Comparison of Expectant Management Versus Induction of Labour at 40 Weeks on Successful Vaginal Birth Rate in Women with a Previous Caesarean Section: A Randomized Controlled Trial and A Pilot Study.

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Abstract

Objective: to compare the vaginal birth rate in women with previous one lower segment caesarean section when induced at 40 weeks compared to expectant management till 41 weeks. Design: A randomized controlled trial Setting: Department of Obstetrics and Gynaecology, JIPMER, a tertiary care teaching institution in the south of India. Population or Sample: Low-risk women with previous one single lower segment caesarean section with a singleton foetus in vertex presentation and eligible for a trial of labour (TOLAC) at 40 weeks gestation. Methods: Block randomization to two groups of thirty each. The induction group was induced at 40 weeks with low dose oxytocin infusion or ripening with a single application of a single balloon Foley catheter followed by oxytocin infusion 24 hours later. The expectant group was managed in the hospital with maternal and foetal surveillance and induced at 41 weeks if they had not delivered by then. Main Outcome Measures: Vaginal birth after caesarean section (VBAC). Results: The demography and pregnancy variables were comparable in the two groups. Twenty out of thirty women (66.67%) had a successful vaginal birth after caesarean section in the induction group compared to ten out of 30 (33.33%) in the expectant group. This difference was significant (RR 2.0, 95% CI: 1.13-3.52; P=0.016) Conclusions: Among low-risk women with previous one lower segment caesarean section willing and eligible for TOLAC, the successful VBAC rate is significantly higher among those induced at 40 weeks compared to those managed expectantly till 41 weeks.

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Methods: Block randomization to two groups of thirty each. The induction group was induced at 40 weeks with low dose oxytocin infusion or ripening with a single application of a single balloon Foley catheter followed by oxytocin infusion 24 hours later. The expectant group was managed in the hospital with maternal and foetal surveillance and induced at 41 weeks if they had not delivered by then.

Main Outcome Measures: Vaginal birth after caesarean section (VBAC).

Results: The demography and pregnancy variables were comparable in the two groups. Twenty out of thirty women (66.67%) had a successful vaginal birth after caesarean section in the induction group compared to ten out of 30 (33.33%) in the expectant group. This difference was significant (RR 2.0, 95% CI: 1.13-3.52; *P=0.016)*

Conclusions: Among low-risk women with previous one lower segment caesarean section willing and eligible for TOLAC, the successful VBAC rate is significantly higher among those induced at 40 weeks compared to those managed expectantly till 41 weeks.

Funding: there is no funding involved in this work.

Keywords: Vaginal birth after caesarean, induced labour, expectant management, repeat caesarean, trial of labour after caesarean.

Clinical Trial Registration : Prospective registration was done with the Clinical Trial Registry of India (number-CTRI/2018/09/015719)

Tweetable abstract

Induction of labour at 40 weeks results in significantly higher VBAC rates compared to expectant management

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Introduction :

The optimal timing of delivery for women with a previous caesarean section without any maternal or foetal complications is not well studied. Trial of Labour After Caesarean section (TOLAC) has been well accepted for all eligible cases and guidelines have been laid for eligibility for TOLAC.[1,2,3] RCOG recommends 41 weeks for termination of these eligible patients if they do not go into spontaneous labour by the expected date of delivery.[4]Spontaneous labour is always considered safer and has a higher chance of successful vaginal birth after caesarean (VBAC) than induced labour in a woman with a previous caesarean section. Studies have shown that there is a one and a half times higher risk of caesarean section and a two to three times higher risk of rupture uterus with the induction of labour compared to spontaneous labour.[4,5,6] Awaiting beyond 40 weeks is with the hope that they will achieve spontaneous labour. However, past dates have their problems.[7,8] like a passage of meconium and reduction in amniotic fluid. Recently published meta analysis[9] also concluded that there is an increased risk of stillbirth after 40 weeks. The largest retrospective study on women with previous caesarean delivery has shown that induction of labour at 39 weeks was found to have lower odds of caesarean section compared to those managed expectantly.[10] Successful and safe vaginal births will be an asset in limiting the escalation in repeat caesarean section rates. There are no randomized controlled trials available to compare expectant management till 41 weeks and induction at 40 weeks among women with uncomplicated pregnancy with a previous one caesarean section. Expectant management and not spontaneous labour is a true comparator for elective induction of labour at term. Hence this randomized controlled trial was undertaken with the primary objective to compare the successful vaginal birth rates in women with previous one lower segment caesarean section when induced at 40 weeks compared to expectant management till 41 weeks.

