

ORIGINAL ARTICLE



Effect of a Locally Tailored Clinical Pathway Tool on VBAC Outcomes in a Private Hospital in India

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Abstract

Background Customized clinical and administrative interventions in the form of a care pathway tool can improve VBAC outcomes and reduce the alarming rise in caesarean sections globally.

Objective To determine the effect of a locally tailored clinical pathway tool on VBAC outcomes in a private hospital in India. **Methods** A pre- and post-implementation study was conducted in a private hospital in India. All women with one previous caesarean section term pregnancy and cephalic presentation were included at baseline from January 2013 to December 2015 (Phase 1) and from January 2016 to December 2018 (Phase 2) after ongoing implementation of a clinical pathway tool by all providers. Background characteristics and clinical outcomes in both phases were reviewed retrospectively from case files. **Results** Overall 223 (13.42%) women among 1661 total births and 244 (11.62%) women among 2099 total births were included in Phase 1 and Phase 2, respectively. Total number of women who underwent trial of labour (TOLAC) increased from 36.77% to 64.34% (P < 0.001) and VBAC rate increased from 23.76% to 58.19% (P < 0.001) in Phase 2. There was no significant difference in perinatal morbidity and mortality in the two phases.

Conclusion A locally customized clinical care pathway tool implemented to support both mothers and care givers for TOLAC seemed to improve VBAC outcomes in a private setting in India.

Keywords Vaginal birth after caesarean section (VBAC) \cdot Trial of labour after caesarean (TOLAC) \cdot Elective repeat caesarean section (ERCS) \cdot VBAC attempt rate \cdot VBAC rate \cdot VBAC success rate \cdot Clinical care pathway \cdot Robson V

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Introduction

International obstetric guidelines universally indicate that attempting VBAC is a safe and appropriate choice for most women.[1, 2]

Nevertheless, hospitals all over the world reveal declining trends of trial of vaginal delivery after one previous caesarean and VBAC. VBAC rates vary significantly from one country to another, ranging from 9.6 to 52.2%.[3] Thirtysix percent women with previous caesarean who attempted labour at a tertiary care hospital in central India had vaginal births.[4] Another study encompassing teaching hospitals in India indicate low overall VBAC rate (16%), although success rate of vaginal births who attempted TOLAC was 62%. [5] The debate over VBAC versus ERCS is critically relevant as the nation witnesses steeply rising primary caesarean rate.

One of the reasons of global decline in TOLAC could be some well-designed studies which cast doubt on the safety of practice of VBAC [6]. The most common deterrent is the fear of rupture uterus. The risk of rupture associated with TOLAC is 0.5% and is comparable to other acute obstetrical events like cord prolapse (0.1–0.6%) and abruption (1%) [7, 8]. However, there is a perception that the risk of rupture is unacceptably high and the culture of care shifts to offering ERCS. Most patients are not able to make objective assessment of the risks involved and feel ERCS is the best option. Some are keen to undergo CS before 39 weeks to avoid labour which increases perinatal morbidity due to respiratory complications in the neonate [9].

Repeat CS also increases the risk of placenta accreta predisposing mother to life-threatening haemorrhage. Placenta accreta risk is 0.24%, 0.31% and 0.57% after first, second and third caesarean section, respectively [10]. The risk of placenta accreta after two previous CS is similar to rupture uterus during VBAC, a crucial fact not to be overlooked while deciding care for mothers who plan to have many children.

Marked international variation in VBAC rates reflects the influence of the healthcare system on plan of care [3]. Inconsistent antenatal counselling, solo practice care, litigation pressures in private sector and lack of manpower with overcrowded facilities in public sector are important determinants of VBAC outcomes. Background data in our hospital in 2013 revealed high overall CS rate (39%) and low VBAC rate (19%). Sensitized to the global epidemic of CS, we introduced a standardized clinical care pathway tool in our hospital in 2016 with the aim of improving VBAC rates without adversely affecting perinatal morbidity.

