Predictive Efficacy of the FLAMM Calculator in Assessing Successful Trial of Labor after Cesarean (TOLAC)

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Abstract: <u>Background</u>: There is increasing trend of cesarean section influencing the rate of repeat cesarean section. The overall rate of cesarean section needs to be reduced by Trial of Labor after a cesarean (TOLAC) which is safe for both fetus and mother. If success of TOLAC can be predicted beforehand by certain parameters it will improve the decision - making process in women attempting TOLAC. <u>Methodology</u>: To evaluate the efficacy of FLAMM calculator in predicting the successful TOLAC among women with previous one LSCS, a prospective observational study was conducted on 100 pregnant women with \geq 37 weeks of gestation with previous one cesarean section. FLAMM score was calculated based on history and clinical examination at the time of admission. Labor was monitored and outcome of each woman was considered in view of successful TOLAC. Specificity, sensitivity and diagnostic accuracy of FLAMM scoring system was 93.18%, 67.86% and 79%, respectively. <u>Conclusion</u>: So, it was concluded that FLAMM calculator is good predictor for TOLAC, and as the total FLAMM score increases, the chance of successful vaginal birth after cesarean (VBAC) increases.

Keywords: TOLAC, vaginal birth after cesarean, LSCS, TTN, FLAMM score

1. Introduction

In modern obstetrics, cesarean section (CS) is the most common operation performed. The rate of cesarean section have increased dramatically worldwide. With availability of modern anaesthesia, improved surgical techniques and prophylactic antibiotics, cesarean section has become a common procedure. Cesarean delivery rates are also increasing all over India. The 2015–2016 India National Family Health Survey (NFHS - 4) estimated that 17.2% of all births nationwide are delivered by cesarean. [1] Repeat cesarean section is the most significant factor contributing to overall increased cesarean rates. [2]

2. Literature Survey

Repeat cesarean section accounts for an increased risk for short - and long - term complications for both mother and baby. Certain significant maternal complications which increase with increasing number of repeated cesarean section are severe adhesions, bleeding, abnormal placentation, uterine rupture, hysterectomy and visceral injury etc. Neonates delivered by cesarean, have increased risks of transient tachypnea of the newborn (TTN), respiratory distress syndrome (RDS), and persistent pulmonary hypertension of the newborn (PPHN). [3]

The overall rate of cesarean needs to be reduced and this can be achieved to a small extent by avoiding primary cesarean done without explicit indications and more importantly by resorting to Trial of labor after a cesarean (TOLAC) which is safe for both foetus and mother. Trial of labor after cesarean (TOLAC) is a planned attempt to allow labor in women who had a previous cesarean birth, regardless of the outcome of previous cesarean. [4]Vaginal delivery after cesarean section (VBAC) can be attempted based on successful trial of labor after cesarean section (TOLAC).

Having prior information regarding the probability of successful VBAC will improve the decision making process regarding the mode of delivery. [4]Hence, before giving TOLAC it is better to predict patients for successful TOLAC by different parameters. Several researches have suggested several models to predict success of VBAC. FLAMM is one of the calculator to predict rate of success of TOLAC by using several maternal factors. This study was conducted to evaluate the rate of successful TOLAC in a prospective cohort of women with previous one LSCS using FLAMM calculator.

3. Materials and Methods

This prospective observational study was conducted at tertiary care center between august 2021 - July 2022. A total of 100 pregnant women were included in the study. Women with previous one LSCS at term (\geq 37 weeks) with singleton vertex presentation were included in the study. Women who had previous 2 or more LSCS, previous myomectomy, hysterotomy or classical cesarean section, recurrent indication of cesarean section, multiple pregnancy, non - cephalic presentation and any patient contraindicated for vaginal delivery were excluded from the study.

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Assuming 76% as the incidence and 9% margin of error, the minimum required sample size at 5% level of significance was 87 patients. Hence, we collected data of 100 women for this study. After taking consent a total of 100 women with previous one lower segment cesarean section with more than 37 weeks of gestation with cephalic presentation in labor were included in the study. All women were given patient information sheet.

A thorough antenatal history including sociodemographic data (name, age, husband's name, address, phone number) and proper examination including general physical examination and obstetrical parameters (indication for index cesarean, the type of index cesarean performed (elective, emergency), preexisting conditions (hypertension, diabetes), interval between last and index pregnancy in months) was done in labor room. Routine investigations including complete haemogram, bleeding time, clotting time, blood grouping, viral markers random blood sugar was done at admission.

Flamm calculator was applied to women at admission. Flamm includes the following parameters maternal age, vaginal birth history, reason other than failure to progress for first cesarean delivery, cervical effacement at admission and cervical dilation \geq 4cm at admission. [5]Total score was calculated for each woman. women were monitored in labor. Outcome of each woman was considered in view of successful TOLAC. Successful TOLAC was defined as vaginal delivery following TOLAC. Maternal and perinatal outcome was recorded. Efficacy of the calculator was found in view of prediction of successful TOLAC.

