from the Guidelines to Perinatal Care developed jointly by the American Academy of Paediatrics and the American College of Obstetricians

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and Gynecologists.⁷ The OB Pearls Committee of the American Society of Health Care Risk Management (ASHRM) does not streamline the DDI to a time limit rather addresses based on the institutional capability providing obstetric care. The ASHRM reads as “emergency cesarean sections should be performed as quickly as possible, in keeping with the capabilities of the institution.⁶ *Currently, there is no general consensus of an acceptable DDI for performance of ECD.*⁴ Most obstetricians would aim to improving outcomes from ECD using common sense principles of a smart and diligent obstetric team.

Understanding the Decision Delivery Interval

In simple words, DDI relates to the 30 minute rule pertinent to critical conduct analysis in conditions of fetal heart rate abnormalities or any acute maternal complication. It may connote an element of negligence in dealing with intrapartum complications that result in delivery of a fetus with evidence of birth or perinatal asphyxia. Since the inception of the rule, several investigators have questioned the feasibility of achieving a 30 minute DDI on all cases of ECD and its negative impact on neonatal outcome. Only in cases of acute and catastrophic non-reassuring fetal status, it is reasonable that CD is performed within the shortest possible DDI and any purposeful wait is inappropriate. It is apparent in subsequent sections that most researchers were unable to prove that standard 30 minute DDI have uniformly improved neonatal outcomes, despite path physiologic possibility. Nevertheless, there are clinical situations that require immediate or emergent operative interference for fetal and maternal well being. It is worth emphasis that in a hospital rendering obstetric care, it is mandatory to identify and be prepared for acute and unpredictable obstetric situations.

The principle of safe obstetric management starts with the concept of “foresee ability of harm principle” a perception first introduced by Justice Benjamin Cardoza in 1916. This concept is rooted in the United States legal system and serves as a roadmap to all obstetric malpractice lawsuits. It started in *MacPherson v Buick*

Motor Company case and Cardoza wrote that “because the danger is to be foreseen, there is a duty to avoid the injury, if it (person) is negligent where a danger is to be foreseen, a liability will follow”.⁸

Though there is no magical blueprint or total preventive strategy to avoid lawsuits, “foresee ability of harm” principle ought to be deeply rooted in obstetric practice as it is in the U.S. legal system, in order to avoid undue stress and medico-legal accusations. In many parts of the world, particularly in the United States, less commonly in Europe, it has been an unfortunate truth and reality that being sued for malpractice is considered an inevitable aspect of obstetric practice regardless of the quality of care rendered by the obstetrician. This has led to changing trends in some hospitals where obstetricians are reluctant to provide labour and delivery services, quoting safety concerns. Present day concerns should be foreseeability of harm principle and commitment to good and evidence-based obstetric practice rather than indulgence in defensive practice.

Steps that can be implemented to improve or minimize the DDI time

Obstetricians’ experience in dealing with fetal and maternal outcomes in appalling situations has lead to developing strategies that looks into a minimum DDI time. Most malpractice allegations against the obstetricians and gynaecologists relate or point in some ways to the care of patients during labour and delivery. Few lawsuits might involve negligence or faulty practice in prenatal or postnatal care. Unfortunately for the obstetricians, the alleged litigation is frequently linked more to the severity of the birth injury than to the quality of care that was provided. As such, obstetricians either focus on risk management with a goal at reducing adverse events encountered in labour and delivery; or withdraw themselves to defensive practice. In an attempt to abate and make uniform approach an arbitrary upper limit to DDI has been set and recommended for practice. This limit relates to cesarean deliveries only and not to vaginal operative procedures. The American College of Obstetricians and

Gynecologists recommends a standard '30 minute' rule for DDI. Attempts to enforce an ideal time limit may not be applicable in most circumstances because in current practice more than half of CD is electively performed. The DDI may be the consequence of individual obstetrician's valued assessment and clinical decision.