Materials and Methods

Sitaram Bhartia Hospital is a 70-bedded tertiary care private hospital with around 700 annual births. Approximately 15% of these women belong to Robson group V classification and may be eligible for VBAC. Our study population comprised of women with one previous CS with cephalic presentation who delivered after 37 weeks of gestation and fulfilled the inclusion criteria. Perinatal outcome was evaluated in two phases—Phase 1 (1 January 2013 to 31 December 2015) prior to introduction of a standardized clinical care pathway (refer Table 1) and Phase 2 (1 January 2016 to 31 December 2018) after introduction of the same. All data were collected anonymously from records.

Exclusion criteria:

- Women with ≥ 2 previous caesarean sections.
- Previous classical caesarean section.
- Multiple gestation.
- Malpresentation.
- Placenta previa.

During Phase 1, eligibility criteria for TOLAC included maternal choice and non-recurring indication for previous CS with an inter-delivery interval of at least 2 years. The providers were practising solo, and there was variable compliance to promoting VBAC. Few women attended the antenatal workshops. Those who declined TOLAC were not offered the option of a second opinion. ERCS when desired by maternal choice was planned at 38-week gestation. If any of these women presented in labour, no further counselling for TOLAC was offered.

In Phase 2, all eligible mothers were subjected to a multidisciplinary evidence-based clinical care pathway utilizing international guidelines and OPTIBIRTH project [1, 2, 11]. A clinical pathway is a tool for achieving coordinated care and desired outcomes within an anticipated time frame by utilizing the appropriate resources available. It is a blueprint that guides the clinician and maps the whole journey of a patient [12]. The care pathways have become a popular response in critical care and surgery [13, 14].

Table 1 Clinical care pathway highlights for improving VBAC rates

Antenatal period	Intrapartum period
Optimum selection for VBAC of eligible women by one of the five senior providers	Uniform protocol for labour management
Participation in antenatal VBAC workshop conducted in the presence of one of the same providers	Partner support
Focused antenatal counselling, motivation and preparedness regarding VBAC at booking visit and in third trimester at least twice Provision of VBAC information sheets with benefits and risks explained	Senior consultant onsite supported for CS within 20 min
One physiotherapy and diet session in each trimester	Senior nurse with 1:1 care and continuous CTG in active labour
Offering sweeping of cervix twice at 39 weeks and 40 weeks. Allowing mothers to labour till 40 weeks + 6 days if no other risk factor Offer selective inductions	Continuous OT and anaesthesia availability
Group practice among consultants	Women planned for ERCS were recounselled for TOLAC if they came in labour

A crucial component of the clinical care pathway was transition from solo to group practice among the same group of senior consultants. Five senior consultants were responsible for providing antenatal and intrapartum care supported by five attending consultants.

Reasons for previous caesarean section were discussed along with the relative merits and disadvantages of ERCS and TOLAC in the first antenatal visit. Video testimonials from women who had experienced successful VBAC were shared. Finally, a mode of delivery was agreed, the care pathway checklists completed and VBAC information leaflets provided to all eligible women.

Care was provided by five senior providers in emergency hours by rotation. Each woman met at least two providers antenatally to instil confidence in the VBAC plan. All women attended the antenatal VBAC education workshop. In case any woman missed the workshop, provision was made to ensure individualized counselling. They were informed about a structured exercise schedule and individualized diet plan to avoid excessive weight gain. Those with residual reservations about vaginal delivery were offered an appointment with a second senior care provider. A final decision on the mode of delivery was confirmed at 36 weeks. All women planning a TOLAC were offered a sweep of cervix at 39 and 40 weeks to increase their chance of going into labour spontaneously. Women who did not spontaneously labour by 40 weeks plus 6 days were reassessed and induction offered if Bishop's score was favourable. Women with an unfavourable cervix were offered elective CS and those who had chosen ERCS from the outset were offered this at 39-week gestation [1].