Methods:

Design and settings : This parallel-arm design randomized controlled trial was carried out in the inwards and labour room of the department of Obstetrics and Gynaecology at Women and Children Block of Jawaharlal Nehru Institute of Postgraduate Medical Education and Research (JIPMER) from November 2018 till June 2020 after obtaining approval from the institute ethics committee (JIP/IEC/2018/0145). This is a tertiary care teaching hospital located in south India.

Eligibility Criteria : Women more than18 years, with previous single lower segment caesarean delivery at 40

weeks with a singleton foetus in vertex presentation and eligible for TOLAC were included. Women with Inter pregnancy interval greater than 18 months, scan estimated foetal weight less than 3.5 kg, non-recurrent indication for the previous section, the previous scar restricted to lower segment, scar thickness more than 3 mm on ultrasonography, and no clinical evidence of cephalopelvic disproportion was considered eligible for TOLAC. The previous caesarean carried out for placenta previa, transverse lie, preterm and late in the second stage of labour, or clinical evidence of uterocervical infections after the previous caesarean section was not considered eligible for TOLAC.

Women with complications like Pre-eclampsia, Diabetes mellitus, oligohydramnios, or Intrauterine growth restriction (IUGR), foetal malformations, multiple gestations, those not willing for the trial of labour after caesarean, women requiring induction of labour for any other maternal or foetal condition before randomization, and women with poor or non-confirmed dating were excluded.

Primary outcome : successful vaginal birth rates in the two groups.

Secondary outcome(s): Maternal complications like scar rupture, postpartum haemorrhage, sepsis, and any mortality. ii) Perinatal outcomes like birth asphyxia, respiratory morbidities, hyperbilirubinemia, sepsis, perinatal mortality, etc.

There were no changes in the outcomes after the trial commenced.

Sample size calculation **:** As it is was a pilot Randomized controlled trial (RCT), 30 cases each were studied in both the groups

Stopping guidelines : Interim analysis after 50% sample size did not reveal a significant difference in the primary outcome so the study was continued.

Randomization details: Block randomization (block size of 6 each) was done using varying numbers generated via computer using randomization software. The allocation ratio was 1:1. Allocation concealment was done by a person unrelated to the study from the Department of Preventive and Social Medicine through serially numbered opaque sealed envelopes. The participants were enrolled by the principal investigator. There was no blinding.

Study procedure **:** Women with uncomplicated pregnancy with a previous caesarean section were screened from 39 weeks onwards clinically and with sonography for eligibility for TOLAC. The period of gestation was calculated as per the last menstrual period (LMP) or calculation based on the early available (<14 weeks scan) dating scan. After obtaining informed written consent, the women fulfilling the study criteria, and willing for TOLAC were randomized on the day of completion of 40 weeks to either group. Bishop Score was reassessed after randomization.

Induction was carried out on the same day (40 weeks) or within 24 hours of randomization in the induction group (group II). If the Bishop score was favourable (>6), induction was done using low dose oxytocin infusion detailed below. If unfavourable (<6), induction was done by ripening of the cervix with a single application of 22 French Foley single balloon catheter just above the internal os, under aseptic precautions. The bulb was inflated to a total of 60ml. The women were monitored for onset of contractions/ leaking/ bleeding/ any other complication and the foetus was monitored by intermittent auscultation and a nonstress test done after 12 hours. If she did not spontaneously expel then the Foley catheter was deflated and removed after 24 hours or earlier if she developed spontaneous rupture of membranes. Bishop's score was noted again. Induction was started with low dose oxytocin infusion delivered through a pump starting from 3mIU/min and incremented by 3mIU every half-hourly and titrated to achieve target contractions or to a maximum of 24mIU/min. The foetal heart and uterine contractions were monitored with the help of an electronic tocodynamometer. The woman was monitored for the progress of labour and symptoms and signs of scar dehiscence. An artificial rupture of membranes was carried out four hours after achieving the maximum dose of oxytocin or when the patient started getting three to four contractions in ten minutes, each lasting for 30 to 40 seconds. After 6 hours of artificial rupture of membranes, if patients failed to achieve active

labour (4cm dilatation with 75-100% effacement), it was considered as failed induction and terminated by caesarean section. If active labour was established, then the trial was continued.

