

To Study the Outcome of Cervical Ripening Balloon versus Foleys Induction as a Method of Induction in Full Term Pregnancy with Previous 1 LSCS Willing For VBAC

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ABSTRACT:

Background: Cervical ripening and/or labour induction in women's have not been proven to be the most effective, safest, or most effective methods. In order to better understand the factors that determine the efficacy of mechanical induction using a Foley's bulb, this study was conducted on patients who had previously undergone a one lower segment caesarean surgery with an unsalvageable infant (in our current configuration). **Aim:** To study and compare maternal and fetal outcome after induction of labor with foleys catheter and cervical ripening balloon in cases of previous 1 LSCS. **Material & Methods:** This was prospective observational study was conducted in the department of obstetrics and gynaecology of rural tertiary health care center, Karad from Dec 2020 – May 2022. **Results:** Among 63 cases were found ≤ 6 postcatheter Bishop Score in cervical ripening balloon (CRB) group whereas 25 (39.7%) in Foleys group. 49 (77.8%) out of 63 cases were found > 6 post catheter Bishop Score in CRB group whereas 38 (60.3%) in Foleys group. A p-value is 0.034 calculated using Chi-square test. There was significance difference found in both the study groups. Here 45 (71.4%) out of 63 cases were found vaginal delivery in CRB group whereas 34 (54.0%) in Foleys group. The mode of delivery, 18 (28.6%) out of 63 cases were observed C-section in CRB group whereas 29 (46%) in Foleys group. The P value was 0.0463 calculated by Chi-square test. In CRB group birthweight of neonate is significantly higher compared to foleys group. **Conclusion:** Bishop Score increment by CRB group is more effective than induction by Foley group.

Keywords: Cervical ripening, cervical ripening balloon, Foley catheter, caesarean section rate, labour induction.

Introduction:

Common obstetric interventions include induction of labour. In about 20–30% of pregnancies, the birth is induced. 10% of women who need an induction are thought to have had a caesarean birth in the past. Worldwide caesarean delivery rates are rising, and more women with damaged uteruses will require induction of labour during subsequent pregnancies. If given a chance to try labour naturally, studies have shown that 60–80% of women with prior caesarean deliveries can deliver safely vaginally. However, there is worry that labour, especially when it is induced, increases maternal and new-born morbidity and mortality in women with a scarred uterus as compared to a repeat caesarean section (CS). [1-3]

After a previous caesarean delivery, Lydon Rochelle et al. found that considerably more uterine ruptures occurred in women whose labour was induced with prostaglandins in 2001. Since then, additional cervical ripening techniques have attracted interest, and it has been questioned whether prostaglandins are safe for use in women who have had a previous caesarean delivery. One of these techniques is trans-cervical Foley catheter-assisted cervical ripening. Previous research has demonstrated that, when compared to intravaginal prostaglandin induction of labour, the use of a trans-cervical Foley catheter for cervical ripening is as successful in attaining vaginal birth. [4]

According to the NHFS-4 (2015-2016), the average caesarean section rate in India is 17.2%, with variations between 5.8% and 58% in the states of Telangana and Nagaland. A previous caesarean delivery itself is one of the most common reasons for a C-section. The repeat caesarean rate can

reach 87.44% in some nations. [5]

However, a maternal or foetal indication may require labour induction. For ripening the cervix, mechanical techniques such as balloon catheters have been suggested. For cervical ripening, Foley's single-balloon catheter has been utilised as an alternative to double-balloon catheters. [6]

In their comprehensive study, Heineman et al. demonstrated that using a Foley catheter in women who had never had a caesarean delivery was significantly more likely to result in maternal infectious morbidity than using pharmacologic drugs. [7] There are few studies on the use of a transcervical Foley catheter to detect cervical ripening in women with a history of caesarean delivery and an unfavourable cervix. [8-11] The Foley catheter may be the best induction agent in these circumstances, according to Norman and Stock, but more research is required to determine its effectiveness and safety. [12]

Objectives:

1. To compare the efficacy for induction of labor in cases with foleys catheter and cervical ripening balloon.
2. To study and compare the maternal outcome after Cervical ripening Balloon (CRB) and foleys induction
3. To study and compare the fetal outcome after Cervical ripening Balloon (CRB) and foleys induction

