Induction with transcervical foleys versus iv oxytocin for trial of labor after cesarean(TOLAC)

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Abstract

Objectives: To compare efficacy and safety of induction with transcervical Foley's catheter and low dose intravenous oxytocin for labor induction in a case of previous LSCS.

Methods: One hundred women at term gestation with one previous LSCS with no contradictions for VBAC, Bishop's score < 6, willing for VBAC (after consent) were selected and divided into two groups of 50 each. Group A was induced with transcervical Foley's catheter and group B of another 50 was induced with intravenous oxytocin

Results: In foleys group induction-delivery interval was less 24.54±6.0 hrs compared to oxytocin group 27.88±7.08 hrs. Successful induction rate significantly higher (80% vs 66%) with foley's as compared to oxytocin group. 76% women delivered within 24 hours of induction in foleys group whereas in the other group 64% delivered within 24 hours. Both methods are safe for labor induction. No significant systemic complications like rupture uterus noted in both groups. Neonatal outcome was similar in both the groups.

Conclusions: Foleys induction and oxytocin induction are cheap, safe, easy methods with least systemic side effects like rupture or uterine hyperstimulation for labor induction in a case of previous cesarean compared to PGE2 gel though failure rates are more with only oxytocin.

Keywords: Intracervical foleys catheter, Oxytocin, Induction of labor, VBAC, TOLAC



Introduction

To lower the rates of rising cesarean sections, clinicians are preferring more and more trial of labor after cesarean. So more and more cases with previous CS are induced. We are achieving even success in VBAC. All that is needed is proper counselling, patience hearing to the patient, telling the couple all risks and benefits associated with VBAC, proper monitoring set up, blood availability and timely intervention. Now the dictum once a cesarean always a cesarean is far behind. Elective Caesarean section in a case of previous LSCS are done in various obstetrical indications like placenta praevia, CPD, various malpresentations short interceptional period of 18 months(though a relative contraindication), previous 2 cesareans, in a case of previous myomectomy or hysteretomy and lastly if the patient demands repeat elective CS. Provided there are no contraindications, a woman with previous one transverse low-segment Caesarean section should be offered a trial of labour after Caesarean (TOLAC) with appropriate discussion of maternal, perinatal risks and benefits and appropriate documentation Studies have shown that 6080% of women with previous cesarean will safely deliver vaginally if allowed a trial of labor^(1,5-8) with continuous intrapartum care under emergency set up facilities. The American College of Obstetricians and Gynecologists (the College) and international guidelines have recommended that resources for emergency cesarean delivery should be "immediately available." (11)

Now the question is what should be the inducing agent? Due to increased risk of uterine rupture, use of prostaglandins for cervical ripening and induction of labor in women attempting vaginal birth after cesarean is discouraged by ACOG^(14,15) Transcervical Foleys catheter is considered to be promising option for induction of labour^(10,11) in case of previous LSCS. In our study we have used foleys catheter and the very old yet effective oxytocin for induction and augmentation.

Materials and Methods

This is a prospective randomized study done in the Department of Obstetrics and Gynecology, Swami Dayanand Hospital Dilshad Garden Delhi during the period between January 2015 and June 2015. 100 women with previous CS were included and divided into two groups. Group A: includes 50 women with previous cesarean who were induced with foleys catheter. Group B: includes 50 patients of previous cesarean induced with oxytocin.

Patients with one previous low transverse CS, singleton live pregnancy with cephalic presentation, reassuring foetal status based on CTG and ultrasound biophysical score, period of gestation (POG) >37 weeks

and BS <6 were included in the study. Exclusion criteria as already mentioned in introduction.

Group A

{50 women in group A with previous one cesarean} labor was induced with 16 Fr Foleys catheter transcervically and was inflated with 30 ml normal saline under direct vision during per speculum examination. Bishops score was checked once at 12 hrs. When Bishops score >6, oxytocin was started simultaneously from 1 mU/min to a maximum of 32 mU/min. Bishops score was rechecked whenever there was expulsion of foleys and accordingly oxytocin was started. If Foleys catheter did not expel even after 24 hrs, catheter balloon was deflated and removed after 24 hours and Bishops score was rechecked followed by surgical fore water amniotomy to check for colour of liquor and again

induction of labour or accordingly augmentation with oxytocin at 1 mu/min with titration, if liquor was clear.

