Outcomes of Elective Induction of Labor Compared with Expectant Management in Nulliparous Women with Unfavorable Cervix

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ABSTRACT

Objectives: The purpose of this study was to test the association between elective induction of labor and cesarean delivery and to determine maternal and neonatal outcomes in elective induction of labor.

Materials and methods: We conducted a retrospective matched cohort study in a tertiary care hospital from January 2014 to December 2015, among 182 nulliparous women at gestational age of $39^{0/7}$ weeks or more who had single live pregnancy with known cervical status of ≤ 5 at $38^{0/7}$ to $38^{6/7}$ weeks and were managed either by elective induction or expectant management. Data were compared using χ^2 and Student's *t*-test, and p < 0.05 was considered significant.

Results: The cesarean delivery rate was 51% in expectant and 46.8% in elective induction group, which was not much different. Women who were electively induced spent more time in labor delivery unit (14 hours, 21 minutes vs 12 hours, 45 minutes, p < 0.01), had labor longer than 12 hours (50 vs 36.5%, p = 0.05), received more frequently oxytocin (63.5 vs 47.9%, p = 0.03), and were more likely to deliver during daytime between 6.00 am and 6.00 pm (64.5 vs 52%, p = 0.07) compared with expectant group. There were no difference with regard to obstetric events and maternal neonatal outcomes.

Conclusion: Elective induction did not result in increased risk of cesarean delivery in nulliparous women with unfavorable cervix. It is relatively safe as we had observed no evidence of any other increased adverse maternal or neonatal outcomes with elective induction.

Keywords: Cesarean section, Induction, Labor, Nulliparous, Outcomes.

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INTRODUCTION

Induction of labor is one of the most commonly performed obstetric procedures and it is undertaken when the benefits of expeditious delivery to either mother or fetus outweigh the risk of continuing the pregnancy.¹ There are many accepted absolute and relative medical and obstetric indications for labor induction. Indications for induction of labor have included preeclampsia/ eclampsia and other hypertensive disorders, maternal diabetes mellitus, premature rupture of membranes, chorioamnionitis, intrauterine fetal growth restriction, oligohydramnios, isoimmunization, fetal demise, and postterm pregnancy.¹ Elective induction of labor refers to the initiation of labor for the convenience of patient and physician, in an individual with a term pregnancy who is free of medical or obstetric indications. It has its pros and cons, it avoids adverse outcomes like impending postterm, unexplained term fetal demise, allows daytime deliveries with better intrapartum and perinatal care, convenient for employed pregnant women. There is a widespread belief that it is an unnatural process, once this intervention is started it can have major effects on the birth experiences of women, such as an increased risk of emergency cesarean delivery or assisted vaginal delivery.²

Multiple studies that have compared elective induction to spontaneous labor in nulliparous women have shown conflicting results. Some observational studies have shown results of increased rate of cesarean delivery. Some observational studies and randomized control trials done for elective induction of labor to expectant management of pregnancy have shown a similar or lower rate of cesarean delivery in electively induced group. Moreover, in some studies the magnitude of identified differences was not quantified, and in some the study samples were not homogeneous.

The purpose of this study was to test the association between elective induction of labor and cesarean delivery, and to determine any difference in maternal and fetal outcomes in elective induction of labor and expectant management among nulliparous women with unfavorable cervix at term pregnancy.

MATERIALS AND METHODS

We conducted a retrospective matched cohort study of nulliparous women with an unfavorable cervix who were either electively induced or expectantly managed at term in a tertiary care hospital. The study was conducted from January 2014 to December 2015. The study population consisted of 182 nulliparous women at gestational age of 39^{0/7} weeks or more, who had single live pregnancy with vertex presentation, with known cervical status of ≤ 5 at $38^{0/7}$ to $38^{6/7}$ weeks with modified Bishop score. They were managed either by elective labor induction or expectant management. Women undergoing induction of labor for medical, obstetric, or nonmedical indication before 39^{0/7} weeks of gestation and women undergoing cesarean delivery without labor induction were excluded from the study. The duration of the study period was chosen to yield the appropriate sample size based on our frequency of labor induction as followed in our institute. Keeping the power as 80% and two-sided significance of 0.05, rate of sample size elective to expectant one, and to detect an increase in cesarean delivery rate of 20% in the expectantly managed group to 40% in the electively induced group, 182 participants were required for analysis, which was divided equally in two groups.