Material and Methods:

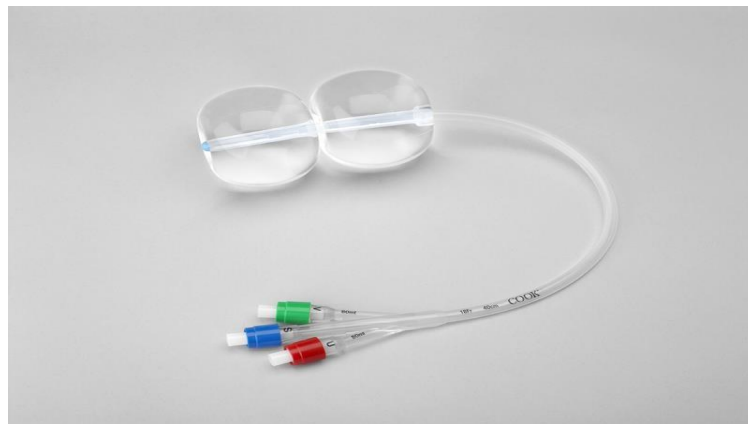
This was a Prospective observational study conducted from December 2020 to May 2022 in the department of obstetrics and gynaecology, Krishna Institute of Medical Sciences and Hospital, Karad which is a tertiary health care center. Patients from local and surrounding districts mainly avail services from the hospital. Where all eligible patients admitted in the maternity ward of Krishna Hospital were considered for inclusion in the study. Full term pregnant women with previous LSCS fitting in criteria for Vaginal Birth after Caesarean (VABC) were included in the study. Any women with full term pregnancy with malpresentation and/or malposition was excluded from the study. Cases with PROM were also excluded from the study. Cases with presence of active genital herpes was also excluded. This study was approved by institutional Ethics Committee, KIMSDU, Karad.

In this study, patients were randomly selected from the cases coming to tertiary care centre and admitted in the maternity ward of the hospital. All the cases were screened for eligibility criteria and those who were eligible were informed about the study in detail and asked for written consent. This process was continued till the desired sample size was achieved. The included cases with history of previous 1 LSCS and fitting in criteria of VBAC and willing for VBAC were randomly divided into 2 groups for induction of labor. Group 1: half cases were induced by foleys induction. Group 2: The other half were induced by cervical ripening balloon. All cases were followed up till delivery to know the maternal and fetal outcome and mode of delivery.

Cervical Ripening Balloon (CRB) versus Single Balloon Foleys Catheter-

- The double-balloon (either Atad or Cook) option has an additional cervico-vaginal balloon, which applies greater pressure to both sides of the cervix and avoids the need for traction whereas in FOLEY's Catheter after insertion gentle traction will be applied for cervical ripening.
- Use of the Cook cervical ripening catheter results in greater cervical ripening compared with the Foley catheter
- The Cook Medical® CRB (Bloomington, USA) was used for labor induction at our department. It is a double-balloon catheter guided by stylet during placement. Internal balloon was placed through the cervix in the uterine cavity and filled with 20 mL of saline, and the external one was outside the cervix, also filled with 20 mL of saline. The

balloons were later enlarged by adding 20 mL of saline to up to 80 mL maximum each. After placement of the catheter, there was no need for rest in bed, as was the case in prostaglandin induced labor. The balloon catheter was removed after 12 hours.



- The Cook Cervical Ripening Balloon is a silicone double-balloon catheter with an adjustable-length malleable stylet. It is a nonpharmaceutical option for dilating the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.

Sample Size:

The sample size was done by using Open Epi software considering, prospective randomized control trial by Solt I et al. [13] found that the rate of caesarian section was 20.0% in cervical mripening balloon group and 46.5% in Foleys catheter group in nulliparous group with two-sided significance level 95% CI and power of 80% . Min 57 samples were estimated in each group considering 10% attrition rate it was 63 samples enrolled in each study groups.

	Kelsey	Fleiss	Fleiss with CC
Sample Size - Exposed	51	49	57
Sample Size-Nonexposed	51	49	57
Total sample size:	102	98	114

References
Kelsey et al., Methods in Observational Epidemiology 2nd Edition, Table 12-15
Fleiss, Statistical Methods for Rates and Proportions, formulas 3.18 & 3.19
CC = continuity correction
Results are rounded up to the nearest integer.
Print from the browser menu or select, copy, and paste to other programs.

