

Outcome with trial of labor after cesarean (TOLAC) or elective repeat cesarean delivery on maternal request (ERCD-MR): a comparative study**Sobia Akram****Senior Resident, Department of obstetrics and gynaecology, Narayan Medical College and Hospital, Jamuhar, Sasaram, Bihar, India***Received: 05-09-2020 / Revised: 15-10-2020 / Accepted: 24-11-2020****Abstract**

Aim: To compare outcomes with trial of labor after cesarean (TOLAC) or elective repeat cesarean delivery on maternal request (ERCD-MR). **Methods:** A prospective study was conducted in the Department of obstetrics and gynaecology, Narayan Medical College and Hospital, Jamuhar, Sasaram, Bihar, India from march 2018 to July 2019. Total 600 patients were included in this study. **Results:** TOLAC was associated with an increased risk of neonatal depression [odds ratio (OR) 3.2, 95% confidence interval (CI) 1.2–9.3] and neonatal intensive care unit admission (adjusted OR 1.7, 95% CI 1.4–2.6). Within the TOLAC group 75% delivered vaginally. In the TOLAC group 2% (n = 8) of the women had a complete uterine rupture. None of these infants had sequelae after 12 months. Significant risk factors for emergency cesarean were no prior vaginal delivery (adjusted OR 1.6, 95% CI 1.1–3.2), index emergency cesarean during labor (adjusted OR 3.2, 95% CI 2.4–4.0), maternal age ≥ 35 years (adjusted OR 2.1, 95% CI 1.4–2.1), pre-pregnancy body mass index ≥ 30 (adjusted OR 2.3, 95% CI 1.1–3.5), and birthweight 4000–4499 g (adjusted OR 1.4, 95% CI 1.2–2.3). Uterine rupture was associated with the use of epidural analgesia (OR 2.2, 95% CI 1.1–4.9) and no prior vaginal delivery (p = 0.02). **Conclusion:** TOLAC is an acceptable individualized option for women without major risk factors.

Keywords: Surgery, Study, women.

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Introduction

Despite cesarean being a major abdominal surgery, the number of cesarean deliveries has been increasing in recent decades in the United States.[1-3] The World Health Organization has stated that national cesarean rates greater than 10-15% indicate unnecessary maternal risk. Nevertheless the current cesarean rate in the US is 32.2% (CDC). With this high rate of cesarean delivery the question of the route of delivery for subsequent pregnancies becomes ever more important. Famously, Edwin Bradford Cragin, an obstetrician in 1916, is quoted as saying “once a cesarean, always a cesarean” and historically this had been true.[1,4] However, in 1980 the National Institute of Health (NIH) and the American Congress of Obstetricians and Gynecologists (ACOG) endorsed trial of labor after

cesarean delivery (TOLAC) leading to an increase in vaginal birth after cesarean (VBAC) in the US.[1] This increase in TOLAC also revealed an increase in TOLAC related complications, such as uterine rupture-related maternal and fetal morbidity.[3] “Uterine rupture is associated with an increased risk of severe maternal complications, such as hysterectomy, hemorrhage, as well as severe fetal complications, such as hypoxic ischemic encephalopathy and perinatal death”.[5] The corresponding rise in TOLAC related complications prompted a 1998 ACOG recommendation that TOLAC should only be considered in institutions equipped for emergency care should complications occur.[3] A few months after releasing this recommendation, ACOG revised the wording from “readily available physicians” to “immediately available physicians” to provide emergency care. This had a significant impact on hospital policy and caused a rapid decline in the number of institutions willing to consider TOLAC as an option for patients, as well as introduced concerns about medical liability claims.[3] The American

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College of Obstetricians and Gynecologists notes that women who desire several children are not good candidates for elective primary cesarean delivery on maternal request.[6] The International Federation of Gynecology and Obstetrics and the Society of Obstetricians and Gynaecologists of Canada, among others, state that cesarean delivery on maternal request cannot be justified and should not be offered.[7] Hence the present study was undertaken with the aim to compare the outcome with trial of labor after cesarean (TOLAC) or elective repeat cesarean delivery on maternal request (ERCD-MR).

Material and Methods

A prospective study was conducted in the Department of Obstetrics and Gynaecology, Narayan Medical College and Hospital, Jamuhar, Sasaram, Bihar, India from March 2018 to July 2019.

