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Original Research Article

A randomised controlled trial of preinduction cervical ripening-dinoprostone versus foleys catheter

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ABSTRACT

Background: Cervical ripening before induction of labour in women with unfavourable cervix is essential to shorten the induction to delivery interval and avoid unnecessary interventions.
Methods: The study was carried out at Raja Sir Ramasamy Mudaliar hospital, Chennai during the period August 2012 to July 2013. 200 antenatal women were recruited and randomly allocated to Foleys and prostaglandin E2 gel group for induction. The change in bishops score, induction to delivery interval, mode of delivery, vaginal delivery within 24 hours, maternal complications, fetal outcome between both groups were compared.
Results: The commonest indication for induction in both groups was postdated pregnancy followed by oligohydramnios in Foleys group and preeclampsia in PGE2 group. Foleys catheter induction improves bishops score better compared to PGE2 gel whereas PGE2 gel causes a significant reduction in the mean induction to delivery interval between the two groups. However, there was no significant difference between mean caesarean deliveries between the two groups. In both Foleys and the PGE2 group, failed induction was the commonest indication for caesarean section. The number of patients delivering vaginally within 24 hrs was similar between the two groups.
Conclusions: Though prostaglandins are a better method of induction, this study shows that Foleys induction has reduced side effects and is also cost effective, making it a superior method for cervical ripening.

Keywords: Cervical ripening, Foleys catheter, Induction, ProstaglandinE2 gel

INTRODUCTION

Induction of labour is a common obstetric intervention, occurring in approximately 25% of term pregnancies in developing countries. The increased ceserean delivery risk associated with induction is strongly influenced by the induction attempt duration, especially with an unfavourable cervix.[1]

The condition of the cervix described as cervical "ripeness" or "favourability" is important to successful labour induction. There are pharmacological and mechanical methods that can enhance cervical favourability, also termed preinduction cervical ripening.[2]

Pharmocological and mechanical methods commonly used are prostaglandin preparations (PGE1 and PGE2) and various intracervical catheters (single or double balloon), respectively. Mechanical methods not only dilate the cervix, but also increase prostaglandin and oxytocin release by causing localised inflammation, while prostaglandins act to promote both cervical ripening and uterine activity.

The success of labor induction varies based on the state of cervix before ripening, which is measured by the Modified Bishop's score. If the score is low or unfavourable, then modes of ripening of the cervix are used to increase the chances of a vaginal delivery.[3]

Table 1: Modified bishops score.

	SCORE			
Dilation (cm)	0	1	2	3
Length(cm)	<1	1-2	2-4	>4
Station (cm)	>4	2-4	1-2	<1
Consistency	-3	-2	-1/10	+1/+2
Position	Firm	Medium	Soft	
Anterior	Posterior	Mid-position, Anterior		

Aim of the study was to determine the safety and efficacy of Foleys catheter compared to dinoprostone gel for preinduction cervical ripening in women with an unfavourable cervix.

The Primary outcome measure

Vaginal delivery within 24 hours.

Secondary outcome measures

To compare

1. Improvement in Bishops score in both groups.
2. Induction to onset of active labour and induction to delivery interval in both the groups.
3. Mode of delivery in both groups.
4. Occurrence of maternal complications and fetal outcome in both groups.
5. Cost effectiveness of both groups.

METHODS

The present study was carried out at Raja Sir Ramasamy Mudaliar Hospital, Chennai during the period August 2012 to July 2013. All pregnant women who satisfy the inclusion and exclusion criteria were included in the study after getting an informed consent from both the patient and their husband.

Inclusion criteria

1. Singleton gestation
2. Gestational age more than 34 weeks
3. Cephalic presentation
4. Medical indication for labor induction.
5. Bishop score of ≤5
6. Reactive fetal heart rate (FHR) on admission
7. Intact membranes

Exclusion criteria

1. Any condition precluding vaginal delivery
2. Any contraindication to receiving prostaglandins, such as history of Bronchial asthma, cardiovascular disease or glaucoma.
3. Previous cesarean section or any other uterine incision
4. Placenta praevia
5. Active infection of genital tract
6. Abnormal fetal heart rate (FHR).
7. Latex allergy.

After being included in the study the patients were randomly allocated to either prostaglandinE2 gel group or the Foleys group.

The time of application of intracervical prostaglandin or insertion of foleys catheter is taken as zero hour. Patient's name, age, parity and gestational age were noted. The indication for induction was noted. A routine obstetric scan was done. General, abdominal and vaginal examination was done.