Group B

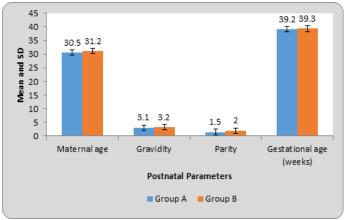
{50 women with previous one cesarean} labor was induced with low dose iv oxytocin starting from one mU/min IV oxytocin and increased to 2 mU/min and maximum upto 32 mU/min according to contractions with continuous strict fetal heart monitoring. Oxytocin should be titrated in such a way that adequate uterine activity is obtained but that there be no more than four contractions in 10 minutes. Bishops score was checked intermittently.

Induction delivery interval, indications for cesarean section, various modes of deliveries {in form of vaginal, C Section, ventouse}, neonatal outcome and NICU admissions were studied in both groups.

Results

Table 1: Antenatal data for the study and control group

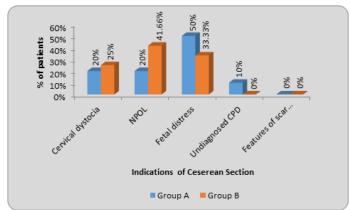
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Parameters	Group A n =50	Group B n=50	P value	
Maternal age	30.5±4.5	31.2±4.6	0.76 > 0.05NS	
Gravidity	3.1±1.2	3.2±1.5	0.36 > 0.05NS	
Parity	1.5±1.1	2.0 ± 1.5	1.90 > 0.05NS	
Gestational age (weeks)	39.2±1.6	39.3 ± 1.6	0.31 > 0.05NS	



There were no between-group differences in maternal age, gravidity, or gestational age at delivery.

Table 2: Indications for cesarean section

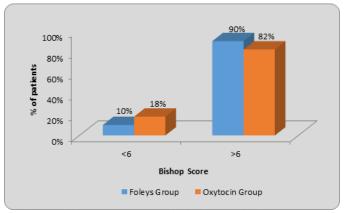
Indications for cesarean section	Group A(10 /50)	Group B(12/50)	P Value
Cervical dystocia	2(20%)	3(25%)	0.71,p=0.39,NS
NPOL	2(20%)	5(41.66%)	11.31,p=0.0008,S
Fetal distress	5(50%)	4(33.3%)	5.95,p=0.014,S
Undiagnosed CPD	1(10%)	nil	10.53,p=0.001,S
Features of scar dehiscence / scar rupture	nil	nil	-
total	10(20%)	12(24%)	0.46,p=0.49,NS
א2-Value	32.72,p=0.0001,S	29.00,p=0.0001,S	



In Group A total LSCS were 10 out of 50. Whereas in Group B total LSCS were 12 out of 50 most common indication was fetal distress for both in groups that is 50% in Group A and 33.33% in Group B. Next common indications were non progress of labor and cervical dystocia. We did not encounter any serious complications like scar dehiscence or rupture in both the groups. Few cases had mild atonic PPH which was unrelated to mode of induction.

Table 3: Post induction Bishops Score after 12-24 hours

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Bishops score	Foleys group	Oxytocin group	P Value	א2-Value both
	n = 50	n=50		Groups
<6	5 (10%)	9(18%)	74.12,p=0.0001,S	2.65
>6	45 (90%)	41(82%)	2.15,p=0.046,S	2.65 p=0.10,NS,p>0.05
P Value	32,p=0.0001,S	20.48,p=0.0001,S		p=0.10,1 v3 ,p>0.03
Total	50	50		

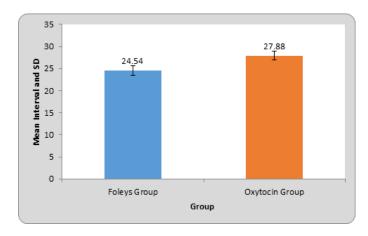


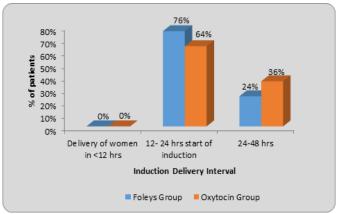
In Group A, 45 (90%) patients within 12-24 hrs post induction had Bishops score more than 6 whereas 5(10%) patients even after 24 hrs had still bishops < 6. In them amniotomy was done and oxytocin was started. Two delivered in 36 hrs whereas others landed up in Emergency cesarean due to non-progress, cervical dystocia and fetal distress.

In group B, 41 (82%) patients within 12-24 hrs post induction had Bishops score more than 6 whereas 9 (18%) patients even after 24 hrs had Bishops score less than 6. In them amniotomy was done and oxytocin restarted till 32 mU/min two of them delivered and others landed up in Emergency cesarean due to non-progress, cervical dystocia and fetal distress.

