Adherence to timeline for decision to delivery interval in accordance with NICE guidelines and its impact on neonatal outcomes in a rural tertiary health care centre of Central India

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Abstract:

Objectives: Aims of this study were to determine the caesarean section rate in our rural tertiary health care centre, to perform an audit of decision to delivery interval for emergency caesarean sections, to compare our timings with the recommended DDI (decision to delivery interval), to evaluate the factors contributing to delay in DDI and to analyse the impact of DDI on maternal and fetal outcomes. **Methods:** This retrospective observational study was conducted in the Department of Obstetrics and Gynaecology at Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra over a period of 18 months from January 2015 to June 2016. Data was retrieved from the hospital files during working hours within 24 hours of the caesarean section. **Results:** Caesarean section rate (CSR) during study period was 36.9%. Main causes of delay were the delay in obtaining consent in 312 (20%), arranging blood in 489 (31.3%) and anaesthesia procedural delay in 659 (42.2%) patients. Among category 1 CS, APGAR score at 1 minute and 5 minutes was not significantly different between CS with DDI≤30 minutes and those with DDI>30 minutes (p - value >0.05). Also, among category 2 CS, APGAR score at 1 minutes and 5 minutes was not significantly different between CS with DDI <75 minutes and those with DDI >75minutes (p - value >0.05). **Conclusion:** DDI should be considered as one of the important contributing factors but not the sole factor in determining the maternal and neonatal outcomes in emergency caesarean sections.

Keywords: Decision to delivery interval, emergency caesarean section, NICE guidelines, maternal outcomes, neonatal outcomes.

Caesarean section is the most commonly performed obstetric operation which involves the delivery of viable fetus through an abdominal and uterine incision. It is done in cases where vaginal delivery is not possible or can put maternal or fetal health or both at risk. Caesarean section (CS) is traditionally classified into elective and emergency. But spectrum of urgency that occurs in obstetrics is lost within a single 'emergency' category as some emergency caesarean sections are more urgent than others¹. And this broad classification limits its usefulness in terms of data comparison at local, national, international level and for the audit of obstetric and anaesthetic outcomes. Also, the

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degree of urgency in a particular case has to be understood by different teams involved in caesarean section like the obstetric, anaesthetic, paediatric and nursing teams to provide the required care for maternal and fetal well-being. So, the Royal College of Obstetricians and Gynaecologists (RCOG) and National Institute for Health and Care Excellence (NICE) guidelines classified caesarean sections into four categories based on the degree of urgency ^{2, 3}. Category 1 comprises cases with immediate threat to the life of woman or fetus; Category 2 comprises cases with fetal or maternal compromise with no immediate threat to life; Category 3 comprises cases without fetal or maternal compromise but requiring early delivery; and Category 4 comprises non-urgent or elective caesareans that can be planned to suit woman or health care provider ³. Historically, the standard adopted was to achieve decision to delivery interval (DDI) of 30 minutes for emergency CS to prevent adverse maternal or fetal outcomes. The National Institute for Health and Care Excellence (NICE) guidelines recommended that category 1 caesarean sections should be performed as soon as possible and in most situations within 30 minutes of making the decision and category 2 caesarean sections should also be performed as soon as possible and in most situations within 75 minutes of making the decisions about rapid birth as rapid birth can be harmful in certain circumstances ³.

This study was aimed to perform an audit of DDIs for emergency caesarean section at our rural tertiary health care centre and to compare our timings with the recommended DDIs and to analyse the impact of DDI on maternal and fetal outcomes. Factors related to patient, obstetrician, anaesthesiologist, staff and resource constraints, contributing to delay in DDI were also evaluated. Identifying these factors responsible for delay in decision to delivery interval will also enable in setting standards and clinical guidelines to provide optimal care to the patients.

Material and methods

This retrospective observational study was conducted in the Department of Obstetrics and Gynaecology at Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra over a period of 18 months from January 2015 to June 2016.