Methodology

The exclusion criteria were diabetes, two prior cesarean sections, any vaginal delivery after the index cesarean, twin gestation, gestational age <37⁺⁰ weeks and antepartum stillbirth. All cesarean procedures were carried out as a low transverse cesarean, and a single-layer suture was primarily used, but a double-layer closure was used for hemostasis when indicated. Women who had an emergency cesarean received prophylactic ampicillin, whereas women who had an elective cesarean did not.

The TOLAC group included women whose labor was initiated by spontaneous contractions or rupture of membranes, or who were induced with prostaglandin, double balloon catheter or artificial rupture of the membranes (AROM). The actual mode of delivery for these women was either a successful vaginal birth or an emergency cesarean (defined as a decision-to-delivery interval <8 h). If mode of delivery was a cesarean at maternal request performed either electively or as an emergency procedure, the woman was included in the ERCD-

MR group. Accordingly, women who intended to deliver by ERCD- MR, but who had an emergency cesarean because of the spontaneous onset of labor, were classified into the ERCD-MR group. The decision on mode of delivery was taken during antenatal consultations with an obstetrician, and in case of a maternal request cesarean delivery, a specific box was checked on the birth registration form. In accordance with this, women with a medically indicated cesarean delivery were not included in this study.

Results

This study included 600 women, of whom 400 (66.67%) undertook a TOLAC and 200 (33.33%) had an ERCD-MR. Table 1 shows the baseline characteristics of the two groups. Women in the TOLAC group were more likely not to have had any vaginal delivery before the index cesarean, and to be younger, have a lower pre-pregnancy BMI, and to deliver a child with a higher birthweight. Within the TOLAC group 300(75%) women delivered vaginally, and 100(25%) women were registered with a failed TOLAC (Table 2). Vacuum extraction was used in 50 (12.5%) deliveries in the TOLAC group. Women in the TOLAC group who delivered by an emergency cesarean were more likely to have had their labor induced, primarily by double balloon catheter or AROM. Reasons for induction and augmentation of labor are shown in Table 2. Table 3 shows the influence of selected risk factors for delivery by an emergency cesarean. Since the inclusion of birthweight in our multivariate regression model did not substantially change the estimates, this parameter was included in the final model. Factors associated with a significantly increased risk of emergency cesarean were no prior vaginal delivery, if the index cesarean was performed as an emergency during labor, maternal age ≥ 30 years, pre-pregnancy BMI ≥ 25 kg/m², and if the birth weight was ≥ 4000 g.

Table 1: Baseline characteristics of the study population undergoing TOLAC section and ERCD-MR

Baseline characteristics	TOLAC		ERCD-MR		p-value
	N=400	%	N=200	%	
Prior vaginal delivery					<0.001
No	360	90	162	81	
Yes	40	10	38	19	
Index cesarean section					0.50
Not emergency during	164	41	90	45	
Acute during labor	236	59	110	55	
Inter-delivery interval, months					0.39
<18	36	9	14	7	

18–24	64	16	26	13	0.002
≥24	300	75	160	80	
Age of mother, years					
<30	100	25	46	23	
30–34	212	53	94	47	
≥35	88	22	60	30	
Pre-pregnancy BMI ^b , kg/m ²					<0.001
<25	288	72	124	62	
25.0–29.9	80	20	40	20	
≥30.0	32	8	36	18	
Birthweight, (gms)					<0.001
<3000	36	9	22	11	
3000–3999	252	63	144	72	
4000–4499	80	20	28	14	
≥4500	36	9	6	3	

TOLAC, trial of labor after cesarean; ERCD-MR, elective repeat cesarean on maternal request; BMI, body mass index.

^ap-Values calculated from a chi-squared test.

