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ORIGINAL ARTICLE

Outcome of Induction of Labor with Foley's Catheter in Women with Previous One Cesarean Section with Unfavorable Cervix: An Experience From a Tertiary Care Institute in South India

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Abstract

Background Induction of labor in women with previous cesarean section is associated by the fear of scar rupture, resulting in high rates of repeat scheduled cesarean section. Mechanical methods are being advocated as a safe method. We present our experience of vaginal birth rates and safety profile with single-balloon Foley's catheter for induction of labor in women with previous one cesarean section.

Methods We studied 96 women admitted in Women and Children Hospital JIPMER, India, with a previous cesarean section at term having unfavorable cervix and undergoing induction of labor. Foley's catheter inflated to 60 ml was used for cervical ripening for 24 h followed by strict oxytocin infusion protocol.

Results The mean Bishop score before induction of labor was 3.3 ± 0.88. Ripening with Foley's catheter resulted in mean improvement in the Bishop score by 2.56 ± 0.67. Forty-seven percent women spontaneously expelled the Foley's catheter, and 53.1% achieved contractions spontaneously. The successful vaginal birth rate was 40%. Emergency caesarean section was more likely in women with poor post ripening Bishop score, meconium stained liquor and abnormal fetal heart rate pattern during labour. There was one scar dehiscence, one neonate with low Apgar score. There was no rupture uterus.

Conclusion Induction of labor with Foley's catheter resulted in a 40% successful vaginal birth rate and was found to be safe with only one scar dehiscence and no perinatal or maternal mortality. There was no perinatal or maternal mortality.

Keywords Cervical ripening · Cesarean section repeat · Labor induction · Rupture · Uterus · Vaginal birth after cesarean

Introduction

The average cesarean section rates in India account for around 17.2% as per the recent NHFS-4 (2015–2016) varying from 5.8% in Nagaland to 58% in Telangana [1]. One of the most prevailing indications for cesarean section is a previous cesarean delivery itself [2]. In some countries, the repeat cesarean rate is as high as 87.44% [3].

Trial of labor after cesarean section (TOLAC) is a well-recommended strategy to achieve vaginal delivery and reduce repeat cesarean section rates in selected women with previous one cesarean section [4, 5]. The biggest concern is scar dehiscence during labor, which is reported to be around 0.1 to 2.4% [6–9] In this regard, prostaglandins are contraindicated for induction of labor due to the high risk of rupture reported[5]. Spontaneous labor is the safest option for the successful vaginal birth in women with a scarred uterus. However, induction of labor may be needed for maternal or fetal indication. Mechanical methods like balloon catheters

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have been recommended for ripening of the cervix [10]. Foley's single-balloon catheter has been used as an alternative to double-balloon catheters for cervical ripening. We present our experience of induction of labor with the Foley's catheter in women with previous one lower-segment cesarean section who required delivery and had unfavorable cervix. The aim was to study the successful vaginal birth rates (VBAC) and any maternal or perinatal complications with its use. We also tried to analyze the factors that can predict successful VBAC in those with previous cesarean sections undergoing induction of labor.

Methods

This observational descriptive study was conducted in the department of Obstetrics and Gynecology of Jawaharlal Institute of Postgraduate Medical education and research (JIPMER), which is a tertiary care teaching hospital with about 1500 deliveries every month. The study was carried out after over 18 months after obtaining approval from the Institute's ethical committee (IEC No. JIP/IEC/2016/1046). Informed written consent was obtained from study participants.

Women with previous one lower-segment cesarean section, more than 18 years of age, fulfilling the eligibility criteria for TOLAC with a single fetus in vertex presentation with Bishop Score less than six and requiring induction of labor were included. Women with unknown or upper segment scars, baby weight more than 3.5 kg, malformed fetus, contraindications to vaginal delivery, and cases with premature rupture of membranes were excluded.

Eligibility criteria (based on three guidelines [4, 5, 11]) for TOLAC included document-confirmed previous one lower-segment cesarean section, inter-pregnancy interval more than 18 months, scar thickness more than 3 mm, adequate pelvis were considered eligible. Previous cesareans done preterm, in second-stage cesarean, for placenta previa and cesareans for transverse lie were also not considered eligible for TOLAC. Women who had complications in the previous cesarean like angle extension, wound infection, postpartum hemorrhage requiring compression sutures, or blood transfusions were also considered ineligible and excluded from the study. We had strict inclusion criteria as per the department protocol for induction of labor. We are more liberal for the eligibility for TOLAC among those in spontaneous labor. Ultrasound was performed in all the women, and pelvic assessment was done. Bishop's score was noted. A nonstress test was done for all women before labor induction.