Results from OpenEpi, Version 3, open source calculator--SSCohort
Print from the browser with ctrl-P
or select text to copy and paste to other programs.

Statistical Analysis:

All the data was tabulated in MS-Excel and analysed by SPSS (Statistical Packages for Social Sciences) 25.0 software. The descriptive and inferential statistical analysis was carried out in the present study. Results on continuous measurements were presented on Mean \pm SD (Min- Max) and results on categorical measurements were presented in Number (%). Student t test (two tailed, independent) was used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Chi-square/Fisher Exact test was used to find the significance of study parameters on categorical scale between two or more groups. Significance was assessed at 95 % CI.

Results:

Table 1: Comparison of pre induction Bishop score between both the study groups

Preinduction Bishop score	CRB group (n=63)		Foleys Group (n=63)	
	Cases	Percentage	Cases	Percentage
≤ 6	52	82.5%	53	84.1%
> 6	11	17.5%	10	15.9%
Total	63	100.0%	63	100.0%
Median (IQR)	3.5 (1-6)		4 (0-6)	

p-value (by Chi-square test) 0.8111 – Not significant

After comparing of pre induction Bishop score between both the study groups. It was found that Bishop Score was almost similar in both the study groups. Here 52 (82.5%) out of 63 cases were found ≤ 6 Bishop Score in CRB group whereas 53 (84.1%) in foleys group. 11 (17.5%) out of 63 cases were found > 6 Bishop Score in CRB group whereas 10 (15.9%) in foleys group. A p-value is 0.8111 calculated using Chi-square test. There was no significance difference found in both the study groups. (Table. 1)

Table 2: Comparison of post catheter induction Bishop scores between both the studies groups

Post-catheter Bishop score	CRB group (n=63)		Foleys Group (n=63)	
	Cases	Percentage	Cases	Percentage
≤ 6	14	22.2%	25	39.7%
> 6	49	77.8%	38	60.3%
Total	63	100.0%	63	100.0%
Median (IQR)	9 (5.3-12.0)		7 (3-11)	

p-value (by Chi-square test) 0.034 – Significant

14 (22.2%) out of 63 cases were found ≤ 6 post catheter Bishop Score in CRB group whereas 25 (39.7%) in Foleys group. 49 (77.8%) out of 63 cases were found > 6 post catheter Bishop Score in

CRB group whereas 38 (60.3%) in Foleys group. P value is 0.034 calculated using Chi-square test. There was significance difference found in both the study groups. (Table. 2)

Table 3: Comparison of Bishop scores increments between both the study groups

Bishop score increment	CRB group (n=63)		Foleys Group (n=63)	
	Cases	Percentage	Cases	Percentage
≤3	20	31.7%	32	50.8%
>3	43	68.3%	11	17.5%
Total	63	100.0%	43	68.3%
Median (IQR)	4 (2-5)		3 (2-4)	

P value (by Chi-square test) <0.001 – Significant

In this study; 20 (31.7%) out of 63 cases were found ≤3 Bishop Score increment in CRB group whereas 32 (50.8%) in Foleys group. 43 (68.3%) out of 63 cases were found >3 Bishop Score increment in CRB group whereas 11 (17.5%) in Foleys group. p < 0.001 by Chi-square test shows that there was significance difference in Bishop score increment found in both the study groups. (Table. 3)

Table 4: Comparison of mode of delivery between both the study groups

Mode of Delivery	CRB group (n=63)		Foleys Group (n=63)	
	Cases	Percentage	Cases	Percentage
Vaginal Delivery	45	71.4%	34	54.0%
Caesarean section: number (%)	18	28.6%	29	46.0%
Total	63	100.0%	63	100.0%

P value (by Chi-square test) 0.0463 – Significant

45 (71.4%) out of 63 cases were found vaginal delivery in CRB group whereas 34 (54.0%) in Foleys group. The mode of delivery, 18 (28.6%) out of 63 cases were observed C-section in CRB group whereas 29 (46%) in Foleys group. The P value was 0.0463 by Chi-square test shows that there was significance difference in mode of delivery in both study groups. (Table.4)