This study was done after obtaining institutional ethics committee approval and consent from patients was also taken for using their data from hospital files for research purpose only.

All the patients who got delivered by lower segment caesarean section from 1st January 2015 till 30th June 2016 and gave the consent to get enrolled in the study, were included the study. Patients who had not given the consent to get enrolled in the study and who underwent upper segment caesarean section were excluded from the study.

Data was retrieved from the hospital files during working hours within 24 hours of the caesarean section. And from files, the information was collected from the doctor's notes, partogram, operation theatre notes, anaesthetist's notes and paediatrician's notes.

Statistical analysis was done by using descriptive and inferential statistics using chi-square test and softwares used in the analysis were SPSS 17.0 version, EPI-INFO 6.0 version and GraphPad Prism 6.0. p – value <0.05 was considered as significant.

Results

Out of total 6908 deliveries conducted during the study period, 4360 were vaginal and 2548 were caesarean deliveries. Thus, the caesarean section rate (CSR) was 36.9%. Most of the patients i.e. 1150 (45.1%) who underwent CS were of age group 25-29 years. Out of total patients who underwent CS, 986 (38.7%) were referred from other health facilities. CSR was 70.8% among the referred patients while it was 28.3% among the booked ones. Among all the patients who had undergone CS, 1347 (52.9%) were nulliparous and 1201 (47.1%) were multiparous. As per the NICE guidelines, all CS were classified into four categories, based on the degree of urgency. Among the 2548 CS, 576 (22.6%) were of category 1, 984(38.6%) were of category 2, 723 (28.4%) were of category 3 and 265 (10.4%) were of category 4.

Most of the patients of category 1 CS i.e. 435 (75.5%) and category 2 CS i.e. 634 (64.4%) were nulliparous while among category 3 CS and category 4 CS, most of the patients were multiparous i.e.521 (72.1%) and 189 (71.3%)

respectively. This was because previous CS was most common indication for category 3 CS and category 4 CS. Most of the patients i.e. 1684 (66.1%) were of term gestation when they underwent the CS. Most of the CS i.e. 1746 (68.5%) were performed in emergency hours.

Among the category 1 CS, most common indication was fetal bradycardia i.e. in 412 (71.5%) patients. Other indications were placenta previa with active per vaginal bleeding in collapsed state in 39 (6.8%), abruptio placenta with maternal or fetal compromise or both in 68 (11.8%), cord prolapse in 19 (3.3%), obstructed labour in 22 (3.8%), previous caesarean section with imminent scar rupture in 11 (1.9%) and retained second twin in 5 (0.9%) patients.

Among the category 2 CS, most common indication was non-reassuring NST i.e. in 382 (38.8%) patients. Breech presentation in active phase of labour in 145 (14.7%) and previous scar with doubtful scar integrity in 141 (14.3%) patients were the next common indications.

Mean DDI for category 1 CS with indication of cord prolapse and obstructed labour was 28.52 minutes and 28.15 minutes respectively. While that for fetal bradycardia, it was 40.48 minutes. Among category 2 CS, maximum mean (70.39 minutes) DDI was for CS done for previous CS with doubtful scar integrity and was minimum (39.80 minutes) for deep transverse arrest. In some cases more than one reasons contributing to delay were there and in some cases delay at one stage was not necessarily followed by delay at other stages (table 1, 2, 3, 4, 5).

Table 1: Decision to delivery interval for category 1 and 2 caesarean sections			
Decision to delivery interval	Category 1	Category 2	Total
≤ 30 min	275(45.5%)	179(18.2%)	454(29.1%)
31-75 min	280(48.6%)	729(74.1%)	1009(64.7%)
>75 min	21(3.7%)	76(7.7%)	97(6.2%)
Total	576	984	1560
P - value = 0.0001, significant; Min: Minutes, CS: Caesarean section			

Table 2: Time interval from decision taken for CS to arrival of patient in operation theatre (OT) in; category 1 and 2 CS (interval 1)				
Decision to arrival in	n OT (interval 1)	Category 1	Category 2	Total
≤ 15min		227(39.4%)	289(29.4%)	785(50.3%)
16-30 min		300(52.1%)	490(49.8%)	584(37.4%)
>30 min		49(8.5%)	205(20.8%)	191(12.3%)
Total		576	984	1560
P - value = 0.042, significant; OT: Operation theatre, CS: Caesarean section, Min: Minutes.				