Reporting in early labour was encouraged and accommodation with intermittent monitoring in a comfortable area away from the labour ward was done. Mothers were shifted to labour ward in active stage. The care pathway was maintained until delivery including one to one care provided by a senior nurse and continuous electronic foetal monitoring. Operating theatre, anaesthetic and senior consultant cover was available onsite 24 h to ensure rapid response to a category 1 CS within 15 min.

Primary Outcome Measures (In Phases 1 and 2)

- VBAC attempt rate—proportion of eligible women who opted for labour (TOLAC).
- VBAC rate—VBAC birth among all women with one previous CS (Robson Group V).
- 3. VBAC success rate—success rate of vaginal birth among the women who opted for TOLAC.

Secondary Outcome Measures (In Phases 1 and 2)

1. Proportion of women who went into spontaneous labour (Va) and those who were induced (Vb).

2. Proportion of women opting for ERCS due to nonmedical and medical reasons (Vc).

- 3. Number of instrumental deliveries.
- 4. Perinatal outcomes.

Categorical variables were presented in number and percentage. Qualitative variables were compared using Chi-square test/Fisher's exact test. Relative risk with 95% CI for maternal and perinatal complications was calculated. A *P* value of < 0.05 was considered statistically significant. The data were entered in MS Excel spreadsheet, and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

Results

Robson V included all women with term pregnancy cephalic with one previous CS with normally positioned placenta. Robson I and II included all nulliparous term cephalic (NTSC) women for comparison.

The age of women in both phases was comparable (P = 0.4033). Majority of the women belonged to age group 30–34 years. Women were distributed into spontaneous labour, induced labour and those who underwent ERCS. In Phase 1, 63.22% women had an ERCS compared to 35.65% in Phase 2. More women were chosen for ERCS at 39 weeks and beyond in Phase 2 (refer Table 2).

VBAC attempt rate in Phase 2 was 64.34% as compared to 36.77% in Phase 1 (P < 0.0001). VBAC rate showed more than twofold rise (58.19% Vs 23.76%) (P < 0.0001). VBAC success rate increased to 90.44% from 64.63% (P < 0.0001) (refer Table 3).

In Phase 1, 53 (64.43%) women delivered vaginally including three instrumental deliveries and 29 (35.36%) underwent emergency CS, whereas 142 (90.44%) women in Phase 2 delivered vaginally including 24 instrumental deliveries and 15 (9.55%) women had emergency CS. Failure of progress of labour was the most common indication of emergency CS followed by foetal distress. One baby had APGAR < 7 at 5 min in Phase 2; baby was later diagnosed with congenital leukaemia. Bladder injury was seen in two patients in each phase. The incidence of PPH was significantly increased in Phase 2. Around 40% women in spontaneous labour in each phase received oxytocin for augmentation of labour (Table 4).

Table 2	Demographic
characte	ristics & distribution
accordin	ng to modified Robson
classific	ation

Table 2 Demonstration

Proportion of women in Robson group I and II and Robson group v among total deliveries in Phase 1 and Phase 2				
Total deliveries	Phase 1 $(n = 1661)$	Phase 2 ($n = 2099$)		
No. of deliveries Robson I and II (%)	946 (56.95%)	1304 (62.12%)		
No. of deliveries Robson V (%)	223 (13.42%)	244 (11.62%)		
Age distribution of women (Robson grou	p V)			
Age (years)	Phase 1 ($n = 223$)	Phase 2 $(n = 244)$		
P=0.4033				
<20	0	0		
20–24	0	2		
25–29	30	30		
30–34	134	137		
35–39	55	66		
≥40	4	9		
Distribution of patients according to mo	dified Robson classificatio	on V		
	Phase 1 ($n = 223$)	Phase 2 $(n = 244)$	P<0.0001	
Spontaneous labour (Va)	57(25.56%)	109(44.67%)		
Induced labour (Vb)	25(11.21%)	48(19.67%)		
ERCS (Vc)	141(63.22%)	87(35.65%)		
Comparison of period of gestation at ER	CS (Vc)			
POG at LSCS (Vc)	Phase 1 $(n = 141)$	Phase 2 $(n = 87)$		
37–37 ⁺⁶ Weeks	5 (3.54%)	9 (10.34%)		
38–38 ⁺⁶ Weeks	50 (35.46%)	17 (19.54%)	P = 0.016	
39–39 ⁺⁶ Weeks	55 (39%)	35 (40.22%)		
40–40 ⁺⁶ Weeks	23 (16.31%)	25 (28.73%)	P=0.039	
≥41 Weeks	2 (1.41%)	1 (1.14%)		