Table 5: Comparison of maternal complications between both the study groups

Maternal complications	CRB group (n=63)		Foleys Group (n=63)	
	Cases	Percentage	Cases	Percentage
Uterine rupture	0	0.0%	0	0.0%

Uterine hyper stimulation	0	0.0%	0	0.0%
PPH	3	4.8%	3	4.8%

The most common maternal complications were PPH 3 (4.8%) and urinary tract infection 1 (1.6%) in group one (CRB group). The common maternal complications in Foleys group was PPH 3 (4.8%). (Table. 5)

Table 6: Neonatal outcome comparison between both the study groups

Neonatal complications	CRB group (n=63)		Foleys Group (n=63)	
	Cases	Percentage	Cases	Percentage
Respiratory Distress	3	4.8%	4	6.3%
Meconium Aspiration	3	4.8%	2	3.2%
Transient tachypnea of new-born (TTN)	1	1.6%	1	1.6%
Intra partum Still birth	0	0.0%	0	0.0%
Neonatal Death	1	1.6%	1	1.6%
NICU Admission required	5	7.9%	7	11.1%

P value (by unpaired t test) 0.0364 – Significant

In CRB group common complication were Respiratory distress 3 (4.8%), Meconium aspiration 3(4.8%), TTN 1 (1.6%) and neonatal death 1 (1.6%). In Foleys group common complication were Respiratory distress 4 (6.3%), Meconium aspiration 2(3.2%), TTN 1 (1.6%) and neonatal death 1 (1.6%). Here 5 (7.9%) cases were required NICU admission in CRB group whereas 7 (11.1%) in Foleys group. In CRB group birthweight of neonate is significantly higher compared to foleys group. More neonatal admission required in Foleys group compared to CRB group. (Table. 6)

Discussion:

Studies on the best way to induce labour in a uterus with scarring, a difficult circumstance, have not yet produced clear-cut recommendations. However, a number of trials, including sizable multicentric ones, are attempting to demonstrate the safety of labour induction in earlier LSCS. Since most studies have been conducted on patients with only one prior scar, American College of Obstetricians and Gynecologists definitely does not advise induction in uterus with two prior caesarean scars. However, it does advise that induction be an option for women who are willing to undergo trial of labour after caesarean. [14-15]

The randomised controlled trial (RCT) comparing the Foley and CRB catheters' efficacy in inducing labour found that the CRB catheter was significantly more effective than the Foley catheter in both nulliparous and multiparous women, though it had no effect on the median interval from catheter withdrawal to delivery time. The study's surprise conclusion was that participants who used the Foley catheter instead of the CRB had a caesarean delivery rate that was twice as high. Additionally, the Foley group's nulliparous hospitalisation length was much greater than that of the CRB group, most likely because of the higher caesarean section rate in that group. [13, 16]

The present study was conducted among 126 pregnant mother to compare the efficacy for induction of labour and to study & compare the fetomaternal outcome after Cervical ripening

Balloon (CRB) and Foleys induction. In present study age, distribution of patients was almost similar in both the groups. Out of total 63 cases in group one (CRB group), 24 (38.1%) cases were in between the age of 25 to 30 years followed by 14 (22.2%) in 20 to 25 years. Out of total 63 cases in group two (Foleys group), 25 (39.7%) cases were in between the age of 25 to 30 years followed by 15 (23.8%) in 20 to 25 years. There was no significance in age distribution in both the groups. The similar results observed in the study by Ido Solt et al (2019) [16], Sayed Ahmed WA et al (2016) [17] and Shetty SJ et al (2022) [18].

In present study BMI, distribution of patients was almost similar in both the groups. Here 38 (60.3%) out of 63 patients were found 18.5-24.9 kg/m² in group one whereas 43 (68.3%) in group two. There was no significance difference in BMI among patients in both the study groups. Also in this study 21 (33.3%) out of 63 cases were found GDM in CRB group whereas 24 (38.1%) in foleys group. 14 (27%) out of 63 cases were found decreased fetal movement in CRB group whereas 13 (20.6%) in foleys group. There was no significance difference found in both the study groups.