Table 4: Mean induction delivery interval

Induction delivery	Foleys (50)	Oxytocin(50)	P value
interval			
Mean interval(hrs) +/-	24.54±6.0	27.88± 7.08	z=2.54,p=0.032,S
SD {either vaginally or			
by cesarean}			
Delivery of women in	nil	nil	-
<12 hrs			
12- 24 hrs start of	38	32	1.71,p=0.19,NS
induction			
24-48 hrs	12	18	1.71,p=0.19,NS

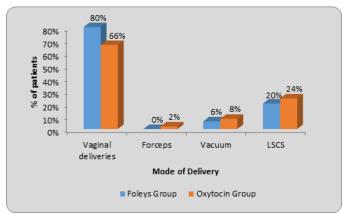




Mean induction delivery interval in foleys group was 24.54±6.0 hours and in oxytocin group was 27.88±7.08 hours. In Group A 38 (76%) women delivered within 12-24 hrs of induction and 12 (24%) women delivered within 24-48 hrs, whereas in oxytocin group 32 (64%)women delivered within 12- 24 hrs and 18 (36%) women delivered within 24-48 hrs. In Group B mean induction delivery interval was more also time taken for delivery after start of induction was more.

Table 5: Comparison of mode of delivery

Mode of delivery	Foleys group n =50	Oxytocin	Total	Statistical significance
				Chi sq =4.97 p=0.025,S
Vaginal deliveries	40(80%)	33(66%)	70	Df =1
				p<0.05
1 (a)Forceps	0(0%)	1(2%)	1	2.02,p=0.15,NS
1(b)Vacuum	3(6%)	4(8%)	7	0.30,p=0.57,NS
2 LSCS	10(20%)	12(24%)	22	0.46,p=0.49,NS
3 Total	50	50	100	



In Group A total 40 (80%) women delivered vaginally out of which 3 were vacuum assisted deliveries. In oxytocin group total vaginal deliveries were 33 (66%) out of 50, 4 were vacuum assisted, 1 was forceps assisted. In Group A total LSCS were 10, whereas in Group B total LSCS were 12 out of 50. Commonest indications in both the groups were foetal distress and non-progress of labor. The differences in the mode of delivery, in both the study groups are compared, the difference is not statistically significant.

Table 6: Neonatal outcome

Variables	Group A(n=50)	GROUP B	א2-value	p-value
Apgar >8	44	43	0.08	0.76,NS,p>0.05
6-8	4	5	0.12	0.72,NS,p>0.05
Apgar ≤ 6	2	2	0.00	1.00,NS,p>0.05
NICU admissions	4	3	0.15	0.69,NS,p>0.05
Neonatal deaths	nil	nil		
Birth weight ≤2.5	7	5	0.37	0.53,NS,p>0.05
Birth weight ≥2.5	43	45	0.37	0.53,NS,p>0.05

The neonatal outcome was studied in the form of Apgar score>8, 6-8, <8 at 1 and 5 minute, birth weight, NICU admissions and neonatal deaths [Table 5]. NICU admissions were 4 in group A and 3 in Group B, The various indications were neonatal jaundice, low birth weight, IUGR and foetal distress babies with low Apgar who recovered later on. No neonatal death noted. There was no significant difference in the Apgar scores and neonatal outcome in two groups.

Discussion

The need for labor induction in women with previous CS always is a hastle and controversy amongst gynaecologists. Cragin phrased "once a cesarean, always a cesarean". That was the era of classical cesarean section. But later the incision were lower segment cesarean section quiet safe. SO to lower the increasing cesarean section rates suggestions were made that vaginal birth after CS (VBAC) might help in reducing the rates of CS. So trial of labor in cases of previous CS has been accepted worldwide. (16) We would like to say once a cesarean always an institutional delivery.

In our study a total of 100 patients with previous one CS were included. In group A of 50 women, foleys catheter was used and group B oxytocin was used as a method of induction. We have analyzed time interval of patients from insertion and expulsion interval of Foley catheter, route of delivery/outcome of delivery,

Induction-delivery interval with oxytocin, side-effects and complications like uterine hyperstimulation, fetal distress, scar dehiscence, uterine rupture. Neonatal outcome in form of APGAR, NICU admissions and neonatal deaths were studied. Main advantage of foley's is that mean induction delivery interval is shorter and VBAC success rates are more when compared to only oxytocin, However both methods are safe as well as cost effective.