Comparison of VBAC attempt rate			
	Phase 1 ($n = 223$)	Phase 2 $(n = 244)$	P<0.0001
Spontaneous labour (Va) + induced labour (Vb)	57 + 25 = 82	109 + 48 = 157	
VBAC attempt rate	36.77%	64.34%	
Comparison of VBAC rate			
	Phase 1 ($n = 223$)	Phase 2 ($n = 244$)	P<0.0001
No. of vaginal deliveries	53	142	
VBAC rate	23.76%	58.19%	
Comparison of VBAC success rate			
Women undergoing trial of scar (Va + Vb)	Phase 1 $(n=82)$	Phase 2 $(n = 157)$	P<0.0001
No. of VBAC	53	142	
VBAC success rate (%)	64.63%	90.44%	

Results are summarized in Fig. 1.

Discussion

Table 3 Primary outcome

measures

Delcare survey showed that previous CS as a sole indicator contributed to about 15% of the total caesarean sections in a population based study in Delhi [15]. This rate continues to increase in parallel with the rapid rise of primary caesarean

sections. An increase in perinatal complications due to high operative interventions is a major national concern. There is an utmost need to offer VBAC to appropriate women and create a process design to support care providers for maximizing success.

In 2015, we realized that by standardizing protocols and audit processes, we were making a significant difference to NTSC rate, but not impacting the VBAC rate. Discussion with senior providers practising solo revealed their

 Table 4
 Secondary outcome measures

Outcome of trial of scar (va+vb)					
TOLAC candidates	Phase 1 ($n = 82$)	Phase 2 $(n = 157)$	P<0.0001		
Normal vaginal delivery	50	118			
Instrumental delivery	3	24			
Emergency caesarean	29 (35.36%)	15 (9.55%)			
Oxytocin use in trial of scar					
	Phase 1	Phase 2			
Oxytocin use in spontaneous labour (Va)	24/57 (42.10%)	42/109 (38.53%)			
Oxytocin use in induced labour (Vb)	24/25 (96%)	34/48 (70.83%)			
Maternal complications and perinatal outc	ome				
	Phase 1 ($n = 223$)	Phase 2 $(n = 244)$	P value RR (95% CI)		
Postpartum haemorrhage (PPH)	5	18	0.017 3.29 (1.24–8.71)		
Third-/fourth-degree perineal tear	1	3	0.381 2.74 (0.29–26.17)		
Bladder injury	2	2	0.928 0.91 (0.13–6.43)		
Scar dehiscence	1	2	0.621 1.83(0.17–20.02)		
Uterine rupture	2	1	0.521 0.46 (0.04–5.00)		
APGAR <7 at 5 min	1	1	0.949 0.91(0.05–14.52)		
Indications of emergency caesarean section	ı in TOLAC group				
	Phase 1 ($n = 29$)	Phase 2 $(n = 15)$			
Failed induction of labour	5 (17.24%)	0 (0%)			
Non progress of labour	12 (41.37%)	7 (46.66%)			
Non reassuring CTG/Fetal distress	7 (24.13%)	5 (33.33%)			
Scar tenderness	4 (13.79%)	2 (13.33%)			
Abruption	0 (0%)	1 (6.66%)			
Refusal for further trial of labour	1 (3.44%)	0 (0%)			
ERCS for non-medical reasons among vc (prelabour cs)				
	Phase 1 $(n = 141)$	Phase 2 $(n = 87)$			
No of Women	35 (24.82%)	2 (2.29%)			

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insecurity about safety of care in emergency hours. Clinician factors play a considerable role in influencing a woman's decision to attempt a trial of labour and subsequent VBAC success rates [3]. Another challenge that we faced was a high number of women opting for prelabour CS. We formulated a clinical pathway tool to overcome these local barriers of attempting VBAC.