The appropriate management should be to increase the understanding of the vulnerability of a fetus to hypoxic insults in labour; and how to decode, when and where necessary, to necessitate a safe time limit for emergency operative intervention. Various steps in minimizing morbidity related to CD in the face of time compromise have been explored by researchers. Modern hospitals setting with obstetric facilities provide 24 hour coverage in labour and delivery ward with an in-house dedicated team consisting of obstetricians, anaesthetist and theatre staff, and neonatal support personnel, so that operative delivery is possible within a short period of time. With efficient team operation, work is targeted at abolishing and thus minimizing unnecessary delay, particularly with transfer of patient to the theatre and induction of anaesthesia. Most cesarean operating theatre is located within the labour and delivery ward, an important step in the process. Hillemanns in a 10 year study had shown that ECD performed in the delivery room results in a shortened DDI without detrimental perioperative maternal or neonatal complications.⁹ Therefore, this can be an option in a hospital setting with provision of a well equipped delivery room.

Reducing time spend on aseptic technique particularly in crash ECD can be safely supported by the use of broad spectrum antibiotics prophylaxis.⁹ Using antibiotic prophylaxis in CD has become a standard practice. The routine insertion of Foley's catheter prior to ECD can be cumbersome and skipped with minimal maternal intra-operative morbidity with careful procedure.¹⁰ However, it is essential that a labouring patient voids urine at frequent intervals. Omission of urethral catheterization may be worrisome in labouring women with previous CD scar where there

is possibility of adhesions or anatomical distortion of pelvic organs.

The primary purpose of ECD is prompt delivery of the fetus keeping the critical conduct interval between abdominal incision and delivery of the fetus short. This crucial interval should not be wasted on securing small bleeders or repairing incurred bowel or bladder injuries. Certainly seniority of the operating surgeon together with a dedicated support team will contribute positively to achieving the recommended 30 minute rule. Kolas from Norway in his study showed that seniority of the surgeon was a significant predictor in achieving the recommended 30 minute rule.¹¹ Availability of efficient blood transfusion service is also mandatory to secure safe and prompt operative deliveries. Preparing the couple in the antenatal period on the possibility of the need for a rapid recourse to operative delivery will facilitate obtaining informed consent, thereby precluding undue delay.

Though the above mentioned actions will contribute to short DDI, timely recognition of a complication is the key element in the management of a non reassuring fetal status or obstetric emergencies that mandate expedited delivery. The previous American College of Obstetricians and Gynecologist guidelines on DDI of 30 minutes⁵ did not take into account any procedures prior to decision-making that may be required for assessment of fetal hypoxia such as fetal scalp blood sampling. The recommendation had been along strict time lines. It was based on the crucial factor that any setback in delivery of a fetus in the event of acute obstetric crisis may have adverse outcome. The 30 minute rule referred to necessity of hospital facilities and setting, for prompt treatment and did not rule or dictate clinical decision.

Currently, there is no strict regulation on upper limit of the DDI that code an acceptable time interval for performance of cesarean delivery.⁴ With a pragmatic approach, decision-making and delivery of the fetus ought to be achieved in a timely manner at the discretion of the attending obstetrician. The DDI is an

imperative element of a critical conduct interval. Phelan and co-workers (2005) analyzed the application of Justice Cardoso's "foresee ability of harm" principle using critical conduct interval for a case of 'fetal distress'.⁸ To foresee the harm and prevent birth asphyxia or low Apgar score in a neonate, a targeted perinatal outcome strategy with a well coordinated and efficient team work is obligatory. The critical conduct interval begins with skilful and timely identification and appropriate interpretation of fetal heart rate abnormalities; evaluation of the clinical scenario; proper decision-making for the best possible perinatal and maternal outcomes; and finally a precise DDI keeping in mind the severity of the situation. In few cases adverse outcome will still occur even with the best preventive protocol in order. As part of quality assurance safety program in dealing with acute obstetric emergencies, a written protocol should be available in the labour suite as part of a mandated educational activity for continued improvement. Such an approach will avoid miscommunication in management, particularly in hospitals lacking adequate facilities; and largely mitigate clinico-legal issues.