The method most commonly used to identify cervical ripening is the modified Bishop score which is a quantitative measure of consistency, dilation of the cervix, station, position of the presenting part. Pre-induction modified Bishops score distribution should be similar both between groups. All patients were monitored with the partogram.

In the women recruited in the PGE2 group, Prostaglandin gel (PGE2 gel) 0.5mg available in a preloaded syringe was placed in the endocervical canal under strict aseptic precautions. A repeat dose of prostaglandin gel (PGE2 gel) was given to patients with no improvement in bishops score after 6 hours. In patients with improvement in bishops score, labour was augmented with oxytocin after 6 to 12 hours since the time of induction. Fetal heart rate monitoring was done before then after each PGE2 insertion for a minimum of 20 minutes.

In the second group, a Foleys catheter was inserted into the cervical canal, and is filled with 30 ml of saline above the level of the internal os and pulled snugly back against the os. The catheter was strapped to the inner aspect of one thigh on slight tension for twelve hours. The catheter was then removed after 12 hours if spontaneous expulsion had not occurred. EFM (Electronic fetal heart monitoring) was conducted before and after induction for a minimum of 20 minutes. Artificial rupture of the membranes and oxytocin infusion was then started if there was improvement in the bishop's score.

The change in bishops score, induction to delivery interval with associated maternal complications, need for oxytocin induction, mode of delivery, incidence of caesarean sections with the indications, vaginal delivery within 24 hours between both groups were compared.

The weight and 5 minute APGAR of all newborn delivered were tabulated.

All parameters were tabulated and statistical analysis done. P value <0.05 is taken as significant.

RESULTS

Table 2: Age group distribution.

Age group in years		Group		Total
		Foleys	PGE2	
18-20	Count	35	45	80
	% within Group	35.0%	45.0%	40.0%
21-25	Count	53	42	95
	% within Group	53.0%	42.0%	47.5%
26-30	Count	9	10	19
	% within Group	9.0%	10.0%	9.5%
Above 30	Count	3	3	6
	% within Group	3.0%	3.0%	3.0%
Mean		22.24yrs	22.22yrs	

P=0.462

The age group distribution between the two groups was found to be comparable. There was no statistical difference between the age distribution of both the groups (P=0.462). Majority of patients were in the age group 21-25yrs in Foleys group and 18-20yrs in the PGE2 group. The mean age in the Foleys group was 22.24yrs and PGE2 group was 22.22yrs.

The parity distribution between the two groups were found to be comparable. There was no statistical difference between the two groups (P=0.508). There were 74 nulliparas in the foleys group and 78 in the PGE2 group.

Table 3: Parity distribution.

			Group		Total
			Foleys	PGE 2	
Parity	Primi	Number	74	78	152
		% within Parity	48.7%	51.3%	100.0 %
	Multi	Number	26	22	48
		% within Parity	54.2%	45.8%	100.0 %
Total		Number	100	100	200
		% within Parity	50.0%	50.0%	100.0 %

P=0.508

Table 4: Gestational age distribution.

			Group		Total
			Foleys	PGE 2	
Gestational Age in days	Below 260	Number	14	18	32
		% within Gestational Age in days	43.8%	56.3%	100.0%
	260-280	Number	49	49	98
		% within Gestational Age in days	50.0%	50.0%	100.0%
	Above 280	Number	37	33	70
		% within Gestational Age in days	52.9%	47.1%	100.0%

P=0.695

Table 5: Indication for induction distribution.

			Group		Total
			Foleys	PGE 2	
INDI	Post dated	Number	36	32	68
		% within INDI	52.9%	47.1%	100.0%
	PIH	Count	18	28	46
		% within INDI	39.1%	60.9%	100.0%
	Oligohydrannios	Count	28	22	50
		% within INDI	56.0%	44.0%	100.0%
	GDM	Count	9	11	20
		% within INDI	45.0%	55.0%	100.0%
	IUGR	Count	6	5	11
		% within INDI	54.5%	45.5%	100.0%
	Anomalous	Count	1	1	2
		% within INDI	50.0%	50.0%	100.0%
	IUFD	Count	2	1	3
		% within INDI	66.7%	33.3%	100.0%

P=0.710 (INDI- Indication, PIH - Pregnancy induced hypertension, GDM- Gestational diabetes mellitus, IUGR - Intra Uterine Growth restriction, IUFD- Intra Uterine Fetal Death).

The mean gestational age in the foleys group was 270.60 days and in the PGE2 group was 269.64 days. There is no statistical difference in the gestational age of both the groups (P=0.521).