Table 2: Mode of delivery for women undertaking TOLAC section

	Non-instrumental=230 vaginal birth		Vacuum extraction=50		Acute caesarean=120	
	N=230	%	N=50	%	N=120	%
Indication for augmentation of labor						
Fetus or mother at risk ^a	–	–	35	70	40	33.33
Suspected uterine rupture	–	–	0	0	8	6.67
Non-progression of labor	–	–	16	32	52	43.33
Breech or transverse lie presentation	–	–	0	0.0	4	3.33
Maternal request	–	–	2	4	12	10
Labor induction	42	18.26	40	20	40	33.33
Prostaglandin	4	1.7	0	0.0	2	1.67
Double balloon catheter	8	3.47	24	12	22	18.33
AROM	28	12.17	16	8	15	12.5
Oxytocin	106	46.08	38	76	70	58.33
Epidural analgesia	85	36.95	30	60	63	52.5

TOLAC, trial of labor after cesarean; AROM, artificial rupture of the membranes.^aSituations with imminent fetal death or preeclampsia

Table 3: Factors influencing the risk of emergency cesarean for women undertaking TOLAC section

	VBAC (n = 300)		Emergency caesarean=100		Crude		Adjusted ^a	
	n	%	n	%	OR	95% CI	OR	95% CI
Prior vaginal deliveries								
Yes (ref)	44	14.67	6	6	1.1			
No	256	85.33	94	94	1.8	1.3–3.3	1.6	1.1–3.2
Index-caesarean								
Not emergency during labor ^b (ref)	160	53.33	30	30	1.2			
Emergency during labor	140	46.67	70	70	3.2	2.4–4.2	3.2	2.4–4.0
Age of mother, years								
<30 (ref)	80	26.67	26	26	1			
30–34	160	53.33	50	50	1.1	1.1–1.6	1.4	1.0–2.1
≥35	60	20	24	24	1.4	1.2–2.5	2.1	1.4–2.1
Pre-pregnancy BMI ^c , kg/m ²								
<25 (ref)	240	80	60	60	1			
25–29	40	13.33	22	22	1.2	1.4–2.6	1.7	1.2–2.5
≥30	20	6.67	18	18	2.3	1.2–3.5	2.3	1.1–3.5
Birthweight, g								
<3000	32	10.67	7	7	0.9	0.2–1.4	.6	0.2–1.5
3000–3999 (ref)	210	70	60	60	1.3			
4000–4499	52	17.33	25	25	1.2	1.2–2.4	1.4	1.2–2.3
≥4500	6	2	8	8	2.1	1.1–4.2	2.3	1.1–4.3

TOLAC, trial of labor after cesarean; VBAC, vaginal birth after cesarean section; OR, odds ratio; CI, confidence interval; BMI, body mass index.^aMultivariate logistic regression with prior vaginal deliveries, index cesarean, age of mother, pre-pregnancy BMI, birthweight.^bIncluding elective, emergency cesarean delivery, but planned to be elective and emergency before labor.

Table 4: Short-term neonatal and maternal outcomes

	TOLAC		ERCD-MR		Crude OR	Adjusted 95% CI	Crude OR	Adjusted 95% CI
	N=400	%	N=200	%				
Uterine rupture	16	4	2	1				
Complete	8	2	0	0	3.5	1.3–3.1	2.7	1.0–7.5
Incomplete	8	2	2	1				
Neonatal depression ^b	8	2	1	0.5	3.2	1.2–9.3	11.3	1.7–86
NICU admission	40	10	16	8	1.7	1.0–2.4	1.7	1.4–2.6
Perinatal death	1	1	0	0.0	NA			
Maternal hemorrhage ≥1000 mL	44	11	16	8	4.8	2.4–8.5	5.8	2.6–10.1

TOLAC, trial of labor after cesarean section; ERCD-MR, elective repeat cesarean delivery on maternal request; OR, odds ratio; CI, confidence interval; NICU, neonatal intensive care unit; NA, not applicable.^aValues adjusted for prior vaginal deliveries, age of mother, pre-pregnancy BMI, birthweight.

Table 5: Factors influencing the risk of uterine rupture for women undertaking TOLAC section