Women in the expectant arm of the study remained admitted in the hospital and were monitored. Non-stress test (NST) was done every 48 hours and a repeat ultrasound for amniotic fluid index and biophysical profile for foetal surveillance at 40 weeks plus 3 days. It was repeated at 41 weeks if she had not delivered by then. In case any complications arose between 40 to 41 weeks, pregnancies were terminated either by induction of labour or by caesarean as per the case. If they had not delivered by 41 weeks, induction of labour was carried out in them as per the protocol followed in the induction group. The neonates and women were followed up till discharge from the hospital. There were no changes made in the inclusion criteria or methodology after trial commencement.

Continuous variables were expressed as mean with standard deviation or median with interquartile range. Categorical were summarized as frequency and percentage or proportion. The primary outcome variable (mode of delivery) was expressed as the proportion with a 95% confidence interval and was analysed using the Chi-square test as the statistical test. Other baseline characteristics were compared using the Chi-square test or Fischer's Exact test if expressed in proportions and using unpaired student-test or Mann Whitney test is expressed in terms of mean with standard deviation or median with interquartile range. Subgroup analysis was attempted for factors associated with successful VBAC after induction of labour by univariate analysis and logistic regression analysis.

Results: A total of 1886 women with previous Caesarean section attending Women and Children Hospital, JIPMER, were screened and 60 women who fulfilled the inclusion criteria and were willing for the study were randomized. (Figure1) All the 60 recruited patients (30 in each group) completed the study, and the study was stopped. Two of the patients in the induction arm went into spontaneous labour after randomization before induction on the expected date of delivery. One woman in the expectant arm had a spontaneous version to breech presentation at 41 weeks and so pre-labour caesarean was performed on her. These three cases were not excluded from the analysis. So, an intention to treat analysis was done.

The demographic and pregnancy-related variables are shown in Table1. The mean age, socio-economic status, parity, previous history of VBAC, the indication of the previous caesarean, and pre-induction Bishop Score, etc was comparable in the two groups.

Twenty out of the 30 (66.67%) women in the induction group had a successful vaginal birth after caesarean section. 53.33% of them had a normal vaginal delivery and 13.33% had an instrumental vaginal delivery. The remaining 10 subjects (33.33%) underwent emergency LSCS for varied indications. The expectant group had a VBAC rate of 33.33% with only 10 out of the 30 women undergoing successful vaginal delivery and this difference was significant. (RR 2.0, 95% CI: 1.13-3.52;*p=0.016)* .

In the expectant group out of the 30 women, thirteen (43.33%) went into spontaneous labour before 41 weeks, 7 underwent induction before 41 weeks for different complications (one developed gestational hypertension, five had oligohydramnios and one had reduced fetal movements), 9 were induced at 41 weeks as per protocol and 1 had a prelab our cesarean section for the spontaneous conversion of cephalic to breech presentation.

The mode of delivery details of the expectant group is shown in table 2. The intrapartum details are shown in Table 3. The proportion of women with abnormal fetal heart rate patterns and meconium-stained liquor and the duration of oxytocin infusion was comparable in the two groups. The birth weight was higher by 270 grams in the expectant group. This was statistically significant though not clinically significant.

The indication for cesarean section in the two groups is shown in table 4 and the difference in indications was not found to be statistically significant.

There was one case of scar dehiscence in the expectant arm, confirmed intra-operatively. This woman did not go into spontaneous labour during the expectant management period. She underwent labour induction at 41 weeks as per protocol. She was taken up for an emergency caesarean for failed induction. However intraoperatively, a 3cm horizontal scar dehiscence was observed. The same was repaired and the recovery

was uneventful. There were no cases of scar dehiscence in the induction at 40 weeks arm. There was no case of a third or fourth-degree perineal tear in women who had a spontaneous vaginal or operative vaginal delivery.