The commonest indication for induction in both the groups was postdated pregnancy (36) in the Foleys group and (32) in the PGE2 group. There was no significant difference between the two groups (P=0.710). The second common indication was oligohydramnios (28) in the Foleys group and preeclampsia (28) in the PgE2 group. There were 2 cases of intrauterine fetal death in the Foleys group and one in the PgE2 group.

The bishops score at the start of induction, i.e. bishops score at zero hours in the foleys group was a mean of 2.09 in nulliparas and 3.27 in the para-1 patients which was statistically significant (P=<0.001). However the change in bishops score after 12 hours of induction was a mean of 5.55 in the nulliparas group and 6.70 in the para-1 group which was not statistically significant (P= 0.016).

The bishops score at induction in the PGE2 group was 1.95 in nulliparas and 2.55 in the para- 1 patients, which was not statistically significant P=0.019. The change in bishops score was a mean of 4.65 in the nullipara and 6.06 in the para-1 patients respectively which was statistically very significant P=0.004. Thus, PGE2 gel in my study increases the bishops score very significantly in the para-1 patients compared to the Nullipara patients.

The mean bishop's score in the Foleys group was 2.40 and in the PGE2 group was 2.08 and it was not statistically significant (P=0.071). The mean change in bishops score in the Foleys group was 5.80 and in the PGE2 group was 4.92 which was statistically very significant P=0.002. Hence Foleys catheter was found to increase the bishops score better than PGE2 gel. In the Foleys group 56.8% of nulliparas and 84.6% of para-1 women delivered by spontaneous vaginal delivery, whereas in the PGE2 group 69.2% of the nulliparas and 50% of the para-1 patients delivered vaginally. This was not found to be statistically significant.

Table 6: Bishops score at induction and change in bishops score (Distribution in both groups).

Bishops score	Group	No.	Mean	P value
B_O (bishops at zero hour)	Foleys	100	2.40	0.071
	PGE2	100	2.08	
Change in bishops score(B_Z)	Foleys	93	5.80	0.002
	PGE2 (with one gel)	89	4.92	

33.8% of the nulliparas in the Foleys group delivered by caesarean section and 11.5% of para-1 patients delivered by caesarean section. In the PGE2 group, 25.6% of the nulliparas delivered by caesarean section and 40.9 of the para-1 patients delivered by caesarean section. The difference was found to be statistically significant for the para-1 group (P=0.005).

9.5% of the nulliparas and 3.8% of para-1 patients in the Foleys group, 5.1% of nulliparas and 9.1% of the para-1 patients in the PGE2 group delivered by outlet forceps.

However the mean of the mode of delivery between both the groups was not statistically significant (P=0.856).

The comparison of the indications for caesarean section in both the groups showed a statistical significance P=0.050.

In both the Foleys and the PGE2 group, with respect to nulliparas, failed induction was the commonest indication-56.3% (18 patients) in the Foleys group and 45.8% (11 patients) in the PGE2 group. The second common indication for LSCS was fetal distress in both the groups with respect to nulliparas-9.4% (3 patients) in the Foleys and 33.3% (8 patients) in the PGE2 group respectively which is statistically significant.

Table 7: Mode of delivery and parity group distribution.

				Parity		Total
				Primi	Multi	
Foleys	Mode of delivery	LN	Number	42	22	64
			% within Parity	56.8%	84.6%	64.0%
		LSCS	Number	25	3	28
			% within Parity	33.8%	11.5%	28.0%
		OF	Number	7	1	8
			% within Parity	9.5%	3.8%	8.0%
PGE 2	Mode of delivery	LN	Number	54	11	65
			% within Parity	69.2%	50.0%	65.0%
		LSCS	Number	20	9	29
			% within Parity	25.6%	40.9%	29.0%
		OF	Number	4	2	6
			% within Parity	5.1%	9.1%	6.0%

(LN - Labour natural, LSCS- Lower segment caesarean section, OF - outlet forceps)

Table 8: LSCS indication group distribution.

Group				Parity		Total
				Primi	Multi	
Foleys	LSCS Indication	FI	Number	18	1	19
			% within LSCS	94.7%	5.3%	100.0%
			% within Parity	56.3%	25.0%	52.8%
		FD	Number	3	2	5
			% within LSCS	60.0%	40.0%	100.0%
			% within Parity	9.4%	50.0%	13.9%
		F to P	Number	2	0	2
			% within LSCS	100.0%	.0%	100.0%
			% within Parity	6.3%	.0%	5.6%
		CPD	Number	2	0	2
			% within LSCS	100.0%	.0%	100.0%
			% within Parity	6.3%	.0%	5.6%
Pge 2	LSCS Indication	FI	Number	11	2	13
			% within LSCS	84.6%	15.4%	100.0%
			% within Parity	45.8%	18.2%	37.1%
		FD	Number	8	8	16
			% within LSCS	50.0%	50.0%	100.0%
			% within Parity	33.3%	72.7%	45.7%
		F to P	Number	1	0	1
			% within LSCS	100.0%	.0%	100.0%
			% within Parity	4.2%	.0%	2.9%
		CPD	Number	2	0	2
			% within LSCS	100.0%	.0%	100.0%
			% within Parity	8.3%	.0%	5.7%

(FI - Failed induction, FD- Fetal distress, F to P- Failure to progress, CPD - Cephalopelvic disproportion)

Table 9: Vaginal delivery in 24 hours group distribution.