Table 3: Time interval from patient's arrival in operation theatre (OT) to delivery of baby in category 1 and category 2 CS (interval 2)			
OT arrival to delivery of baby (interval 2)	Category 1	Category 2	Total
≤15 min	144(25%)	149(15.1%)	486(31.1%)
16-30 min	405(70.3%)	537(54.6%)	689(53.7%)
31-75 min	27(4.7%)	298(30.3%)	385(22.6%)
Total	576	984	1560
P - value = 0.0012, significant; OT: Operation theatre; CS: Caesarean section; Min: Minutes.			

Table 4: Causes of delay in interval 1 in category 1 and 2 CS			
Causes of delay	Category 1 CS	Category 2 CS	Total
Delay in obtaining consent	102 (17.7%)	210 (21.3%)	312 (20%)
Delay in arranging blood	95 (16.5%)	194 (19.7%)	489 (31.3%)
Delay in preparing patient	42 (7.3%)	81 (8.2%)	123 (7.9%)
Non availability of OT table	61 (10.6%)	119 (12.1%)	180 (11.5%)
Ward assistant engaged	49 (8.5%)	91 (9.2%)	140 (9.0%)
Total	349 (60.6%)	695(70.6%)	1244 (79.7%)
CS: Caesarean section; OT: Operation theatre.			

Table 5: Causes of delay in interval 2 in category 1 and 2 CS			
Causes of delay	Category 1	Category 2	Total
OT assistant engaged	78 (13.5%)	123 (12.5%)	201 (12.9%)
Anaesthesia procedural delay	202 (35.1%)	457 (46.4%)	659 (42.2%)
Failed spinal converted to GA	3 (0.5%)	0	3 (0.2%)
Delay in extraction of baby due to adhesions	149 (25.9%)	255 (25.9%)	404 (25.9%)
Total	432 (75%)	835 (84.9%)	1267 (81.2%)
CS: Caesarean section; OT: Operation theatre; GA: General anaesthesia			

In present study, maternal morbidities noted were - spinal headache in 353 (13.9%), fever in 304 (11.9%), paralytic ileus in 293 (11.5%), wound infection in 225 (8.8%), acute respiratory distress syndrome in 18 (0.7%), sepsis in 19 (0.8%), pulmonary edema in 12 (0.5%), pulmonary embolism in 1 (0.04%) patient. Maternal mortality among all the patients who underwent CS was 0.03% i.e. in 8 patients. Causes of death were - medical causes in 3 (37.5%), hypertensive disorders in pregnancy in 2 (25%), sepsis in 2 (25%) and pulmonary embolism in 1 (12.5%).

Out of total 2548 CS, neonates born were 2577 as 29 were twin CS deliveries. Fetal bradycardia in 8(47.1%) and antepartum haemorrhage in 5 (29.4%) patients were the most common indications for CS in neonates with APGAR score less than 4. Also, in neonates with APGAR score 5-7, common indications were fetal bradycardia in 79 (33.1%) and antepartum haemorrhage in 51 (21.3%) patients.

Out of 2577 neonates, 433 (16.8%) got admitted in NICU during their hospital stay. Out of those 433 neonates, 256 (59.1%) got admitted at birth, 110 (25.4%) within 24 hours of birth and 67 (15.5%) got admitted after 24 hours of birth.