Data was recorded in the FLAMM model. Maternal and perinatal outcome was recorded in the successful and failed TOLAC. The data entry was done in the Microsoft Excel spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, version 25. The presentation of the Categorical variables was done in the form of number and percentage (%). On the other hand, the quantitative data were presented as the means \pm SD and as median with 25th and 75th percentiles

(interquartile range). The data normality was checked by using Kolmogorov - Smirnov test. The cases in which the data was not normal, we used non parametric tests.

4. Results

During the study period of one year, 100 women with previous one cesarean section were enrolled. Out of 100 women 56 (56%) women underwent successful Trial of vaginal birth and 44 (44%) required cesarean section. Among the successful vaginal delivery, 1 patient had assisted vaginal delivery to cut short second stage in prolonged labor. In majority, mode of delivery was normal vaginal delivery (NVD) followed by LSCS. Instrumental delivery was seen in only 1 out of 100 women. The mean maternal age and body mass index (BMI) was 26.59 ± 4.5 years and 21.38 ± 1.59 kg/m² respectively (Table 1).

 Table 1: Demographic and gestational characteristics of the study participants (N=100)

Variable	Frequency (N=100)
Age (years)	
Mean± SD	26.59 ± 4.5
≤ 20	3
21 - 25	43
26 - 30	38
>30	16
BMI	
Mean \pm SD	21.38 ± 1.59
<18.5 kg/m ² (Underweight)	1
18.5 to 22.99 kg/m ² (Normal BMI)	89
23 to 24.99 kg/m ² (Overweight)	9
\geq 25 kg/m ² (Obese)	1
Period Of Gestation (Weeks) Mean± SD	38.98 ± 1.11
Inter pregnancy interval (Years) Mean± SD	3.8 ± 2.05

Women having previous vaginal delivery before and after cesarean section has 100% successful TOLAC. There was 1 failed TOLAC in a subject after 1st cesarean section, whereas 5 subjects had failed TOLAC before 1st cesarean section. (Table 2).

Table 2: Distribution of vaginal birth according to the successful trial of labor after cesarean

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Vaginal birth	Total	Successful TOLAC (Vaginal delivery) (n=56)	Failed TOLAC (CS) (n=44)			
Before and after cesarean section	2 (100%)	2 (100%)	0 (0%)			
After 1st cesarean section	16 (100%)	15 (93.75%)	1 (6.25%)			
Before 1st cesarean section	20 (100%)	15 (75%)	5 (25%)			

Cervical factors, in terms of dilatation and effacement have been studied individually in this study and found to be useful in predicting vaginal birth. Proportion of women with successful TOLAC had significantly higher cervical dilatation (cm) >3 cm (100%) as compared to cervical dilatation (cm) \leq 3 cm (43.59%) with odds ratio of 58.078 (3.192 to 1056.694) (Table3).

Cervical factors		Successful TOLAC	Failed TOLAC	p value	Odds ratio	
	Total women	(Vaginal deliver) (n=56)	(CS)(n=44)	1		
Cervical dilatation						
\leq 3 cm	78 (100%)	34 (43.59%)	44 (56.41%)	<0.001*	1 (Ref)	
> 3 cm	22 (100%)	22 (100%)	0 (0%)		58.078 (3.192 to 1056.694)	
Cervical effacement (%)						
<25%	35 (100%)	7 (20%)	28 (80%)		1	
25 - 75%	55 (100%)	40 (72.73%)	15 (27.27%)	< 0.001*	10.148 (3.694 to 27.875)	
>75%	10 (100%)	9 (90%)	1 (10%)		24.220 (3.348 to 175.200)	

Table 3: Association of cervical factors with successful trial of labor

^{*}Fisher's exact test

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In the present study, mean FLAMM score for successful and failed TOLAC was 5.25 ± 1.38 and 3.43 ± 0.82 respectively as shown in Table 4. Chances of success of TOLAC increases with increasing FLAMM score. (p <0.001)

FLAMM score	Total	Successful TOLAC (Vaginal deliver) (n=56)	Failed TOLAC (CS) (n=44)	P value
0 to 2	5 (100%)	1 (20%)	4 (80%)	< 0.001*
3	23 (100%)	2 (8.70%)	21 (91.30%)	
4	31 (100%)	15 (48.39%)	16 (51.61%)	
5	19 (100%)	17 (89.47%)	2 (10.53%)	
6	11 (100%)	10 (90.91%)	1 (9.09%)	
7	8 (100%)	8 (100%)	0 (0%)	
8 to 10	3 (100%)	3 (100%)	0 (0%)	
Mean \pm SD	4.45 ± 1.47	5.25 ± 1.38	3.43 ± 0.82	
Median (25th - 75th percentile)	4 (3 - 5)	5 (4 - 6)	3 (3 - 4)	< 0.001#
Range	2 - 9	2 - 9	2 - 6	

Table 4: Association of FLAMM score with successful trial of labor

*Fisher's exact test, [#]Mann Whitney test

The area under the curve for predicting the successful TOLAC by FLAMM scores was determined as 0.876 (p<0.001). At a cut - off of 4 (>4), FLAMM score of >4 was able to predict the successful TOLAC with a sensitivity of 67.86%, specificity of 93.18%, positive predictive value of 92.7%, negative predictive value of 69.5% and diagnostic accuracy of 79%.

