

Respiratory Morbidity in Term Infants delivered by Elective Cesarean Section at a Tertiary Care Hospital in India: A Randomized Controlled Trial

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ABSTRACT

Objectives: (1) To investigate the association between term elective cesarean sections and neonatal respiratory morbidity and the importance of timing of the cesarean. (2) To assess the maternal morbidity when emergency lower segment cesarean section (LSCS) was required.

Participants: All women with singleton term (37–41 + 6 weeks) pregnancies and planned for elective cesarean section in Christian Medical College, Vellore, India.

Outcome measures: The primary outcome measures were neonatal morbidities such as transient tachypnea of newborn (TTN) and respiratory distress syndrome (RDS). The secondary outcome measures were emergency cesarean section and maternal morbidities such as scar dehiscence, urinary tract infection (UTI), endometritis, peritonitis, and hemoperitoneum in the mother.

Results: The percentage of TTN in the infants in group I was 1.3% while there were none in group II. No infants were diagnosed to have RDS. Out of the 150 women who were planned for elective cesarean section, 55 women underwent emergency cesarean section. Among this, 19 (25.3%) of women were from group I as compared with 36 (48.0%) in group II. The difference in proportion between the two groups was -22.7 [95% confidence interval (CI): -37.7 , -7.7], which was statistically significant ($p < 0.01$). The incidence of scar dehiscence, UTI, endometritis, and hemoperitoneum in the mothers of group II was marginally higher than that in the mothers of group I. There was one woman with peritonitis in group I while none was reported in the other group. All the maternal morbidities occurred to women who underwent emergency cesarean section. Out of the 19 women in group I and 36 women in group II who underwent emergency cesarean section, 1 (5.3%) and 6 (16.7%) women had morbidities.

Conclusion: Women requiring elective cesarean section can safely be done between 37 and 39 weeks with no further significant increase in the rates of neonatal morbidity such as TTN and RDS.

Keywords: Elective cesarean section, Emergency cesarean section, Maternal morbidity, Neonatal morbidity.

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INTRODUCTION

Deliveries by cesarean section continue to increase in both developed and developing countries. Cesarean section used to be carried out primarily because of obstetric complications or serious maternal illness.¹⁻³ Lately, many other factors, such as reduced risk to the mother as a result of improved anesthetic procedures and surgical techniques, have increased the rates of elective cesarean sections without any obvious or generally accepted medical or obstetric indication.⁴⁻⁷ If no indication is present, evidence-based information about risks and benefits for mothers as well as newborns becomes all the more important for adequate counseling, and planned LSCS is usually performed at 39 weeks.⁸

The movement to perform a cesarean delivery in the absence of a medical indication has been building for over a decade. Brazil was one of the first countries where cesarean delivery on request became popular;⁹ ethicists have proposed that cesarean delivery is a woman's right,¹⁰ and cesarean delivery has most recently been publicized as a way to avoid incontinence and uterine prolapse problems. Consequently, more physicians and patients today believe that cesarean delivery is a fast, safe, and convenient way to have a baby. The problem is that most of this is opinion-based rather than evidence-based. This wave of enthusiasm is suspiciously similar to early campaigns

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for continuous electronic fetal monitoring, tocolysis to prevent preterm birth, and mandatory trial of labor.

According to the American College of Obstetricians and Gynecologists recommendations in 2013,¹¹ cesarean delivery on maternal request or planned cesarean delivery should not be performed before a gestational age of 39 weeks. Cesarean delivery on maternal request particularly is not recommended for women desiring several children, given that the risks of placenta previa, placenta accreta, and gravid hysterectomy increase with each cesarean delivery.

Previous studies have shown elective cesarean section to be associated with an increased risk of respiratory morbidity in neonates.¹² It is plausible that hormonal and physiological changes associated with labor are necessary for lung maturation in neonates and that these changes may not occur in infants delivered by elective cesarean sections.¹³⁻¹⁸ Gestational age at the time of elective cesarean section may also be important for respiratory morbidity in neonates.^{19,20}

This study aimed at investigating the association between elective cesarean sections and neonatal respiratory morbidity such as TTN and RDS and the importance of timing of elective cesarean sections. Maternal morbidity was also taken into consideration depending on whether the pregnant woman underwent elective or emergency cesarean section.

MATERIALS AND METHODS

All eligible pregnant women based on the inclusion criteria were enrolled into the study at 35 to 36 weeks after informed consent and randomized into either group I (37–38 + 6 weeks) or group II (39–41 + 6 weeks) and planned for elective cesarean section based on the randomization.