A 22-French Foley's catheter was introduced into the cervical canal with the tip just beyond the internal os, under all aseptic precautions, after visualizing the cervix and stabilizing the anterior lip of the cervix with a ring forceps. The Foley catheter was directed toward the wall opposite of the placental site. The bulb was inflated with 5 ml saline and pulled back to rest over the internal os, and thereafter, it was filled to a total of 60 ml. The Foley catheter was strapped on the thigh and kept in place for 24 h. Nonstress was done after catheter insertion. The women were monitored for onset of labor/leaking/bleeding/any other complaints, and the fetus was monitored by auscultation every 4 h. If she did not spontaneously expel the catheter, then it was removed after 24 h of insertion. Repeat Bishop score was noted, and oxytocin was started with an infusion pump at 2 mIU/min and escalated every half an hour by 2miu/min till a maximum of 22 mIU/min or good contraction was achieved. Artificial rupture of membranes (ARM) was done with good uterine contractions or after 4 h of maximum dose of oxytocin. The women were carefully monitored for the progress of labor and features of scar dehiscence. The fetus was monitored by cardiotocography. If the women failed to achieve an active stage of labor even after 6 h of ARM, then it was considered failed induction, and an emergency cesarean section was performed. Injection ampicillin 1 gm was administered after ruling out an allergy to all women after artificial rupture of membranes.

Sample size calculation For an expected proportion of successful vaginal delivery of 55% [12] and absolute precision of 10%, a total of 96 women were studied for an alpha error of 5% and 95% confidence interval. Continuous variables were expressed as mean with standard deviation. Categorical variables were expressed as percentages. Continuous variables were compared in the successful and failed TOLAC group using an independent Student's t-test or Mann–Whitney U test depending on the normality of the data. Categorical variables were analyzed using Chi-square or Fischer's exact as applicable. A p-value of < 0.05 was taken as significant. Multivariable analysis was done for factors found significantly different on univariate analysis.

Results

During the study period, 620 women with a previous cesarean were screened and finally 96 women were recruited and completed the study (Fig. 1).

The mean age of the study group was 27 years (± 3.3). The majority of study population ($n = 89$, 92.7%) were primiparous. Prior VBAC was there in only 4.2% of women ($n = 4$).

The mean inter-pregnancy interval was 37.6 months (12 months).

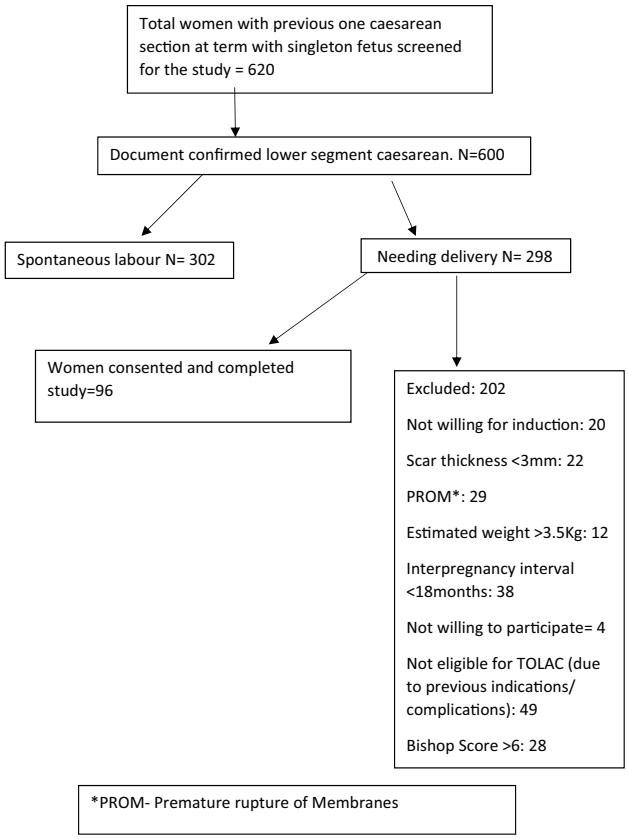

Fig. 1 Flow chart showing the recruitment of study population

The most common indication of the previous cesarean section was fetal distress ($n=38$, 40%). In 12.5% ($n=12$) cases, previous cesarean was done for nonprogress of labor.

The mean period of gestation of the study population was 39.5 ± 0.93 months. Twenty-five women (26%) had comorbidities. These details and the indication of induction are shown in Table1.