Neonatal morbidities requiring NICU admission were - meconium aspiration syndrome in 70 (16.2%), respiratory distress syndrome in 36 (8.3%), seizures in 43 (9.9%), sepsis in 98(22.6%), hyperbilirubinemia in 37 (8.5%), transient tachypnea of newborn in 26 (6.0%), hypoglycemia in 39(9%), hypoxic ischemic encephalopathy in 43(9.9%), intracranial hemorrhage in 7 (1.6%), disseminated intravascular coagulopathy in 34 (7.9%) neonates. Most common indication of category 1 CS was fetal bradycardia (406) and among those, 100 (24.6%) neonates had moderate to severe birth asphyxia. Most common indication of category 2 CS was non-reassuring NST (382) and among those, 40 (10.5%) neonates had moderate to severe birth asphyxia.

Table 6: Relationship between decision to delivery interval and APGAR score at 1 min and 5 min				
Decision to delivery interval	APGAR score <4 among category 1 CS (576)	APGAR score <4 among category 2 CS (984)	APGAR score 5- 7among category1 CS (576)	
<30 min	8 (1.4%)	1 (0.1%)	80 (13.9%)	12 (1.2%)
31-75 min	6 (1%)	2 (0.2%)	52 (9%)	43 (4.4%)
>75 min	0	0	8+2* (1.4%)	32+10 (3.3%)
Total	14 (2.4%)	3 (0.3%)	140+2* (24.3%)	87+10* (8.8%)
P - value > 0.05, not significant; Min: Minutes; CS: Caesarean Section; *Twin				

Neonatal mortality out of all the neonates born by caesarean section was 1.5% (38). Among those 38 neonates, 17(0.7%) were delivered by category 1 CS, 18 (0.7%) by category 2 CS, 2(0.08%) by category 3 CS and 1 (0.04%) by category 4 CS.

Discussion

Caesarean section rate (CSR) in our rural tertiary health care centre was 36.88% during the study period. This rate is higher than the WHO recommended rate of 10 to 15 percent ⁴. Our hospital is a referral centre. So, higher caesarean section rate in our centre may be because we get high risk referrals from nearby hospitals.

Most of the caesarean sections performed during study period were of emergency, of category 1 (22.62%) and 2 (38.61%) as compared to elective of category 3 (28.37%) and 4 (10.40%). Our results were comparable with the other studies 5,6 .

Fetal bradycardia was the most common indication of category 1 CS (70.49%). Similar result was seen in a study done by Naeem M et al⁵. However, in a study done by Kathyryn et al, obstructed labour was most common indication of caesarean section ⁷. Also, in a study done by Barber et al, dystocia followed by fetal distress were most common indications of CS⁸. In present study, only 22 (3.8%) CS were done for obstructed labour. This may be because of continuous electronic fetal monitoring which is associated with greater likelihood of CS.

In our centre, mean DDI for category 1 CS was 38.40 minutes which is more than the recommended 30 minutes. However, for category 2 CS, mean DDI was 45.62 minutes which is within the recommended <75 minutes. Among the category 1 CS, in 45.49% patients recommended 30 minutes. DDI was achieved and among category 2 CS, in 92.28% patients DDI was within 75 minutes. However, the results of our study were better than similar studies done in Nigerian centers which reported mean DDI of 200 minutes and 252 minutes ^{9, 10}. Similar studies, done in Europe, have reported mean DDI of 39.5 minutes and 52.4 minutes ^{11, 12}. This huge difference in DDI in those studies may be because of improved facilities, more effective co-ordination of services in developed countries and infrastructure challenges, more patient load, lesser manpower in developing countries which holds true for our study also. Some studies had shown that the current recommendation of 30 minutes interval is difficult to achieve in practice ^{13, 14}. Hence, in the guidelines for perinatal care published jointly by the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics, it was agreed that hospitals should have the capability of accomplishing the delivery of baby within 30 minutes of taking the decision for CS. But this timing should take into consideration the maternal, fetal risks and benefits and hence the DDI should be acceptable based on local circumstances and logistics ¹⁵.