The primary objective of the study was to correlate the association between elective cesarean sections and neonatal respiratory morbidity (TTN, RDS) with relation to the timing of elective cesarean sections. The secondary objective of the study was to investigate into the number and morbidity of patients planned for elective cesarean section but who underwent emergency cesarean section.

Study Design

The study was a randomized controlled study.

Study Population

All women with singleton term pregnancies, fulfilling the inclusion criteria and planned for elective cesarean section (gestational ages between 37 and 41 + 6 weeks) in Christian Medical College, Vellore, India, were enrolled for the study.

Inclusion Criteria

- All women with singleton babies
- Gestational age between 37 and 41 + 6 weeks
- Planned for elective cesarean section
- Sure of their last menstrual period with regular cycles or have their gestational age confirmed by ultrasonography
- With or without any complications such as pregnancy-induced hypertension (PIH), malpresentations, pre-gestational diabetes/gestational diabetes mellitus with controlled sugars, and previous cesarean section.

Exclusion Criteria

- Preterm babies
- Multiple pregnancies
- Antepartum hemorrhage/placenta previa
- Previous two cesarean sections
- Intrauterine growth restriction.

Study Period

Two years.

Approval

The study was approved by the Institutional Review Board. All the patients gave written informed consent.

Sample Size Calculation

The incidence of respiratory morbidity was reported to be 10% in the 37 to 38 + 6-week elective cesarean section group, while this was only 2.1% in the 39 to 41 + 6-week elective cesarean section group.

Since the difference in both groups was 0, by a pilot study done here in Christian Medical College, Vellore, India, sample was calculated for an alpha error of 5% and beta error of 20%. The sample size finally obtained was 150. Nearly 75 women were randomized into each group (groups I and II).

Randomization was done using blocks of 2, 4, and 6 with 30, 30, and 40% respectively. The SAS (version 9.2) software was used to generate randomization codes. The difference in the incidence of respiratory morbidity between the two groups was computed. The 95% CI for the difference was computed using approximate method (Agresti REF). The data were analyzed using Statistical Package for the Social Sciences software.

The antenatal folders were marked specifically for identification of the patients. The baseline characteristics such as age, body mass index (BMI), parity, and gestational age were noted. The women were randomized to one of two groups I or II for the timing of the elective LSCS. Since the elective theater list was only once a week, the women were given a date closest to the elective theater date.

For the sake of analysis, deliveries were categorized into five groups: (a) Elective cesarean section at 37 to 38 + 6 weeks, (b) elective cesarean section at 39 to 41 + 6 weeks, (c) intended elective cesarean section at 39+ weeks but underwent emergency cesarean section before 39 weeks, (d) intended elective cesarean section at 39+ weeks but underwent emergency cesarean section at 39 weeks, and (e) intended elective cesarean section between 37 and 38 + 6 weeks but underwent emergency cesarean section at 39 + weeks.

Analysis though was done as per categorization into only two groups: (a) Elective cesarean section at 37 to 38 + 6 weeks and (b) elective cesarean section at 39 to 41 + 6 weeks. This was done by intention to treat analysis.

The diagnosis of neonatal respiratory morbidity was established from the case sheets and discharge cards of the Department of Neonatology, Christian Medical College, Vellore, India. Babies requiring treatment for 3 or more days with continuous oxygen supplementation, nasal continuous positive airway pressure, or any period of mechanical ventilation were treated as respiratory morbidity.

The primary outcome measures were neonatal morbidities such as TTN and RDS. The secondary outcome measures were emergency cesarean section and maternal morbidities such as scar dehiscence, UTI, endometritis, peritonitis, and hemoperitoneum in the mother.

Definitions

Transient tachypnea of newborn is a self-limited disease commonly seen in neonates throughout the world within the first few hours of life with tachypnea and other signs of respiratory distress and increased oxygen requirement. Respiratory distress syndrome of newborn is a syndrome in premature infants caused by developmental insufficiency of surfactant production and structural immaturity in the lungs.

Uterine scar dehiscence is defined as full-thickness disruption of the uterine wall which does not involve the overlying visceral peritoneum (uterine serosa). Urinary tract infection is an infection in any part of the urinary system: kidneys, ureters, bladder, and urethra. Endometritis is an inflammatory condition of the endometrium or decidua, with extension into the myometrium and parametrium. An inflammation of the peritoneum, the tissue that lines the inner wall of the abdomen, is called peritonitis.