The mean pre-induction Bishop score was 3.3 ± 0.88. After removal of the Foley catheter, the mean increase in Bishop score was 2.56 ± 0.67. 47% of women spontaneously expelled the Foley catheter. 53.1% also achieved contractions spontaneously at 24 h of Foley insertion. Most of the women delivered within 24 h. Mean duration of the first stage was 332.10 ± 78.02 min. Mean duration of the second stage was 34.32 ± 8.5 min.

In three-fourth of the study population, there was no fetal heart rate abnormality during labor.

Successful VBAC was observed in 38 women (40%). Fifty-eight women had failed TOLAC requiring a cesarean section. Among the 38 women, 22 were delivered by instrument. The commonest indication for cesarean was failed induction ($n=32$) followed by fetal distress in 18 women. One woman had prolonged first stage of labor after achieving active phase of labor. Seven women had maternal tachycardia and abnormal fetal heart rate pattern. They were taken up for cesarean section suspected scar dehiscence. However, only one had actual scar dehiscence. She had developed spontaneous contractions after the removal of Foley's catheter. She was taken up for a cesarean section due to suprapubic pain and abnormal fetal heart rate pattern. Scar repair was done uneventfully. There were no other maternal complications. None of the women with instrumental delivery had anal sphincter tear or any hematoma formation or traumatic postpartum hemorrhage. There was no case of the ruptured uterus, sepsis, postpartum hemorrhage, intensive care unit admission, or blood transfusion in the study population. There was no maternal mortality.

Table 1 Demographic and obstetric details of the study population

Demographic parameters	N (%)	
Age (years)	20–25	33(34.4)
	26- 30	47(49)16(16.7)
	31–35	
Indication for induction	Past dates	20(20.8)
	Pastdates + oligohydramnios	15(15.6)
		40 (41.7)
	Decreased liquor (< 8)	6(6.3)
	Hypertension (2 had oligohydramnios)	11(11.5)
		3 (3.1)
	Diabetes	1(1.04)
	Rh incompatibility	
	Others	
AFI† at induction	< 3	1(1)
	3–5	22(22.9)
	5.1–8	34(35.4)
	> 8	39(40.6)

†AFI- amniotic fluid index

Only one neonate had an Apgar score of five at birth and needed a bag-and-mask ventilation. Only two babies were admitted to intensive care. One had a low birth weight of 1.6Kg but a good Apgar score, and the other had an Apgar score of five at the first minute and seizures 24hours later. The baby recovered well and was discharged after six days.

Factors associated with successful vaginal delivery are shown in Table 2. There were a significantly higher pre- and post-induction Bishop score and a higher proportion of women who spontaneously expelled the Foley in the vaginal delivery group compared to the emergency cesarean group. The presence of abnormal fetal heart rate patterns and meconium-stained liquor was significantly higher in the emergency cesarean group.

A multivariate analysis is not presented as the confidence interval was found to be very wide. The study was not powered to determine the predictor of successful VBAC.

Table 2 Univariate analysis of various factors associated with successful VBAC

Variables		Mode of delivery Vaginal, Cesarean $N=38$ N = 58	Student's t value (95% CI §,) / Chi-square X^2, *P* value
Pre-induction Bishop's score (Mean ± SD†)		3.55 ± 0.50 3.15 ± 0.41	t = 4.05 (3.2 − 3.4), *P* = 0.0001
Post-induction Bishop's score (Mean ± SD†)		6.52 ± 055 5.48 ± 0.53	t = 9.10(5.7–6.0) P = 0.0001
Spontaneous Foley expulsion. N (%)	YES NO	32(71.11) 13 (28.89) 6(11.76) 45 (88.24)	$X^2 = 35.2072$, P = 0.0001
Abnormal fetal heart rate N (%)	NO YES	37(51.39) 35 (48.61) 1(4.17) 23 (95.83)	$X^2 = 16.78$, P = 0.0001
Oxytocin requirement (mIU‡) Mean (± SD†)		10.6 ± 2.9 16.2 ± 4.4	t = − 6.60, (12.8–15.8), *P* = 0.0001
Liquor status N (%)	Clear meconium	38 (43.48) 49 (56.32) 0 9 (100)	$X^2 = 6.5065$, *P* = 0.011

†-SD: standard deviation, ‡-mIU = Milli-international unit, §- CI = Confidence interval

Discussion

Labour induction has been recommended for properly selected women eligible for TOLAC by most of the guidelines as an initiative to reduce repeat cesarean section rates [4, 5, 11]

Our study involved a cohort of 96 women with previous cesarean undergoing induction of labor with Foley single balloon catheter for 24 h followed by oxytocin infusion. Our successful VBAC rates were 40%. We had no perinatal mortality or maternal complications. Mechanical methods have been studied for pre-induction cervical ripening for women with previous cesarean section and found to be safe [10, 13, 14].