None of the women developed any complications like sepsis or postpartum haemorrhage. None of them required a blood transfusion or hysterectomy.

There were no stillbirths. None of the babies was born with a low Apgar score. None of the neonates required admission to an intensive care unit. There were no morbidity or mortality amongst these sixty new-borns.

We did subgroup analysis to find the factors associated with successful VBAC amongst the forty-four women who were induced (16 from group I and 28 from group II). We found that the mean pre-induction Bishop score was significantly higher in the successful VBAC group (3.86+ 1.12) compared to the emergency caesarean section group (3.04+ 1.29) (t=-2.24, p=0.029, 95% CI for mean difference: 0.08 to 1.5) and duration of oxytocin infusion was significantly shorter in the VBAC group(5.9 hours+ 3.1) compared to the emergency caesarean group(8.67+ 4.65hours) (t=2.26, P=0.028, 95% CI for mean difference: -5.10 to -0.29). After adjusting for the intervention, Birthweight, scar thickness, interpregnancy interval, and parity, these two factors (Pre-induction Bishop score and duration of oxytocin) were not significantly associated with VBAC (Table5). We excluded Indication from LSCS from multivariable analysis as the sample size is too small to run an analysis with too many categories under indications.

The sample size was too small for subgroup analysis to find the factors associated with spontaneous onset of labour(n=13) in the expectant group.

Discussion :

Main Findings : In our pilot randomized controlled trial we found that in the low-risk pregnant woman with a previous caesarean delivery, induction of labour (IOL) at 40 completed weeks achieves significantly higher successful vaginal deliveries than expectant management till 41 weeks. We recruited only 30 women in each group and the study was not powered to analyse maternal or perinatal outcomes. We had strict inclusion criteria. Though 43% of the women in the expectant group in our study went into spontaneous labour, only half of these women successfully delivered vaginally. 23 % of women in the expectant group developed a maternal or foetal complication. One woman (3.3%) in the expectant group developed gestational hypertension de novo after 40 weeks.

The landmark ARRIVE trial[11], as well as the two metanalysis[12,13] of randomized controlled trials, have shown a reduction in the adverse perinatal outcome and caesarean delivery rates in those undergoing IOL at 39 weeks compared to those managed expectantly. However, all these involved women without a previous caesarean section. The meta-analysis of cohort study by Grobman et al [14] also reported similar results. None of the 6 cohort studies analysed by them had included women with a previous caesarean section.

There are no randomized controlled trials on this subject in women with previous caesarean delivery. There are only a few cohort studies comparing IOL with expectant management in women with a previous caesarean section at term. The first study was a large retrospective cohort of 16 years.[10] It showed lower odds of caesarean and higher odds of spontaneous vaginal delivery in the IOL group at various periods of gestation from 39 to 41 weeks. They did not find a higher rate of rupture in the IOL group. However, heterogeneity and changing practice over the 16-year study period could have influenced the results. In another study[15] the authors reported higher VBAC rates (OR1.3) in the IOL group but an increased rate of rupture in the IOL group. This was a secondary analysis of a registry from a 4-year multicentre observational study.[16] The original study has not detailed the induction protocol. Many women had received prostaglandins with or without oxytocin and information on confounder-like cervical status in the two groups was not available.

In yet another secondary analysis study of an obstetric cohort from Consortium of safe labour, among women with previous caesarean section who attempted TOLAC, the authors [17] observed higher rates of failed VBAC in the women induced from 37 to 39 weeks but not at 40 weeks. This cohort included both high and low-risk women, which could have influenced a quicker decision to terminate labour by emergency caesarean section.

A 3- year retrospective cohort has been recently published.[18] The authors observed that among women with previous caesarean section, induction of labour at 39 weeks was associated with lower intraamniotic infection and improved 5-minute APGAR score in the IOL arm but at the cost of 70% increase in caesarean delivery rates. They also observed that 2.2% of the expectant arm women developed new-onset hypertension after 39 weeks. In this study, the induction protocol was not detailed and oligohydramnios as an indication for induction was not excluded. Also, women who did not go into spontaneous labour in the expectant arm but opted for scheduled caesarean section instead of IOL were excluded. This could have influenced the higher caesarean rates in the induction arm.