RESULTS

The baseline characteristics of the 150 women who had cesarean section in groups I and II are presented in Table 1. The risk factors of all the women included in the study are presented in Table 2 as per their groups.

The mean (standard deviation, SD) of age of patients enrolled for the study was 27.8 (4.8) and 28 (4.5) years in

Table 1: The distribution of baseline characteristics by study groups: group I (37–38 + 6 weeks) or group II (39–41 + 6 weeks)

Characteristics	Group I		Group II	
	Mean	SD	Mean	SD
Age (years)	27.8	4.8	28.0	4.5
Body mass index	25.1	4.0	25.6	6.1

SD: Standard deviation

Table 2: The distribution of risk factors in pregnancy by study groups: group I (37–38 + 6 weeks) or group II (39–41 + 6 weeks)

Risk factors in pregnancy	Group I		Group II	
	No.	%	No.	%
Hypertension	2	2.6	3	4.0
Diabetes mellitus (well controlled)	2	2.6	1	1.3
Malpresentations	8	10.6	12	16.0
Previous LSCS	63	84.2	59	78.7

groups I and II respectively. The mean (SD) of BMI of the two groups was 25.1 (4) and 25.6 (6.1) in groups I and II respectively. The number of hypertensives in group I was 2 (2.6%) as compared with 3 (4%) in group II, and diabetes mellitus was 2 (2.6%) in group I and 1 (1.3) in group II. In group I, there were 8 (10.6%) malpresentations as compared with 12 (16%) in group II. The major indication for elective cesarean section in our study was previous cesarean section which was 63 (84.2%) in group I as compared with 59 (78.7%) in group II.

The results of primary and secondary outcomes are presented in Table 3.

The percentage of TTN in the infants in group I was 1.3% while there were none in group II. The difference in the proportion of infants with TTN between the two groups was 1.3 (95% CI: -1.3, 3.9). In our study, none of the infants had RDS. The infant who was diagnosed to have TTN was born by emergency cesarean section.

Out of all the 150 women posted for elective cesarean section, 55 women underwent emergency cesarean section. Among this, 19 (25.3%) of women were from group I as compared with 36 (48.0%) in group II. The difference in proportion between the two groups was -22.7 (95% CI: -37.7, -7.7), which was statistically significant (p < 0.01). None of the women had maternal morbidities such as scar dehiscence, UTI, endometritis, and hemoperitoneum in group I while there was one woman each with scar dehiscence and endometritis and two women each with UTI and hemoperitoneum in group II. Hence, the incidence of scar dehiscence, UTI, endometritis, and hemoperitoneum in the mothers of group II was marginally higher than that in the mothers of group I. There was one woman with peritonitis in group I while none was reported in the other group. The difference in proportion of women with scar dehiscence was -1.3 (-3.9, 1.3), UTI was -2.7 (-6.3, 1.0), endometritis was -1.3 (-3.9, 1.3), peritonitis was 1.3 (-1.3, 3.9), and hemoperitoneum was



Table 3: The comparison of incidence of respiratory morbidity among infants and maternal morbidities among pregnant women by groups: group I (37–38 + 6 weeks) or group II (39–41 + 6 weeks)

Outcome Measures	Group I (n = 75)	Group II (n = 75)	Difference (95% CI)	p-value
	n (%)	n (%)		
Primary outcomes				
<i>Respiratory morbidity</i>				
TTN	1 (1.3)	0 (0)	1.3 (-1.3, 3.9)	0.3
RDS	0 (0)	0 (0)	–	–
Secondary outcomes				
Emergency LSCS	19 (25.3)	36 (48.0)	-22.7 (-37.7, -7.7)	<0.01
<i>Maternal morbidity</i>				
Scar dehiscence	0 (0)	1 (1.3)	-1.3 (-3.9, 1.3)	0.3
UTI	0 (0)	2 (2.7)	-2.7 (-6.3, 1.0)	0.2
Endometritis	0 (0)	1 (1.3)	-1.3 (-3.9, 1.3)	0.3
Peritonitis	1 (1.3)	0 (0)	1.3 (-1.3, 3.9)	0.3
Hemoperitoneum	0 (0)	2 (2.7)	-2.7 (-6.3, 1.0)	0.2

-2.7 (-6.3, 1.0). No statistical significant difference was observed in the maternal morbidities between the two groups.