	No rupture (n = 380)		Rupture (n = 200)		OR	95% CI
	n	%	n	%		
Interdelivery interval, months						
<18	38	10	1	5	0.8	0.1–2.7
18–24	48	12.63	3	15	0.8	0.3–2.1
≥24 (ref)	294	77.36	16	80	1	
Oxytocin						
No	180	47.37	8	40	1	
Yes	200	52.63	12	60	1.4	0.6–2.8
Epidural analgesia						
No	204	53.68	5	25	1	
Yes	176	46.32	15	75	2.4	1.1–4.7
Double balloon catheter						
No balloon	342	90	16	80	1	
Balloon	38	10	4	20	1.7	0.5–3.7
AROM						
No AROM	340	89.47	33	91.7	1	
AROM	40	10.53	3	8.3	0.9	0.1–2.4
Index cesarean performed during labor						
No	152	40	6	30	1	
Yes	228	60	14	70	1.7	0.7–3.1
Age of mother, years						
<30	90	23.69	5	25.0	1.1	
≥30	290	76.31	15	75.0	1.2	0.4–2.2
Prior vaginal deliveries						
Yes	38	10	0	0.0		
No	342	90	20	100	NA ^b	
Pre-pregnancy BMI ^a , kg/m ²						
<25	266	70	12	60		
25–29	76	20	6	30	1.3	0.6–3.6
≥30	38	10	2	10	1.1	0.2–4.4

TOLAC, trial of labor after cesarean; OR, odds ratio; CI, confidence interval; AROM, artificial rupture of the membranes; BMI, body mass index; NA, not applicable.^aMissing values for pre-pregnancy BMI: 119 women without rupture and 7 with rupture. ^b $p = 0.03$

Neonatal and maternal outcomes in the TOLAC groups are shown in Table 4. Clinically less relevant but substantial changes in all risk estimates shown were noticed after multivariate adjustment for baseline characteristic imbalances. Univariate logistic regression showed that the main part of this impact was attributed to the influence of BMI (numbers not shown).

The risk of uterine rupture was increased (adjusted OR 2.7, 95% CI 1.1–7.5) in the TOLAC group compared with the ERCD-MR group, and the risk

was also significantly increased when only complete ruptures were analysed. In the TOLAC group, 20/400 (5%) women had a uterine rupture of which 8/400 were complete (2%), and seven with a part of the child protruding into the abdominal cavity. The risks of neonatal depression, NICU admission, and maternal hemorrhage ≥1000 mL were significantly increased in the TOLAC group. Cases of neonatal depression included 8/400 (2%) neonates in the TOLAC group and 1/200 (0.5%) neonates in the ERCD-MR group with an Apgar score <7 after 5 min, and 4/400 (1%) neonates in the TOLAC group compared with no neonates in the ERCD-MR group with pH <7.0. 1 neonates from the TOLAC group died: one due to terminal asphyxia after vacuum

extraction. Uterine rupture did not occur in any of these cases.

In the TOLAC-group an adverse neonatal outcome was registered in 40/400 (10%) neonates in mothers without uterine rupture compared with 8/16 (50%) neonates in mothers with a uterine rupture (OR 4.2, 95% CI 1.7– 9.2). From these 8 cases, 4 were complete ruptures with a part of the child in the abdominal cavity, 2 were complete ruptures without a part of the child in the abdominal cavity, and 2 were incomplete ruptures. All the neonates were admitted to the NICU. 4 of the children were seen at the pediatric outpatient clinic, but had no sequelae after 5, 8 (two of the children), 9 and 12 months, respectively. In 4 (11%) women with uterine rupture, hemorrhage was ≥ 1000 mL compared with 44 of the women without rupture, but the difference was not significant (OR 1.5, 95% CI 0.5–4.3).

The use of epidural analgesia was associated with a significantly increased risk of uterine rupture (OR 2.1, 95% CI 1.2–4.7); it was administered to 53.68% of the women who had a rupture and 42.36% of the women who did not (Table 5). All cases of uterine rupture occurred in women who did not have a prior vaginal delivery ($p = 0.02$). The use of oxytocin, induction of labor by double balloon catheter, index cesarean performed as an emergency during labor, and high pre-pregnancy BMI were all associated with uterine rupture, but no risks were significantly increased. The inter-delivery interval, the age of the woman, and induction of labor by AROM were not found to be associated with the risk of uterine rupture. Since the crude OR estimates did not substantially change in a multivariate regression analysis model (results available on request from the authors), only crude ORs were shown.