The care pathway in our study was inclusive of evidence based management guidelines and best practice recommendations to address our barriers for attempting VBAC. We made several opportunities to meet multiple experienced providers in the care pathway. Focussed motivation and open discussion of fears resulted in withdrawal of CS requests.

Intensive intrapartum surveillance in TOLAC is the backbone of ensuring safety. Provision of a senior nurse for 1:1 labour support provided immense confidence to mother but also meant logistic issues like a flexible roster for nurses. Group practice among senior providers increased the reliability of care and instilled confidence of safety within the team. Anaesthetists and neonatologists were also sensitized regarding urgency of an emergency CS in a woman undergoing VBAC. These strategies required sustained financial support from administration. Interdepartmental meetings in the presence of CEO reinforced the seriousness of the leadership resolve to address the problem.

A similar study involving only two management strategies and three senior consultants in St George Hospital, Sydney, was found to improve VBAC rates. The strategies studied were (i) allocating responsibility for VBAC candidates attempting labour to the hospital's three high-risk obstetric consultants and (ii) implementing a next birth after caesarean (NBAC) antenatal clinic [16].





Fig. 1 Flowchart showing women included in the study

However, OPTIBIRTH project which had a similar vision did not show promising results. The intervention used a motivational design and consisted of two antenatal education classes of two hours each and a one-hour information session for clinicians. The clinical effectiveness of the intervention was tested through a cluster randomized trial in three countries with low VBAC rates [11].

Strategies such as NBAC clinic and computer-based paper decision aids have not demonstrated a significant subsequent improvement in VBAC rates [17]. This indicates that antenatal interventions alone may not be enough, and customized antenatal and intrapartum strategies are required for visible impact.

Globally, VBAC success rate ranges from 70 to 75% [1]. It was 64.63% in Phase 1 which is comparable to international figures. However, with implementation of our clinical care pathway, the rate showed a rise to 90.44% which is comparable to another Indian study [18]. VBAC success rates in some studies were reported to be lower [4, 19]. These studies were retrospective and did not involve multiple structured processes to improve outcome. Overall our vaginal births among women with one previous CS were 58.19% in Phase 2 which is comparable to countries with the highest overall VBAC rates [3].

Attempting VBAC in women who have maximum chance of success is important, as the morbidity and mortality in emergency CS following failed VBAC are increased compared to planned CS [1]. We could achieve a low emergency CS rate of 9.55% among TOLAC patients in Phase 2 by implementation of the care pathway tool.

There was no maternal mortality; scar dehiscence and rupture were rare. Scar dehiscence may be asymptomatic in up to 48% of women [20]. In Phase 1, a 1-cm area of scar dehiscence in midline of lower uterine segment was noted during emergency CS for scar tenderness in one patient who presented in spontaneous labour. The baby was born in good condition. Two cases of scar dehiscence occurred in Phase 2. One of them presented with ruptured membranes with fever and refused induction. She underwent emergency CS (on demand) which inadvertently revealed scar dehiscence. The baby did well. In the other case, acute foetal bradycardia in the second stage led to instrumental delivery. The baby was born with Apgar scores of 4, 7 and 9 and needed resuscitation. Postpartum USG due to PPH suspected scar dehiscence which was managed conservatively. The patient required no further intervention.