In our study, all the maternal morbidities occurred in women who underwent emergency cesarean section. Out of the 19 women in group I and 36 women in group II undergoing emergency cesarean section, 1 (5.3%) and 6 (16.7%) women had morbidities respectively.

DISCUSSION

The risk of neonatal respiratory morbidity after elective cesarean section in singletons born at Christian Medical College Hospital, Vellore, India, was 1.3% in the infants in group I while there were none in group II. No infants were diagnosed to have RDS. Among term deliveries, there was no major association between elective cesarean section and respiratory morbidity by gestational age. This was not consistent with the conclusion in the study by Hansen et al,¹² which stated that elective cesarean sections at 37 weeks of gestational age have more association of respiratory morbidity than cesarean sections performed later.

Out of the 150 women posted for elective cesarean section, 55 women underwent emergency cesarean section. Among this, 19 women were from group I and 36 women were from group II. The difference in proportion between the two groups was statistically significant. Similar results were noted in the study conducted by Althabe and Belizán²¹ and MacDorman et al.²²

The incidence of scar dehiscence, UTI, endometritis, and hemoperitoneum in the women of group II was higher than that in the women of group I. This was consistent with the conclusion in the study by Lumbiganon et al,²³ which stated that emergency cesarean sections have higher incidence of maternal morbidity.

A study by D'Souza and Arulkumaran,²⁴ observed that requests for cesarean delivery in the absence of

medical indications were increasingly being encountered in clinical practice worldwide, and cesarean delivery on maternal request (CDMR) is posing a medical, financial, and ethical dilemma. They also stated that, to avoid neonatal respiratory complications and iatrogenic prematurity, CDMR should not be performed prior to 39 weeks of gestation unless there was documentation of fetal lung maturity. Our study proved that, though cesarean sections were performed from 37 to 38 + 6 weeks, there was no increase in neonatal morbidity and mortality.

A previous large cohort study by Morrison et al¹⁹ aimed to establish whether timing of delivery by elective cesarean section between 37 and 42 weeks of gestation influenced respiratory morbidity in neonates. The inference in the study was that respiratory morbidity was found to be a little higher in the 37 to 38 + 6-week group, which is contrary to the inference of the present study.

All the maternal morbidities occurred to women who underwent emergency cesarean section. One woman in group I and 6 women in group II had morbidities. This result was seen in similar studies done in various populations.^{25,26}

All other studies on this subject failed to take gestational age into consideration while comparing maternal morbidities associated with the LSCS.¹²

IMPLICATIONS

Even when elective cesarean section was carried out at 39 completed weeks of gestation, an increased risk of respiratory morbidity remained evident in a few studies.¹⁹ Lack of hormones associated with labor could explain this association.^{27,28} This may also be mediated by a raised level of catecholamines in the fetus.¹³⁻¹⁶ When cesarean sections were carried out before labor, this catecholamine surge was absent.^{17,18}

Stutchfield et al²⁹ suggested that giving corticosteroids during the antenatal period to women who deliver by

elective cesarean section might reduce neonatal respiratory morbidity. This was tested in a randomized controlled trial, which showed that betamethasone given during the antenatal period reduced neonatal respiratory morbidity.²⁹ The long-term safety of antenatal steroid administration is, however, still being debated.³⁰

Carrying out elective cesarean sections at greater gestational ages (39 to 41 + 6 weeks), however, results in higher rates of emergency cesarean sections because some women would go into spontaneous labor, especially in the Asian population.³¹ Compared with elective cesarean sections, emergency cesarean sections may carry an increased risk of complications such as uterine rupture in women with previous cesarean section, infections such as endometritis and UTIs, or even maternal mortality.²⁵ In addition, personnel and operation theaters have to be geared up for more emergency LSCS, if the policy of elective LSCS at 39 weeks is routinely carried out.³²

CONCLUSION

Newborns delivered by cesarean section at 37 to 38 + 6 weeks of gestational age had no increased risk factors of developing respiratory morbidities such as TTN or RDS in comparison with newborns delivered at 39 to 41 + 6 weeks of gestational age. The rates of emergency cesarean section as well as maternal morbidities were considerably more when women were posted for elective cesarean section beyond 39 weeks. Thus, it can be concluded that women requiring elective cesarean section can safely undergo the procedure between 37 and 38 + 6 weeks with no further increase in the rates of neonatal morbidity, though, more evidence-based information on the effect of timing and cesarean section in labor is required with randomized controlled trials performed on larger populations.

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