In our study, we had strict inclusion criteria. We took 3mm as the cut-off for eligibility for TOLAC though RCOG recommends scar thickness above 2mm. We took a higher cut-off for the full thickness of scar on sonography because induction of labour has 2 to 3 times higher risk of scar rupture and meta-analysis done in 2013[19] had shown variable sensitivity for variable cut-offs and that the full thickness more than 3mm provided the strongest negative predictive value of occurrence of defect during TOLAC. We used Foley single balloon catheter for ripening of the cervix which is considered a safe method in women with previous caesarean section.

Strengths and limitations : The biggest strength of our study is that it is a randomized controlled trial. The two groups were comparable for important variables like Bishop score and previous vaginal delivery that are known to influence VBAC rates. We had a strict induction protocol for both groups. We excluded any maternal or foetal complications requiring induction including oligohydramnios at the time of recruitment at 40 weeks. Since we followed standard induction protocol and monitoring, the results can be generalized to most tertiary centres with infrastructure for delivering women with previous caesarean pregnancy. The limitation of our study is that our study had a small sample size as it was a pilot study. It was powered for our primary outcome of successful vaginal delivery rates and was not powered for adverse maternal and perinatal outcomes. We terminated labour by emergency caesarean section if the women failed to go into the active phase of labour within 6-8 hours of artificial rupture of membranes. So, the trial of labour did not last longer than 24 hours if the women had not gone into the active phase of labour. We did not give a second application of Foley if the Bishop score had not improved.

Interpretation : The successful VBAC rate is significantly higher with the induction of labour at 40 weeks compared to expectant management till 41 weeks. Expectant management is likely to increase the risk of a maternal or foetal complication. Even though around one-fourth of women went into spontaneous labour after 40 weeks, only half of them delivered vaginally.

Conclusion : We recommend induction of labour at 40 weeks instead of expectant management till 41 weeks, for women with previous one lower segment caesarean section, with singleton foetus and uncomplicated pregnancy, who are eligible for TOLAC. We recommend larger trials for studying the adverse maternal and perinatal outcomes of this strategy.

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Author contribution : GD Conceived the work. GD and RK planned it. RK carried out the work. SSK and CP analysed the data. GD wrote the manuscript. RK, GD, SSK, and CP approved the final manuscript.

Details of Ethics Approval: Ethical clearance was obtained from the Institute Ethics committee. *Reference no* : JIP/IEC/2018/0145.

Name of the Ethics Committee : Institutional Ethics Committee (Human Studies), JIPMER.

Date of approval by the Ethics committee: 6thJuly 2018.

And prospective registration was done with the Clinical Trial Registry of India (number-CTRI/2018/09/015719),

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Legends

Fig1: CONSORT DIAGRAM

Table1: Demographic and pregnancy characteristics in the two groups.

Table 2: Mode of delivery for women in the Expectant arm

Table 3: Comparison of intrapartum details between the two groups

Table 4: Comparison of indications for emergency caesarean section in present pregnancy between the two groups.

Table 5: Multivariable analysis of factors associated with caesarean delivery amongst those induced. N=44.

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Table1 : **Demographic and pregnancy characteristics in the two groups.**