In 50 induced cases of foleys group, 40 cases (80%) delivered vaginally, 10 (20%) underwent CS. In 50 oxytocin induced and augmented 33 (66%) cases delivered vaginally whereas 12 cases (24%) were taken for emergency caesarean section for different indications. Among induced patients the most common indication for previous caesarean section was foetal distress, the next common indication was non progress of labor and cervical dystocia. 10% cases were undiagnosed CPD in group A.

Prediagnosis of CPD is very important and Elective repeat CS should be planned for. Study done by. Zelop CM et al $^{(26)}$ showed the rate of uterine rupture for women with infants weighing < or =4000 g was 1.0% versus a 1.6% rate for those with infants weighing >4000 g (P = .24). VBAC success rate was 80% in Group Foleys and 66% in group oxytocin. Vaginal delivery was accomplished in 66% of the patients who received oxytocin. $^{(22)}$

Mean induction delivery interval in foleys group was 24.54±6.0 hours and in oxytocin group was 27.88±7.08 hours. In Group A 38 women delivered within 12-24 hrs of induction and 12 women delivered within 24-48 hrs, whereas in oxytocin group 32 women delivered within 24-48 hrs. In Group B mean induction delivered within 24-48 hrs. In Group B mean induction delivery interval was more also time taken for delivery after start of induction was more. This is almost reverse to study conducted by Laishram Trinity, Meetei et al⁽²⁰⁾ where 66.67% in oxytocin group delivered within 24 h, but only 30% in Foley group. However, 93.3% and 86.7% delivered within 36 h in Foley and oxytocin group, respectively.

In Jackson et al. only 75% delivered within 36 h. with oxytocin when compared with PGE2. (21)

Study conducted by Chelmow D et al showed fortysix (74%) of augmented patients with oxytocin delivered vaginally. There were no maternal deaths, uterine ruptures, or hysterectomies.⁽²⁷⁾

Study done by Revathi et al.⁽¹⁹⁾ The mean induction to delivery interval in Foley's group is 18.49±6.59 hrs. and Prostaglandin E2 Gel group is 17.6±6.52 hrs which was less than our study.

Study done by Lieberman et al⁽²³⁾ concluded that balloon ripening was found to be more effective than Oxytocin infusion, resulting in shorter induction-delivery interval.

In our study we did not encounter any serious complications like uterine rupture, scar dehiscence or uterine hyperstimulation. Horenstein and Phelan have reported 3% scar dehiscence when oxytocin was used for induction of labor⁽²²⁾ A study which was conducted on the VBAC induction by D. Ravasiax et al., showed that Foley's catheter induction was associated with a lowest rupture rate in the induced TOL group.⁽¹⁷⁾ In the large NICHD study, the risk of the uterine rupture was 140/10,000 inductions with the use of prostaglandins as compared to the 89/10,000 inductions with the use of a Foley catheter to dilate the cervix.⁽¹⁸⁾

In an analysis of nationally collected data from Scotland, prostaglandin induction compared with non-prostaglandin induction was associated with a statistically significant higher uterine rupture risk (87/10,000 versus 29/10,000)^[24]. In 2001, Lydon-Rochelle et al⁽²⁵⁾ demonstrated a 3-fold increase in the risk for uterine rupture when comparing patients induced with prostaglandins with those induced with oxytocin.

The PGE₂ exposure during the TOL was associated with more than a 6 fold increase in the uterine ruptures as compared to that in the spontaneous labour^[17]. Ravasia et al have reported incidence of scar rupture of 0.8% with Foley in the previous section. No incidence of scar dehiscence/rupture was seen in the Foley group in the present study

However, the patient's number in our study is too small to draw a final conclusion. Larger studies are needed.

Incidence of NICU admission and neonatal complications was not statistically significant in both groups. The neonatal complications appear to be incidental, and not related to induction/mode of delivery. Two babies in each groups had APGAR <6. NICU admissions were 4 in group A and 3 in Group B. The various indications for admission were neonatal jaundice, low birth weight, IUGR and foetal distress babies with low Apgar who recovered later on. No neonatal death noted in both groups

Conclusion

This study has shown that induction in women with previous one cesarean with both intracervical foleys catheter and oxytocin is safe, simple and effective. These methods are reversible and have least systemic side effects like rupture or hyperstimulation of uterus as compared with PGE2 in other studies. However mean induction delivery time was more in oxytocin group and failure rates were more with oxytocin group compared to foleys group. We luckily did not encounter any serious life threatening maternal or fetal complication may be because patient's number in our study is too small to draw a final conclusion. Larger studies are still needed.

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