In study by Shetty SJ et al (2022) [18], 27 (54%) out of 50 cases were found elective induction in Foleys group whereas 24 (48%) in prostaglandin group. 10 (20%) were found PIH in Foleys group whereas 18 (36%) in prostaglandin group. 7 (14%) were found oligohydramnios in group one. 2 (4%) were found IUGR in group Foleys whereas 5 (10%) in PGE2 group.

In present study distribution of pre-induction Bishop score is almost similar in both the group. Here 52 (82.5%) out of 63 cases were found ≤ 6 Bishop Score in CRB group whereas 53 (84.1%) in foleys group. 11 (17.5%) out of 63 cases were found > 6 Bishop Score in CRB group whereas 10 (15.9%) in foleys group. P value is 0.8111 calculated using Chi-square test. There was no significance difference found in both the study groups.

Among 63 cases were found ≤ 6 post catheter Bishop Score in CRB group whereas 25 (39.7%) in Foleys group. 49 (77.8%) out of 63 cases were found > 6 post catheter Bishop Score in CRB group whereas 38 (60.3%) in Foleys group. A p-value is 0.034 calculated using Chi-square test. There was significance difference found in both the study groups.

In the study by Ido Solt et al (2019) [13], multiparous women showed statistically significant variations in induction outcomes between the two catheters; the mean Bishop Score increment between pre- and post-catheter was substantially smaller with the Foley catheter than with the CRB catheter (3.4 ± 2.0 and 4.4 ± 1.9 , respectively, $p = 0.02$). For the Foley and CRB catheters, the median Bishop Score improvements were 3.0 and 5.0, respectively ($p = 0.02$). With median increments of 4.0 points for both catheter groups, the Bishop Score increment did not differ significantly between the Foley catheter and the CRB catheter in nulliparous women (3.8 ± 2.0 and 4.4 ± 2.0 , respectively, $p = 0.25$).

The Cook cervical ripening balloon greatly outperformed the Foley catheter in terms of Bishop score after catheter removal or spontaneous expulsion. The ultimate goal of using cervical ripening techniques, a shorter induction to delivery interval, was not achieved because of this reality. According to studies by Mei-Dan et al. [19] and Atad et al. [20], using a Foley catheter resulted in a smaller mean rise in Bishop score than using a double balloon catheter.

Salim et al (2011) [21] found that with the Foley and Cook catheters, respectively, the mean rise in Bishop Score following catheter removal was $2.94 (\pm 1.91)$ and $3.21 (\pm 2.04)$.

Despite the fact that the second Bishop score was lower in this group, which is consistent with the findings of Mei-Dan et al. [19], the shorter insertion expulsion time of the Foley catheter most

likely contributed to the shorter induction to delivery period.

No of the type of catheter used, Salim et al. found that women who spontaneously expelled the catheter had a better outcome in terms of shorter induction to delivery times and a considerably lower percentage of surgical deliveries.

The mean pre-induction Bishop's score for the women divided into the two groups in the study by Shetty SJ et al. (2022) [18] was essentially the same. Bishop's scores for the two groups before and after induction did not differ significantly. The difference between the post-induction and pre-induction Bishop scores for each approach was found to be statistically significant with a P value of 0.001. Therefore, for pre-induction cervical ripening, each approach proved effective.

In present study 20 (31.7%) out of 63 cases were found ≤ 3 Bishop Score increment in CRB group whereas 32 (50.8%) in Foleys group. 43 (68.3%) out of 63 cases were found > 3 Bishop score increment in CRB group whereas 11 (17.5%) in Foleys group. P value is 0.001 calculated using Chi-square test. There was significance difference found in both the study groups.

In the study by Ido Solt et al (2019) [13], the improved Bishop scores across all research groups show that mechanical induction using both catheters was successful. Only among multiparous women did the mean Bishop Score increase following catheter extraction differ significantly between the CRB and the Foley catheter. Both nulliparous and multiparous parturient experienced the same median increase in Bishop Score following catheter extraction.

A study of 607 women with unfavourable cervix found similar median Bishop score increment in both nulliparous and multiparous parturient after removal of the Foley catheter and the CRB catheter.