In both the recommendations on DDI– Guidelines to Perinatal Care "30 minute rule" and OB Pearls Committee Guideline, definition of ECD remains unclear. The former delineates the indications that mandates expedited operative delivery in acute fetal distress – acute placental abruption, prolapsed cord, haemorrhage from placenta praevia and uterine rupture. Therefore, a 30 minute rule may not be applicable to all emergency operative deliveries and a clear classification of the types of CD based on acuteness of the obstetric problem can be helpful. Reports from various studies has shown that in clinical reality a standard 30 minute DDI is not feasible and not related in most cases to adverse outcome of the fetus. A workable approach would be to define ECD and make recommendations facilitating obstetricians to optimal conduct for best perinatal and maternal outcomes. Lucas suggested with a classification of CD based on the severity of fetal and/or maternal situation, viz.¹²

- I. *Emergency cesarean delivery*: when surgical delivery is performed in situations that are extremely life-threatening for the mother or fetus or both. For example fetal bradycardia (recovery of a normal fetal heart rate does not occur within 10 min), failed assisted or operative vaginal delivery with fetal distress, cord prolapse, acute placental abruption, placenta praevia with profuse bleeding, difficulty in delivering second twin, and in rare perimortem cases
- II. *Urgent cesarean delivery*: when surgical delivery is performed in situations that are not immediately life threatening but has high maternal and fetal risks, e.g. abnormal fetal heart rate but not acute fetal compromise, failed assisted vaginal delivery without fetal distress, previous two CD in labour.
- III. *Scheduled cesarean delivery*: when surgical delivery is planned in situations requiring an early intervention but without maternal or fetal danger.
- IV. *Elective cesarean sections*: when surgical delivery is performed at a time convenient to the patient or the obstetric team or both.

An accepted uniform classification as noted above avoids vagueness in putting theory into practice. Despite the advent of several fetal monitoring techniques, there is no standardization of methods used for assessing fetal heart rate. Further compounding the issue is that the terminology of a possible hypoxic fetus differs; American obstetricians favour using the term "non-reassuring fetal status" to describe a hypoxic fetus⁵ though in Great Britain and in most parts of the world "fetal distress" is widely used until today to refer to an acutely compromised fetus.

Overriding these differences, it is generally agreed that "acute fetal distress" is present when there is a sudden, rapid and sustained deceleration of the fetal heart rate, not responsive to corrective measures and tocolytic drugs. The common potential causes of acute hypoxia are acute placental abruption; prolapsed cord,

severe bleeding from placenta praevia and uterine rupture. Katz et al reviewed data in the more serious level of fetal hypoxia, from a retrospective study for analysis of neonatal outcome in maternal cardiac arrest (perimortem). He concluded that for fetal salvage less than 5 minute DDI is ideal and rarely helpful after 15 minutes. It would then be meaningful to propose that for cord prolapse, major placental abruption, massive haemorrhage from placenta praevia, and prolonged fetal bradycardia would benefit with minimal DDI intervention as has been shown by Katz and co-workers.¹³

The Guidelines to Perinatal Care “30 minute rule” and ASPRM recommendations are essential in Lucas’s emergency category which some authors may refer to as “crash” CD. In an extreme life threatening indication in a fetus or mother or both, a 30 minute rule or ASPRM guideline is obligatory. Crash cesarean delivery drills should be implemented in hospitals offering labour and delivery care, to enhance efficiency of team members. The standards for CD adopted in the United Kingdom, by the Clinical Negligence Scheme of Trusts (CNST)¹⁴ have been encompassed in decision-making for medical indemnity costs for individual trusts. It would be prudent in the present day climate for authoritative professional bodies to set a time limit for ECD so as to improve coordinated care in urgent circumstances. High risk pregnancies including intra-uterine growth restriction, oligohydramnios, placental abruption, and prolonged and repetitive fetal heart rate decelerations or bradycardia may exhibit fetal heart rate pattern changes, and risk preventive strategies ought to focus on predictive early warning signs derived from fetal monitoring to facilitate meeting DDI time limits.