In present study, it was found that the delay in DDI was mainly due to the delay in obtaining consent, arranging blood and anaesthesia procedural delay. Similar results were found in other studies ^{16, 17}. Many other factors which influenced the DDI were – patient preparation before shifting to OT, non-availability of OT table as during elective hours sometimes OT table was not available due to ongoing elective surgeries and during emergency hours because of lined up patients for CS due to increased referrals, ward or OT assistant engaged in some other work, failed spinal anaesthesia converting to general anaesthesia, intraoperative adhesions. Overall, this obvious delay poses a potential risk of litigations in the event of poor feto-maternal outcomes. Delay in shifting the patient to OT emphasizes the need of adequate manpower in labour room. In some studies, it had been seen that anaesthesia procedural time and baby extraction time depends on the seniority of anesthetist and obstetrician also ^{11, 17}. So, in tertiary health care centres attached to teaching medical college, like ours, atleast for category 1 and 2 CS consultants should supervise the procedure. To some extent DDI also depends on the perception of degree of urgency in the same way by all the members of the healthcare team. For this, categorization of every CS and the sensitization of each member is important.

Mean DDI for category 1 CS with indication of cord prolapse and obstructed labour was 28.52 minutes and 28.14 minutes respectively while that for fetal bradycardia, it was 40.48 min. Our study results were comparable with the results of other studies ^{18, 19}. Among category 2 CS, maximum mean (70.39 minutes) DDI was reported for CS done for previous CS with doubtful scar integrity and minimum (39.80 minutes) for deep transverse arrest. This may be because of intraoperative adhesions in previous CS patients.

In the present study, most common postoperatively maternal morbidity found was postdural puncture headache (13.85%). A study, done by Hassan Ali et al, also found postdural puncture headache in 32.58% cases after spinal anesthesia for caesarean sections ²⁰. A study, by Liu et al, reported 2.7% anaesthesia complications in caesarean sections ²¹. Other common morbidity noted in our study was fever, in 11.93% patients which was less as compared to that noted in the study done by Jakobi et al²².

Maternal mortality among all the patients who underwent caesarean section was 0.03%. Most of the deaths (37.5%) among those were due to medical factors. Maternal mortality rate in current study was lower as compared to the study done in Tikur Anbesa (1.6%) and Jimma in Ethiopia $(0.4\%)^{23,24}$.

Relationship between DDI and APGAR score was analyzed (table 6). It showed that among category 1 CS, APGAR score at 1 minute and 5 minutes was not significantly different between CS with DDI≤30 minutes and those with DDI>30 minutes (p- value>0.05). Also, among category 2 CS, APGAR score at 1 minutes and 5 minutes was not significantly different between CS with DDI≤75 minutes and those with DDI>75 minutes (p- value>0.05). This may be because the fetuses were already in a state of irreversible distress. Similar results were found in a study done by Onah et al⁹.

In the present study, it was observed that neonatal mortality out of all the neonates born by caesarean section was 1.5%. And maximum mortality was among the neonates born by emergency CS i.e. category 1 CS (0.7%) and category 2 CS (0.7%) as compared to elective CS i.e. category 3 CS (0.08%) and category 4 CS (0.04%). Similar findings were observed in a study done by Benzouina and Muhammad et al ^{25, 26}.

Conclusion

The present study concluded that it was difficult to achieve recommended DDI in every category 1 and 2 CS. Most important factors contributing to delay were obtaining consent from patient's relatives, arranging blood and anaesthesia procedural related factors. Neonatal and maternal outcomes were not significantly different between CS which were done within the recommended DDI and those which took more than recommended DDI. This suggests that DDI should be considered as one of the important contributing factors but not the sole factor in determining maternal and neonatal outcomes in emergency caesarean sections. It is not an indispensable measure to prevent neonatal morbidity and mortality. But as observed in this study, DDI of 30 minutes was not unachievable in cases of urgent indications like cord prolapse. Hence, it is necessary for each emergency obstetric unit to effectively triage the emergency CS and develop the capabilities of commencing such cases as soon as possible.

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