PARAMETERS	**PARAMETERS**	**GROUP I (Expectant) N=30**	**GROUP II (Induction) N=30**	**P-Value**
Age (years)	21-25 26- 30 31-35	46.67% 43.33 % 10%	46.67% 40% 13.33%	X^2=0.182, P=0.91
Socioeconomic status	Upper middle Lower Middle Upper Lower Lower	6.67% 20% 36.67% 36.67%	6.67% 3.33% 60% 30%	X^2=5.46, P=0.14
Parity	Primiparous Multiparous	90% 10%	86.67% 13.33%	X^2=5.2, P=0.50
Occupation	Housewife Daily waged Monthly waged Business	63.33% 23.33% 10% 3.33%	73.33% 16.67% 10% 0	X^2=01.55, P=0.67
Previous VBAC	**Previous VBAC**	3.33%	3.33%	P=1
Mean Age(years)	**Mean Age(years)**	26.13+3.41	26.4+3.8	
Bishop score at 40 weeks (mean ± SD*)	**Bishop score at 40 weeks** (mean ± SD*)	3.07 ± 1.11	3.5 ± 1.17	t=-1.47, P=0.07
Interpregnancy interval in months (mean ± SD*)	**Interpregnancy interval** in months (mean ± SD*)	36.07 ± 17	38.87 ± 20.64	t=-0.5, P=0.57
Scar thickness in mm (mean ± SD*)	**Scar thickness** in mm (mean ± SD*)	3.95 ± 0.25	4 ± 0.24	t=-0.86, P=0.39
AFI (mean ± SD*)	**AFI** (mean ± SD*)	10.08 ± 2.53	10.31 ± 2.48	t=-0.35, P=0.72

VBAC- vaginal birth after caesarean, AFI = Amniotic fluid index * SD- standard deviation, X^2- Chi Square, t- student test.

Table 2: Mode of delivery for women in the Expectant arm

Mode of delivery N=30	**N (%)**	**VBAC**	**Emergency LSCS**
Induction of labour Per protocol at 41 weeks Between 40 – 41 weeks	9 (30%) 7 (23.33%)	2 (12.5%) 1 (6.25%)	6 (37.5%) 7 (43.75%)
Spontaneous onset of labour	13 (43.33%)	7 (53.8%)	6 (46.15%)
Prelabour caesarean section	1 (3.33%)	-	-

Table 3: Comparison of intrapartum details between the two groups

Parameter	**Group I N=30**	**Group II N=30**	**P-value**
Birth weight (mean ± SD*)	3.295 ± 0.304	3.022 ± 0.348	t= 3.24, P=0.002
Duration of oxytocin infusion (hours) (mean ± SD*)	7.76 ± 4.63	6.92 ± 3.81	P= 0.511
Meconium-stained liquor. n (%)	8 (26.67%)	6 (20%)	P=0.542
Fetal heart rate pattern, n (%) Early deceleration Late deceleration Variable deceleration	2 (6.67%) 1 (3.33%) 2 (6.67%)	4 (13.33%) 1 (3.33%) 2 (6.67%)	P=0.861

*SD- Standard Deviation. t- student t-test.

Table 4: Comparison of indications for emergency caesarean section in present pregnancy between the two groups.

Indication N (%)	**Group I N=20**	**Group II N=10**	**P-value**
Failed Induction	9 (45%)	4 (40%)	0.8
NPOL*	2 (10%)	0	
Fetal Distress	4 (20%)	4 (40%)	0.2
CPD** diagnosed in labour	0	1 (10%)	
Suspected scar dehiscence	3 (15%)	0	
Meconium-stained liquor with unfavourable Cervix	1 (5%)	1 (10%)	0.6
Spontaneous Conversion to Breech	1 (5%)	0	

*NPOL = Nonprogress of labour, **CPD = Cephalo-pelvic disproportion.

Table 5: Multivariable analysis of factors associated with cesarean delivery amongst those induced. N=44.

VARIABLE	RR	95% CI for RR	95% CI for RR	P-value
Group I (N=16)	1.00			
II (N= 28)	3.06	0.79	11.86	0.105
Starting Bishop score	1.15	0.87	1.52	0.328
Oxytocin duration	0.97	0.88	1.06	0.48
Birth weight	0.86	0.43	1.73	0.669
Scar thickness	1.68	0.57	4.95	0.344
Inter pregnancy interval	0.96	0.81	1.14	0.634
parity 1	1.00			
2	1.27	0.76	2.12	0.352

RR- Relative risk, CI – Confidence Interval.

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`Figure 1. consort diagram raji paper.pdf` available at https://authorea.com/users/391670/articles/505709-comparison-of-expectant-management-versus-induction-of-labour-at-40-weeks-on-successful-vaginal-birth-rate-in-women-with-a-previous-caesarean-section-a-randomized-controlled-trial-and-a-pilot-study