What is known about Decision- Delivery Interval and Neonatal or Perinatal Outcomes

Electronic database NIH/NLM Medline and manual bibliography searches of peer reviewed sources from last decade were conducted to identify studies on DDI time. Standard textbooks search results was also included. Most research studies were reported from hospitals in industrialised countries, and only a couple from

developing countries. It is worth understanding that a prompt vaginal or cesarean delivery with shorten possible DDI require appropriate hospital facilities that may not be easily available in developing countries. For appropriate of what ought to be the DDI time, studies from developing countries should be encouraged for comparative notes towards global approach to recommendations.

The National Health Service Maternity Unit in England¹⁵ study to determine the DDI for performing an ECD, 66 percent of babies were delivered within 30 minutes and 88 percent within 40 minutes; and 4.0 percent remain undelivered at 50 minutes. There was no significant impact of DDI on term babies born, those who required admission in special care unit with differences in the decision delivery intervals. The study suggested that DDI interval of 30 minute was not an important predictor for neonates requiring admission to the intensive care unit. Eight percent babies with DDI of less than 30 minutes and 13 percent with an interval of more than 50 minutes required admission. The study concluded that 30 minute DDI was not realistic in routine practice and furthermore, failure to deliver babies within recommended time frame did not have adverse effects on neonatal outcome.

Mackenzie had similar conclusions in a prospective study on non elective CD.¹⁶ In their hospital 30 minute DDI was the obstetric unit policy. Less than 40% of emergency ECD performed for fetal distress was achieved within 30 minutes DDI. There was no evidence to support that even an interval up to 120 minutes had adverse affects on neonatal outcome unless if the delivery had been a crash ECD. The study suggested that a 30 minute time line was applicable in emergency-crash cesarean deliveries. Sayegh and co-workers¹⁷ evaluated the DDI in ECD and reported a mean DDI of 39.5 minutes in the emergency and urgent group and 55.9 minutes in the non-emergency or elective group. The main reason for increase in DDI was delay in the theatre and lack of communication between neonatal and anaesthesia teams. Similar findings was also reported by Bloom and

co-workers from the National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units Network; 69 per cent of ECD commenced more than 30 minutes after the decision was made to operate.¹⁸

A multi centre cross sectional survey¹⁹ was carried out in Maternity Units in England and Wales, to determine if the DDI in emergency CD was a critical factor that affected maternal and neonatal outcome. With babies delivered within 15 minutes and those delivered within 75 minutes, there was no difference in neonatal outcome. After 75 minutes there was a significant higher chance of babies having five minute Apgar score of less than 7 and 50 percent chance of admission to special care unit. In a retrospective chart review carried out at the Department of Obstetrics and Gynaecology, University of Texas Medical Branch, Texas to evaluate the effect of the current ACOG guidelines of 30 minute DDI for emergency CD on neonatal and maternal outcome,²⁰ the overall median DDI was 20 minutes. He reported that on the contrary, there were more babies born with low Apgar score at 1 and 5 minute, cord pH less than 7.0 and neonatal seizures in group of mothers with DDI of 30 minutes or less, than in the group of mothers with DDI exceeding 30 minutes, though not statistically significant. There were no statistical differences between the two groups of neonates in terms of neonatal admission to intensive care unit and/or length of stay. Chauhan and co-workers²¹ in a 2 year retrospective study on ECD concluded that a < 30 minute DDI is an ideal preventive measure in acute fetal distress though failure to achieve this goal is not associated with significant adverse perinatal outcome.

Similar findings were reported from a retrospective analysis of ECD in a tertiary university centre in Israel.²² The study showed that in emergency group 71 percent of CD was achieved within 30 minutes compared to 35 percent in non-emergency group. In emergency-crash group 100 percent delivered within the recommended time compared to 59 in non-crash-emergency group of patients. The researchers classified

the CD into emergency and non-emergency, further classified emergency to emergency-crash and emergency-non-crash groups. Though the obstetricians took into account that those in the emergency-crash group needed very prompt intervention, they found no correlation between DDI and umbilical artery pH or Apgar score at 1 and 5 minutes in infants in both CD groups. In another study, Holcroft from Division of Maternal-Fetal Medicine, John Hopkins University School of Medicine examined the relationship between umbilical arterial gas analysis and DDI in ECD performed for non-reassuring fetal status. He noted that in most neonates there was no deterioration in cord gas results even when born with DDI more than 30-minutes.²³