Uterine rupture is associated with significant morbidity with need for prompt caesarean and uterine repair or hysterectomy. In our study, two cases of uterine rupture were seen in Phase 1 and one case in Phase 2. Oxytocin was used in all three cases of rupture uterus. In Phase 1, one woman had a rare posterior wall rupture at 4-cm dilatation and this reinforces the need to check the entire uterine integrity before closure in an emergency CS after TOLAC. Baby was born in good condition. The second woman came with premature rupture of membranes and underwent CS for abnormal CTG after epidural analgesia. Intraoperatively rupture was noted involving 2 cm of left lateral wall of uterus. The baby had severe hypoxia at birth and early neonatal death.

The woman in Phase 2 presented in spontaneous labour, but underwent CS in view of pathological CTG which revealed scar rupture. Baby responded immediately to resuscitation and had an Apgar score of 3, 7 and 9. A high index of suspicion and constant continuous vigilance is a prerequisite for TOLAC.

The reported incidence of uterine rupture with prior CS ranged from 0.22 to 0.5% in some developed countries [21, 22]. A study in India reported the incidence of uterine rupture in prior CS as 1.69% [23]. Our study reported 0.4% incidence of scar rupture in Phase 2. Good maternal and foetal outcomes are achievable, with prompt coordinated team response and swift recourse to caesarean section in the rare case of uterine rupture.

Bladder injury was seen in two patients in each phase. The incidence of bladder injury during caesarean section was quoted as 0.47% in a large case series [24]. Incidence of PPH was significantly increased in Phase 2. In Phase 1, PPH was recorded from case files which documented PPH as per assessment of individual care provider. In the year 2016, at the start of the second phase we had modified the labour and delivery record sheet in case files where specific columns were added to document PPH as per estimated blood loss during delivery [25]. Hence, possibly all cases of PPH including minor PPH were documented accurately in Phase 2. This could potentially impact the quantitative documentation of PPH in the second phase. However, two women in each phase required blood transfusion due to major PPH and none required surgical intervention. This indicates comparable morbidity due to PPH in both phases.

Around 40% women in spontaneous labour in each phase received oxytocin for augmentation of labour. There is a twofold to threefold increase risk of uterine rupture with oxytocin induction or augmentation [1], and we note that the use of oxytocin as part of our VBAC policy may have the potential of serious morbidity. However, if oxytocin use was to be abandoned, VBAC success rates are likely to be reduced. This raises the inevitable question of balance between whether the cost of lowering ERCS by increasing VBAC rates is too great.

It is unclear which particular strategy in the VBAC pathway had more impact than another; this represents a limitation of our study. We had five senior obstetricians willing to provide a 24-h on-call service which may not be generalizable to other clinical settings. The weakness of our study is that it was performed in a single centre, non-randomized with a modest sample size, and management strategies were not independently studied. These factors may limit the external applicability of our results. However, having a provision of a specialized VBAC labour ward in low resource settings with a lower nurse-patient ratio can be considered. Promoting VBAC in such centres is especially important as subsequent pregnancies may be unsupervised with the looming dread of placenta accreta after caesarean births.

The pre–post-approach had applicable process and outcome measures. To the best of our knowledge, this is one of the few studies on process improvement for VBAC outcomes in private sector. The private sector caters to a considerable fraction of maternity care in Delhi [12]. We understand that multiple confounding factors not included in the study can affect mode of delivery. But the clinical pathway tool after implementation showed improvement outcomes with the same senior providers in the same clinical setting and emphasizes the need of systemic changes in all institutions.

We conclude that a structured clinical pathway tool can improve VBAC rates but acknowledge that the application of this multifaceted care pathway may not be universally feasible.

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Compliance with Ethical Standards

Conflicts of interest Nikita Kumari, Neeru Jain and Rinku Sen Gupta Dhar declare that they have no conflict of interest.

Research Involving Human Participants and Informed Consent Our study involved anonymous review of relevant clinical parameters from case records, before and after implementation of a clinical care pathway tool which was a bundle of evidence-based practices. No consent was taken as data were collected from case records retrospectively. Ethical approval was taken from institutional ethics committee.

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