We obtained data from the labor ward parturition register, computer records, and retrieving clinical notes from medical records section of our institute. Women induced for nonmedical indications like impending postterm pregnancy between $39^{0/7}$ to $40^{5/7}$, psychosocial reasons, clinically decreased amniotic fluid index (but AFI >5), suspected macrosomia (but estimated fetal weight by sonography <4 kg), complaining of decreased fetal movement [but nonstress test (NST) reactive] were included in electively induced group. We had included 96 participants in this group. Each admission history and physical examination was reviewed; women with modified Bishop score ≤ 5 on admission were included in this group.

A control group was chosen from all women meeting the inclusion criteria who delivered during the selected study period. These women were eligible for the control group if they had reached $39^{0/7}$ weeks and were expectantly managed. The group included patients who experienced spontaneous labor onset or induced for obstetric indications like oligohydramnios, prolong pregnancy at $40^{6/7}$ or ≥ 41 weeks (American College of Obstetricians and Gynecologists), term prelabor rupture of membrane, atypical NST, gestational hypertension, gestational diabetes, and prolong latent phase. As per institutional protocol, women at term were routinely followed up at weekly intervals for antenatal care, and cervical examination data between $38^{0/7}$ and $38^{6/7}$ weeks of gestation were reviewed from medical records. Women with modified Bishop score of ≤ 5 were randomly selected using a computer-generated random number table and were included in the control group.

We recorded the primary outcome, i.e., cesarean delivery rate, and maternal outcomes like postpartum hemorrhage, perineal tears, and cervical tear were assessed. Neonatal outcomes like birth weight, APGAR <7, neonatal intensive care unit (NICU) admission, perinatal mortality, and obstetric outcomes like time of delivery, length of labor (admission to labor ward and delivery unit to time of delivery) from nurses record notes, labor longer than 12 hours, daytime delivery, and augmentation by oxytocin were also noted.

Categorical data were compared using χ^2 or Fisher's exact test where appropriate. Continuous variables between the groups were compared using Student's *t*-test or Mann–Whitney U-test where appropriate, and p < 0.05 was considered significant. Significant differences between the groups were quantified by calculating the odds ratios (ORs) and 95% confidence intervals (CIs).

RESULTS

During the study, a total of 96 nulliparous women with unfavorable cervix having a Bishop score of ≤5 were taken in elective induction group and they were compared with 96 nulliparous women with unfavorable cervix having Bishop score of ≤ 5 who delivered following expectant management. The minimum age was 20 years and the maximum age 35 years in both groups. Women electively induced are between 273 days to 245 days and women having expectant management are between 273 days to 293days of gestation The elective induction and expectant management groups were similar with respect to age, ethnicity (belonging to South Indian population) except that the expectant group were more likely to be delivered at a later gestational age (281.4 ± 3.57 days) compared with electively induced group $(278.9 \pm 4.27 \text{ days})$, p < 0.0003 (Table 1).

Table 1: Characteristics of study population

	Expectantly managed (n = 96)	Electively induced (n = 96)	p-value
Age (years)	23.6 ± 3.28	23.9 ± 3.45	0.53
delivery (days)	201.4 ± 3.37	210.9 ± 4.21	0.0003

Age in years and gestational age at delivery in days of study population are shown. The minimum age was 20 years and the maximum age 35 years in both groups. Women electively induced are between 273 and 245 days, and women having expectant management are between 273 and 293 days of gestation; *Significant (p < 0.05)