In a Norwegian study,¹¹ 52.4 minutes was the average interval for all emergency cesarean delivery; and 11.8 minutes for urgent -emergency CS. From the study results they came to a conclusion that there were several significant factors that may predict when 30 minute DDI is vital to optimize pregnancy outcome and these included acute fetal distress, placental abruption and cord prolapse. Seniority of the surgeon was also a significant predictor in his study to a more expeditious delivery.¹¹ Mackenzie in his study did not support such finding.¹⁶ A study reported the results of an audit of all cesarean deliveries done in five different periods, in a general district hospital in Kent, United Kingdom.²⁴ The recommended DDI exceeded in 64 percent of cases of CD. The main factors observed in their study causing delay in performing the surgery were transferring the women to the operating theatre and inducing anaesthesia. The study proposed that introduction of a time sheet may improve the decision delivery interval. With implementation of a time sheet only 71 percent of CD had a DDI of 30 minutes.

Korhonen J conducted a prospective study in Finland²⁵ on ECD to compare perinatal mortality and morbidity with a hospital team in house and on call. Fetal loss and consequences of birth asphyxia was evident when the hospital team is on call from outside the hospital. His study suggests that 24-hour coverage of

anaesthesia and theatre staff is crucial for optimum management of ECDs.

The last data in this literature review is a prospective observational study from the University of Nigeria Teaching Hospital, Nigeria, the only report from a developing country evaluating DDI in cesarean births. The study was conducted in two tertiary centres, to assess the DDI for ECD and effects of DDI on neonatal outcome. In the study the researchers tried to explore the practicality, its effect on neonatal outcome and its legal importance. None of the CD in that study was performed within the recommended 30 minutes decision delivery interval. The major factor that accounted for delays was starting anaesthesia, availability of theatre staff and blood transfusion facilities. Despite their findings, the study found no significant correlation between DDI and perinatal outcome. The study recommended that a 30-minute decision delivery interval should be the standard practice, though DDI of up to three hours may not have adverse effects on neonatal outcome.²⁶

Most researchers (hospitals in western countries) agree to a standard DDI of 30 minutes and also realize that the recommended “30 minute rule” DDI cannot be achieved in routine practice. Its practicality and implications on negative neonatal outcome was questioned because there was no strong evidence to support a 30-minute DDI in all cases. Decision delivery time exceeding 30 minutes did not have adverse affects on the neonates. There were some significant predictors for performing crash CD – acute fetal distress, cord prolapse and placental abruption when DDI becomes a crucial factor and any delay may result in deteriorating fetal and maternal outcome. Studies also reported that factors causing delay in initiating ECD were: transferring patient to the theatre, induction of anaesthesia, inadequate coordination between the anaesthesia and neonatology teams; and lack of essential drugs and blood transfusion service. Therefore, based on the above mentioned research findings it is obligatory for hospitals offering labour and delivery

services to have coordinated team work and in house obstetricians, anaesthetist and theatre staff, and neonatology support to manage unpredictable acute emergencies that mandate immediate operative delivery.

Conclusion

A decision delivery interval of 30 minutes or less may not be applicable to all ECD but when faced with an acute and catastrophic fetal or less commonly maternal conditions, expedited delivery is warranted and any purposeful delay is unjustified. Decision to delivery time is an important and integral part of critical conduct interval in acutely compromised fetus. Katz et al¹³ in his study with more serious level of fetal hypoxia in maternal cardiac arrest (perimortem) concluded that for fetal salvage less than 5 minute DDI is ideal and rarely helpful after 15 minutes. Therefore, maternity care units must possess full operational strength to deliver appropriate care in volatile acute emergencies. Perinatal litigation is not a rarity to the practicing obstetrician. Perinatal risk management using the concept of foresee ability of harm and its potential application to obstetric care, together with common sense approach improve outcomes from ECD.

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