Discussion

This study showed that neonatal depression was more frequent after TOLAC than after ERCD-MR. Furthermore, TOLAC failed in 25% and this risk was associated with no prior vaginal delivery, an index cesarean performed during labor, maternal age ≥ 35 years, and a pre-pregnancy BMI ≥ 30 kg/m². The risk of complete uterine rupture after TOLAC was 2%. Major strengths of the study are the exclusion of women who already had a vaginal delivery after their cesarean section and the prospective classification of each ERCD-MR case ensuring that all women in this group were eligible to undertake a TOLAC. Therefore, it seems reasonable to assume that the women in the TOLAC and the ERCD-MR groups had very similar beforehand risks for adverse outcomes[8], which might

not have been the case in previous publications on this issue.[9] Another strength was the use of standardized definitions of uterine rupture and a reliable registration of outcomes and confounders, although information about smoking was not available. As a result of the registration method, women who planned an ERCD, who presented with spontaneous onset of labor and had a vaginal delivery, were registered as a TOLAC. We assume this concerned a limited number of women. Though we adjusted for confounders in the outcome analyses, residual confounding may persist. This may in particular apply to women with a previous vaginal delivery, who were not surprisingly over-represented in the TOLAC group. Furthermore, the study was underpowered to evaluate associations to perinatal mortality, and a short inter-pregnancy interval.[10] Concerning external validity, the results can be used when counseling pregnant women with one prior cesarean and with no contraindications for vaginal delivery in a setting where continuous cardiotocography is used, the midwife who cares for the woman is present continuously during active labor, and where it is possible to conduct a cesarean section within 15–30 min after the decision. The generalizability of our results may be slightly limited regarding centers only using double-layer suture. However, it must be emphasized that the absolute risks of neonatal depression after TOLAC, with 1% having had 5-min Apgar scores < 7 and 1% having umbilical vessel pHs < 7.0 , were not much higher than those associated with a first time vaginal delivery. Furthermore, it should be noted that no children died or had sequelae related to uterine rupture. The low incidence of neonatal death in this study is consistent with results from larger cohort studies.[11-13] The chance of VBAC after an index cesarean conducted during the second stage of labor was not addressed in the present study, but it might be as low as 10% [14] TOLAC has been associated with VBAC-rates of 49– 87%.8 Studies with higher rates, however, included women with prior VBAC (2) or excluded women who had their labor induced (10), whereas a study with a lower rate included women with medical complications.[12] The ORs in the present study concerning age, BMI and birthweight were consistent with those in previous publications[8,15-17] and so was the increased risk of acute cesarean if the index cesarean was performed during labor.[15] Publications showing somewhat higher ORs of failed TOLAC among women without any vaginal delivery before the index cesarean are not directly comparable to the present study as they did not distinguish between prior VBAC and vaginal delivery before the index

cesarean.[15,17] Our rate of uterine rupture was low, but somewhat higher than those between 0.2 and 0.9% reported previously.[18,12] Of major importance are different definitions of uterine rupture. We did not only include women who had symptoms and rupture, but also women with ruptures found during a cesarean section procedure performed for other indications. The discrepancy in rates might also be related to an increased risk of rupture associated with the use of single-layer closure of the uterus found in one of two recent studies and rejected in a meta-analysis.[19-21]. The discrepancy might also be related to differences in registration practice, to different definitions of TOLAC, to the inclusion of patients with prior VBAC, and to different handling of TOLAC, such as the use of epidural analgesia 23 and oxytocin for augmentation.[22,23]. It is noteworthy that the risk of rupture with induction of labor by double balloon catheter (OR 1.7, 95% CI 0.5–3.7) seems to be less than seen at induction of labor by prostaglandins22,-24 (5,7,20). The rate of vacuum extractions was 14% for the TOLAC group, which is close to the rate for women in Robson group one (16.3% in Denmark in 2010, data from the National Birth Registry).25. The risk of maternal hemorrhage was in our study more than five times greater for women attempting TOLAC compared with women who had an ERCD. This association is consistent with a study by Crowther et al, but is in contrast to some other reports.26

Conclusion

Our study suggests that TOLAC, in addition to being associated with uterine rupture and maternal hemorrhage, is associated with an increased risk of neonatal depression and NICU admission. Despite this, none of the infants in our study had sequelae after 12 months. The gain from TOLAC is found in the majority of women who end up giving birth vaginally without rupture and without an affected child. These women have a better chance of future vaginal birth and so can avoid the increased risk of severe complications associated with repeated cesarean sections, such as placenta previa and placenta accrete.[8,27]We therefore conclude that it is reasonable to advise women to undertake TOLAC when individual risk factors are also taken into account.

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