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Table 2:	Obstetric	outcomes of	of study	y po	pulation
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	Expectantly managed (n = 96)	Electively induced (n = 96)	OR (95% CI)	p- value
Mode of delivery				
SVD	41 (42.7)	49 (51.04)	1.1 (0.6–2.0)	0.56
Instrumental	6 (6.25)	2 (2.08)		0.14
Cesarean	49 (51.04)	45 (46.8)	0.8 (0.4–1.4)	0.56
Hours in labor and delivery unit	12.5 ± 4.47	14.2 ± 5.12		0.01*
Mean ± SD	(7.5–17.3)	(9.9–19.3)		
Labor > 12 hr	35 (36.5)	48 (50)	1.7 (0.9–3.1)	0.05
Oxytocin use	46 (47.9)	61 (63.5)	1.8 (1.06–3.3)	0.03*
Daytime delivery between 6.00 am and 6.00 pm	50 (52)	62 (64.5)	1.6 (0.9–2.9)	0.07

*Significant, values are given in n (%); SD: Standard deviation; SVD: Spontaneous vaginal delivery

Comparison of obstetric outcomes between two groups is shown. No significant differences were observed in different modes of delivery between the groups. Labor characteristics were significantly different between the two groups. The 95% CI for mean hours in labor delivery unit was 7.5 to 17.3 hours in expectant group and 9.9 to 19.3 hours in elective group

The frequency of cesarean delivery was 51% (49/96) in expectant and 46.8% (45/96) in elective induction group. The rate of cesarean delivery was not much different between the groups. Women who were expectantly managed, 28.1% delivered between 39^{0/7} and 39^{6/7} weeks of gestation, 62.5% delivered between $40^{0/7}$ and $40^{6/7}$ weeks of gestation, and 9.3% delivered between 41^{0/7} and 42 weeks of gestation. Labor induction was required in 57.2%, and 42.7% came with spontaneous onset of labor. There were no expectantly managed women who required cesarean delivery without labor. The most common reasons of labor induction was prelabor rupture of membrane (21.8%), followed by oligohydramnios (14.5%), postdates (9.3%), gestational hypertension (6.25%), and gestational diabetes (6.25%). Labor characteristics were significantly different between the two groups. Women who were electively induced spent more time in labor delivery unit (12 hours, 45 minutes vs 14 hours, 21 minutes, p<0.01). The 95% confidence interval for mean hours in labor delivery unit was 7.5 to 17.3 hours in expectant group and 9.9 to 19.3 hours in elective group. Among electively induced group, 50% women had labor longer than 12 hours compared with 36.5% women in expectant group (50 vs 36.5%, p = 0.05). Electively induced women received oxytocin more frequently as compared with expectantly managed group (63.5 vs 47.9%, p = 0.03). Electively induced women also were more likely to deliver during daytime between 6.00 am and 6.00 pm (64.5 vs 52%, p = 0.07) (Table 2). There were no difference with regard to obstetric events and complications (Table 3).

Table 3: Maternal outcomes in study population				
	Expectantly managed (n = 96)	Electively induced (n = 96)	p-value	
Perineal injury	1 (2.1)	1 (1.9)	0.97	
Postpartum hemorrhage	3 (3.1)	2 (2)	0.62	
Intrapartum fever	2 (2)	4 (4.1)	0.39	

Values are given as n (%)

Comparisons of maternal outcomes between two groups are shown. Maternal outcomes were similar between the groups

Table 4: Fetal	outcomes in	study po	pulation
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	Expectantly managed (n = 96)	Electively induced (n = 96)	p-value
NICU admission	9 (9.3)	13 (13.5)	0.36
Birth weight (kg)	3 ± 0.41	2.9 ± 0.34	0.06
Apgar score less than 7 at 5 min	4 (4.1)	5 (5.2)	0.73
Thick meconium present	5 (5.2)	7 (7.2)	0.52
Stillbirth	0	1	0.32
Early neonatal death	1	0	0.32

Comparison of neonatal outcome and birth weight (kg) is shown. Neonatal outcomes were similar between the groups. There was one early neonatal death of anomalous baby in expectant group and one baby was stillbirth due to birth asphyxia in elective group. A minimum birth weight was 2 kg and the maximum was 4.5 kg in both the groups. There was no difference in the mean birth weight

Neonatal outcomes were also similar between the groups. There were no differences in NICU admission and mean birth weight between the two groups There was one early neonatal death of anomalous baby in expectant group and one baby was stillbirth due to birth asphyxia in elective group. A minimum birth weight was 2 kg and the maximum was 4.5 in both the groups. There was no difference in the mean birth weight (Table 4).