A retrospective cohort study by Gonsalves et al. included 68 women from Muscat Oman [15]. Like our study, the most common indication for induction in their study was oligohydramnios. They observed an overall success rate of 69%. One-third of their study group were multiparous. They also observed that the successful VBAC group had a higher pre-induction Bishop score and a higher proportion with previous vaginal delivery. The oxytocin dose and duration used are not detailed in the study by Gonsalves et al. Prior vaginal delivery has been reported to be an important predictor of successful VBAC by other authors also [16, 17]. In our study group, the VBAC rate was lower and only 8% had a previous vaginal delivery.

Meetei et al. [18] conducted a study to compare Foley with oxytocin for induction of labor in women with previous one cesarean section. The authors included 30 women in each group and found a success rate of 66.7% in the Foley group. They used oxytocin up to 34miu/min.

The highest recommended dose of oxytocin in women with the previous cesarean section as per RCOG guidelines is 20 muIU. We used up to 22 mIU in our study. The proportion of women undergoing cesarean for failed induction in our study was 60%. We performed an emergency cesarean section if the woman failed to be in the active phase of labor within 6 h of the highest dose of oxytocin and or artificial rupture of membranes.

Hemalatha et al. reported 30 women with previous cesarean sections induced with Foley catheter inserted for 24 h. They reinserted the Foley catheter if Bishop's score did not improve after a gap of 12 h after removal. Only 21 women had live fetuses; nine were induced for intrauterine fetal demise. They found a VBAC rate of 50%. There were no cases of the ruptured uterus, though three out of thirty were suspected to have scar dehiscence and taken up for emergency cesarean section [19].

In the study by Jozwiak et al. on women with previous cesarean requiring induction of labor, the Foley's catheter was inserted and repeated two more times. Amniotomy was done if Bishop's score was improved and oxytocin was given for augmentation if needed. They studied 208 women over nine years and observed a successful VBAC rate of 71%. The first-stage arrest was the commonest indication for repeat cesarean section. These authors also found prior vaginal delivery to be an important predictor of successful VBAC. They had two perinatal deaths of which one was due to a ruptured uterus. This study was conducted in the Netherlands, which has the lowest cesarean rates. They had higher infectious morbidity and postpartum hemorrhage of 6% and 12%, respectively [20]. Later in the PROBAAT study, they found a 23% cesarean rate in the Foley's arm. In this randomized trial also, the authors considered failed induction after 5 days of effort at induction, and repeat Foleys were inserted [21].

In the randomized trial carried out in Medical College Vellore, India, by Manish et al., the VBAC rates were low at 19.5% in the 80 ml inflation and 23.4% in the 30 ml inflation group. They observed a high rate of scar dehiscence of 9.1% in the 80 ml group [22]. They had used a balloon for 12 h only, and only single insertion was done. A study was carried out by Soni et al. in the rural area of

Himachal Pradesh, India. They studied TOLAC in 482 women with a previous cesarean section. However, labor was induced in only 34 women and only 14 of them delivered vaginally (successful VBAC rate of 41% among the induced group). They observed that 4% of women undergoing cesarean section had a scar dehiscence [23].

Our study involved a cohort of 96 women with previous cesarean undergoing induction of labor. Our successful VBAC rates were 40%. We took a higher cutoff of full thickness of scar on sonography because induction of labor has 2 to 3 times higher risk of scar rupture, and meta-analysis [24] done in 2013 showed variable sensitivity for variable cutoffs and the full thickness more than 3 mm provided the strongest negative predictive value of occurrence of defect during TOLAC. We had no perinatal mortality or maternal complications. The reason for the low VBAC rates could be attributed to the fact that more than 90% population in our study group did not have a previous vaginal delivery; only one insertion of Foley was done for ripening of the cervix and we had a low threshold for defining failed induction to qualify for an emergency cesarean, unlike the Dutch protocols where they gave multiple Foley insertion and waited for 5 days before defining it as a failed response to Foley catheter. We used 22 mIU as the maximum dose for oxytocin.

We found induction with Foley to be extremely safe for well-chosen women with previous one lower-segment cesarean section requiring induction of labor with poor Bishop score.

Strict induction and monitoring protocols and rigorous screening of women for selecting for induction of labor are associated with minimal to no maternal or perinatal complications.

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Compliance with Ethical Standards

Conflict of interest The authors declare that there is no conflict of interest.

Ethical statement The study was approved by the Institute Ethics Board. No IEC No. JIP/IEC/2016/1046.

Informed consent Informed consent was obtained from all the participants.

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