5. Discussion

The trial of labor after cesarean section should be considered in women without any contraindications, to decrease the rising cesarean and its complications. An obstetrician should be involved in the counselling during antenatal period regarding mode of delivery. Ideally, the decision process regarding the approach to delivery should be started early in pregnancy, and part of that process should be the provision of information, such as the likelihood that a VBAC will occur if TOLAC is undertaken. TOLAC calculators aims to predict the chances of successful VBAC based on patient's demographic and clinical factors. [6, 7] Several calculators are available to predict the rate of successful TOLAC. The use of such calculators may enable the obstetricians to predict the chances of success in the individual patient and to evaluate the risks and benefit, thus improving outcome in a trial of labor after previous cesarean section.

The current study was conducted in the Department of obstetrics and Gynaecology at Pt. B. D. Sharma PGIMS, Rohtak to assess the rate of successful TOLAC in a prospective cohort of women with previous one cesarean delivery using FLAMM calculator. [5]A total of 100 women with \geq 37 weeks with previous one LSCS with singleton vertex presentation were studied. Out of total 100 women, 56 women were found to have successful TOLAC and 46 women were found to have failed TOLAC. Mean age of the study group was 26.59 ± 4.5 years.

Previous vaginal birth is a strong predictor of success of TOLAC. Moreover, multiparous women with previous history of vaginal birth have less fear and anxiety regarding vaginal delivery and thus increasing the self - efficacy of mother to proceed for TOLAC. In our study women with history of vaginal delivery both before and after cesarean section was found to have 100% successful TOLAC. Successful TOLAC rate was comparatively higher in women

with vaginal delivery after first cesarean section than history of vaginal delivery before cesarean section. In our study 16 women had history of VBAC out of which 15 women (93.75%) had successful TOLAC whereas 20 women had history of vaginal birth before cesarean section out of which 15 women (75%) had successful TOLAC. Prior vaginal birth and specially prior vaginal birth after cesarean section have been observed to be a strong predictors of successful TOLAC. [8, 9] Sahu R et al also performed a study on 75 women with a history of previous cesarean section and obtained results similar to our study. [10]

It was observed in our study that patients having cervical dilatation >3cm had 100% successful TOLAC. Cervical dilatation was significantly associated with a successful outcome (p<0.001). This is because as cervical dilatation increases, there is release of prostaglandins and this in turn invade the cervix mediating the release of metalloproteases that break down collagen causing increase in cervical vascularity and softening. [11]This probably increases the rate of successful TOLAC. Similar outcome was also documented in a study conducted by Patel MD et al where successful TOLAC was found to be 82.9% (p=0.0001) in patients with cervical dilatation >3cm. [12] Hence, dilatation of cervix is an important predicting factor for success of TOLAC.

Women with cervical effacement >75% and 25 - 75% had successful TOLAC in 90% and 72.73% cases respectively, while women with cervical effacement <25% at the time of admission had successful TOLAC in only 20%. This difference was found to be statistically significant (p<.0001). Similar result (P<.0001) were also observed in study conducted by Patel MD. [12] Cervical effacement is an important component of assessment of progress of labor. As the cervical length shortens during labor, the probability of successful TOLAC increases and this can be due to the formation of lower uterine segment from the isthmus. As the lower uterine segment starts forming there is progressive descend of head causing the advancement of labor. [13]

Mean FLAMM score of women in successful TOLAC group was 5.25 ± 1.38 and was found to be comparatively less with women in failed TOLAC group i. e. 3.43 ± 0.82 . The difference was statistically significant with p value<.0001. At a score of ≤ 2 the probability of successful TOLAC was 20% and as the score increases to 4, 5, 6 the probability of

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successful TOLAC was 48.39%, 89.47%, 90.91% respectively. As the FLAMM score increases the probability of successful TOLAC increases and was found to be 100% at a score \geq 7. This corroborates well with other studies conducted by Patel RM et al and Sahu R et al. [10, 14] In the present study, when score was >4 success of TOLAC increased significantly to 89.47% or more. At a FLAMM cut off score >4, sensitivity at 95% CI was 67.86% and specificity was 93.18%. The diagnostic accuracy was found to be 79%

6. Conclusion

From the present study, it was observed that FLAMM is a good calculator for predicting success of TOLAC. The main factors related to the success of TOLAC were history of previous vaginal deliveryespecially prior VBAC, cervical dilatation and effacement. The results of our study have practical significance and can provide information to evaluate eligible women for TOLAC. So, by applying good predictive tool like FLAMM calculator patient can be selected initially for TOLAC based on the calculator parameters and score.

Conflict of Interest: None

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Data availability statement: The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author/s.

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