We also analyzed and compared women of elective induction who performed between $39^{0/7}$ and $39^{6/7}$ with women who were expectantly managed after $39^{6/7}$ weeks of gestation thinking that the observed outcomes could be the effect of elective induction performed at a later gestational age. The frequency of cesarean delivery was 36.3% in elective induction group and 32.2% in expectant group (36.3 *vs* 32.2%, p = 0.33). We also observed that the frequency of cesarean delivery in elective induction group was neither statistically significant with the medical induction of expectant group (46.8 *vs* 60%, p = 0.13) nor statistically significant with the spontaneous onset of labor of expectant group (46.8 *vs* 46.3%, p = 0.9).

Further, the elective induction group and expectantly managed group were analyzed by comparing the risk of

Table 5: Birth weight of study population						
	Ex	pectantly	Ele	ectively		
Fetal birth	managed		induced			
weight (kg)	Ν	LSCS (%)	Ν	LSCS (%)	OR (95% CI)	p-valu
2–3.0	63	28 (44.4)	49	16 (32.6)	0.6 (0.2–1.3)	0.20
3.1–>3.5	33	14 (42.4)	47	35 (74.4)	3.9 (1.5–10.2)	0.004*

*Significant; LSCS: lower (uterine) segment cesarean section Association of cesarean delivery with birth weight (kg) is shown. A minimum birth weight was 2 kg and maximum weight was 4.5 kg. The electively induction group was associated with increased odds of cesarean delivery rate at birth weight ≥3.1 kg than the expectantly managed group

cesarean delivery rate after excluding the birth weight \geq 3.1 kg. There was no significant difference in the two groups (ORs 0.6, CI 0.2–1.3, p = 0.20). However, elective induction was associated with increased odds of cesarean delivery rate at birth weight \geq 3.1 kg than the expectantly managed group in the present study (ORs 3.9, CI 1.5–10.2, p = 0.004; Table 5).

DISCUSSION

There is an increased risk of cesarean delivery among nulliparous women with an unfavorable cervix by induction of labor, as stated in many studies.³⁻⁵ The results of these studies cannot be universally applicable because of inappropriate comparison between nulliparous women undergoing elective induction of labor with women having spontaneous onset of labor.⁶⁻⁸ Another issue in the selection of the control group is including women with medical indications for delivery, such as overt diabetes or chronic hypertension in expectantly managed group, these indications itself are independent risk factors for cesarean delivery. To control for potential confounders, we attempted to exclude most women with chronic medical conditions complicating pregnancy, we included women belonging to same ethnicity, who have not received epidural analgesia during labor and delivered in consultant-led labor delivery unit. The present study has focused on the cervical status, an important confounding variable, by including women whose cervix was unfavorable at the time when elective induction or expectant management was undertaken.

In our study, we found no difference in the proportion of cesarean delivery between the elective induction of labor and expectant management groups and also in maternal and fetal health outcomes. Women electively induced were noted to have an increased mean length of labor, spent more time in labor and delivery unit, and received oxytocin more frequently, this additional time may translate into increased costs in management with significant differences in resource utilization between the two groups.

Our results are contrary to the widespread belief that elective induction increases the cesarean delivery rate. This view was purported by a majority of observational studies. In a study done on 2,200 women by Vahratian et al,⁴ an increase in the cesarean delivery rate from 13.9% among women in spontaneous labor to 41.3% among electively induced women who required cervical ripening was shown. Similarly, one large cohort study from Sweden, on nulliparous women, reported a threefold increase in cesarean section, while in another study an increase in cesarean rate of 25.4% in induced women as compared with 16.6% in women was shown with spontaneous onset of labor.^{9,10} The results yielded by comparison of elective induction of labor with spontaneous labor are neither clinically relevant nor useful for prospective counseling of women as the control group was not representative.