The internal balloon of the CRB catheter covers the internal OS and secures the device in place, while the external balloon keeps pressure on both balloons on each side of the cervix. This maybe one of the reasons for the catheter's benefit. The pressure may not be maintained, however,

if the Foley catheter balloon slides into the uterus in a direction away from the cervical canal. Additionally, the internal uterine balloon in the CRB's cervical pressure may tear the membranes from the decidua, releasing endogenous prostaglandins from the surrounding deciduas.

In the present study 45 (71.4%) out of 63 cases were found vaginal delivery in CRB group whereas 34 (54.0%) in Foleys group. The mode of delivery, 18 (28.6%) out of 63 cases were observed C-section in CRB group whereas 29 (46%) in Foleys group. The P value was 0.0463 calculated by Chi-square test indicating that caesarean delivery rate was significantly higher in Foleys group compared to CRB group.

In the study by Ido Solt et al (2019) [13], both nulliparous and multiparous women who used the Foley catheter compared to those who used the CRB saw a higher caesarean section rate (47.5 against 20% in the former case and 12.5 versus 6.7% in the latter).

The risk of caesarean section was comparable between mechanical techniques of induction and no induction (416 women, RR 1.00; 95% CI 0.76-1.30) in a Cochrane analysis of 71 randomised studies including 9722 parturient. The balloon catheter (Foley and CRB) and prostaglandin (RR 1.19, 95% CI 0.62-2.29) had the same caesarean section rate.

In Shetty SJ et al (2022) [18] study, there is no significance difference found in mode of delivery in both the groups.

In present study the most common maternal complications were PPH 3 (4.8%) and urinary tract infection 1 (1.6%) in group one (CRB group). The common maternal complications in Foleys group were PPH 3 (4.8%) and urinary tract infection 2 (3.2%).

In a previous meta-analysis of 30 RCTs, only one of which included the CRB, the authors came to the conclusion that intracerebral catheters rather than pharmacological treatments are more likely to result in maternal infections during labour induction. However, there was no difference in the incidence of endometritis between the two in that study. Pre-induction vaginal and rectal smears, uterine smears during caesarean sections, and newborn throat smears were all comparable between the groups in the Ido Solt et al (2019) [13] study. Both catheters had a low risk of postpartum febrile morbidity, and there was no statistically significant difference between them. The use of both varieties of balloon catheters is associated with low rates of infection, according to other researchers. The current investigation, nonetheless, lacked the necessary power to compare the infectious morbidity of the two catheters.

In CRB group common complication were Respiratory distress 3 (4.8%), Meconium aspiration 3 (4.8%), TTN 1 (1.6%) and neonatal death 1 (1.6%). In Foleys group common complication were Respiratory distress 4 (6.3%), Meconium aspiration 2 (3.2%), TTN 1 (1.6%) and neonatal death 1 (1.6%). Here 5 (7.9%) cases were required NICU admission in CRB group whereas 7 (11.1%) in Foleys group. The P value was 0.0364 calculated by unpaired t test. There was significance difference found in neonatal outcome in both the groups.

The Foley catheter represents a successful and more affordable method of pre-induction cervical ripening due to the lack of significant differences between the groups in terms of delivery method, indications for caesarean sections, neonatal Apgar scores, maternal complications, and satisfaction, as well as the significant price difference between the catheters.

The VBAC rates were low in the randomised experiment conducted in Medical College Vellore, India, by Manish et al., at 19.5% in the 80 ml inflation group, and at 23.4% in the 30 ml inflation group. In the 80 ml group, a high rate of scar dehiscence of 9.1% was noted. Only one insertion and 12 hours of balloon use were completed. Soni et al. conducted a study in the countryside of Himachal Pradesh, India. They looked at TOLAC in 482 women who had undergone a C-section in the past. Only 14 of the 34 women who had their babies vaginally (a 41% success rate for VBAC in the induced group) had labour induced. They discovered that 4% of caesarean section patients had a scar dehiscence.

Conclusion:

Bishop score was significantly higher in cervical ripening balloon group compared to foley group. There was significant higher successful vaginal delivery in CRB group compared foley's group. PPH and urinary tract infection were common maternal complications in both cervical ripening balloon as well as Foleys group. There was no single case of uterine rupture or hyper stimulation in any of the two groups. We recommend by our results that using cervical ripening balloon over foleys for induction as a method of induction in full term pregnancy with previous single LSCS willing for vaginal birth.

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