Evidences regarding the relationship between elective induction of labor at early term (37 and 38 weeks) and term (39 and 40 weeks) and a variety of maternal and neonatal outcomes were lacking. Good evidence exists for the use of induction in late term $(41^{0/7} \text{ to } 41^{6/7} \text{ weeks})$ gestation) and postterm (42 completed weeks of gestation). Even in nulliparous women, a significantly lower cesarean delivery rate was seen in elective induction group compared with expectantly managed group (21.2% induction group vs 24.5% expectant group, p = 0.03), which is so far the largest trial conducted by Hannah et al.¹¹ Dyson et al¹² in a randomized controlled trial have compared the rates of cesarean delivery between women with induction of labor and those with expectant management of pregnancy, and have generally concluded that the cesarean rate was unchanged or lower among the induced group. Different studies have also emphasized on the observation that the proportion of cesarean delivery was at par or lower in electively managed low-risk nulliparous women as compared with expectantly managed women at 38, 39, 40, and 41 weeks.¹³⁻¹⁶ Two recent systematic reviews have come up, of which the first, which comprises of 157 trials, concluded that an overall reduction in cesarean section rate in the induction group (RR 0.88; 95% CI 0.84-0.93) is seen when both low- and high-risk pregnant women were included.¹⁷ Similar conclusion was arrived by the second review as well, where 27 RCTs were analyzed showing a low OR of 0.82 and 95% CI of 0.73 to 0.92 in the induction group.¹⁸

We found there is no significant increase in instrumental deliveries, neonatal complications, and maternal complications between both the groups; this is comparable with studies done by Osmundson et al,¹⁴ Macer et al,¹⁹ and Prysak and Castronova.²⁰ We also found a statistically significant prolongation of duration of a labor, hours spent in labor and delivery unit in the electively induced group. This is similar to a study done by Vahratian et al⁴ and Osmundson et al¹⁴ but contradictory to Macer et al¹⁹ study who found no difference in the duration of labor between both groups. Cochrane Database Systemic Review by Gulmezoglu et al²¹ suggested that policy of labor induction between 37 and 40 weeks was associated with fewer perinatal deaths and fewer cesarean sections as compared with expectant management. A lower risk of 5-minute Apgar score,¹² meconium aspiration syndrome, admission to neonatal intensive care unit, was reported by Cheng et al¹⁵ in women who had induction compared with expectant management, this association was seen for induction at 39, 40, and 41 weeks compared with the expectant groups.

Our study was adequately powered with appropriate sample size, thereby decreasing the possibility of type II error. The groups chosen were homogeneous in terms of ethnicity, parity, and age, even the study and the control groups were well matched, we even assessed the cervical status unlike other studies. A single investigator was involved in reviewing the charts and medical records, thereby minimizing the selection bias in group assignment.

Our study had few limitations. It is a retrospective, observational study so it is susceptible to confounding. Even though the sample size was adequate based on the power of the study for concluding the primary outcome, still subtle clinical differences could have been missed. Our study could not find out the differences in maternal and neonatal outcomes that occur less frequently than cesarean delivery as it would need an extremely large sample. This study was not able to assess the impact of cost or patient satisfaction with induction of labor.

CONCLUSION

From our study, we observed that there was no difference in the proportion of cesarean delivery in women who were induced electively, a finding that opposes the commonly held view that induction of labor actually increases the risk for cesarean delivery. Obstetric management has changed significantly over the past 30 years, as has the baseline cesarean delivery rate. In rural setup, where regular antenatal follow-up at term is difficult, obstetric care and fetal monitoring facilities are not available like tertiary care centers; hence, elective induction could be beneficial. Based on our study, we are not in a position to recommend any major changes in the currently followed clinical practice as our data are insufficient, rather we emphasize upon conducting large prospective, randomized studies which are necessary to assess the relationship between elective induction of labor at term and potential benefit in low-risk women in such clinical settings. Then perhaps a reasonable role of elective induction of labor may become evident.

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