			Group		Total
			Foleys	PGE 2	
Vaginal 24 hours	Yes	Number	72	71	143
		% within Vaginal 24 hours	50.3%	49.7%	100.0%
		% within Group	72.0%	71.0%	71.5%
	No	Number	28	29	57
		% within Vaginal 24 hours	49.1%	50.9%	100.0%
		% within Group	28.0%	29.0%	28.5%
Total		Number	100	100	200
		% within Vaginal 24 hours	50.0%	50.0%	100.0%
		% within Group	100.0%	100.0%	100.0%

P=0.876

In para-1 patients in the Foleys group of 3 patients who delivered by caesarean section, 2 patients indication for LSCS was fetal distress (50%). In the PGE2 group, para-1 patients 8 underwent LSCS for fetal distress (72.7%) which is statistically significant.

Out of 100 patients in each group, the number of patients delivering vaginally within 24 hrs was comparable between the two groups,72 patients in the Foleys group and 71 in the pge2 group with no statistical difference (P=0.876).

The number of patients in the PGE2 group developing nonreassuring fetal heart rate during induction and subsequently ending up in caesarean section was 9 compared to none in the Foleys group. This was statistically very significant (P=0.002).

7 patients in the PGE2 group developed hyper stimulation to induction but there were no adverse affects in the Foleys group which was statistically very significant (P=0.007).

Table 10: Non-reassuring FHR in the induction group distribution.

			Group		Total
			Foleys	PGE 2	
Non-reassuring	Yes	Number	0	9	9
		% within Non-reassuring - Induct	0.0%	100.0%	100.0%
		% within Group	0.0%	9.0%	4.5%
	No	Number	100	91	191
		% within Non-reassuring - Induct	52.4%	47.6%	100.0%
		% within Group	100.0%	91.0%	95.5%

P=0.002

Table 11: Maternal complication group distribution.

			Group		Total
			Foleys	PGE 2	
MC	Yes	Number	0	7	7
		% within MC	0.0%	100.0%	100.0%
		% within Group	0.0%	7.0%	3.5%
	No	Number	100	93	193
		% within MC	51.8%	48.2%	100.0%
		% within Group	100.0%	93.0%	96.5%

P=0.007, (MC- maternal complications)

Table 12: Second gel group distribution.

			Group		Total
			Foleys	PGE2	
Second Gel	Yes	Count	0	39	39
		% within II Gel	0.0%	100.0 %	100.0 %
		% within Group	0.0%	39.0 %	19.5 %
	No	Count	100	61	161
		% within II Gel	62.1%	37.9 %	100.0 %
		% within Group	100.0 %	61.0 %	80.5 %

P<0.001**

39% of patients in the PGE2 group needed regel as bishops score was not favorable after induction with one PGE2 gel. This was statistically very significant P<0.001**.

Table 13: Birth weight distribution.

	Group	N	Mean	P Value
Birth weight	Foleys	100	2.8442	0.429
	PGE 2	100	2.8886	

The average birth weight of the newborn in the Foleys group was 2.8442 kilograms and in the pge2 group was 2.8886 kilograms which was not statistically significant (P=0.429).

Table 14: Neonatal outcome.

	Group	N	Mean	P value
APGAR	Foleys	96	8.07	0.099
	PGE2	97	8.27	

P=0.099

The mean APGAR in the Foleys group was 8.07 and in the PgE2 group was 8.27 with no statistical significance between the groups (P= 0.099).

DISCUSSION

In our study, the age group distribution was even between both the groups. The mean age group in the Foleys group was 21-25 yrs and 18-20 yrs in the PGE2 group. This is similar to other studies where similar age group patients were included in both the groups.

In our study, the parity distributions between the two groups were found to be comparable. Study done by Jackson et al included 50 patients, both nulliparous and para-1 patients similar to the present study whereas some studies were done exclusively on nulliparous women such as a study by Ekman et al included only 20 nulliparous women and study by Bernstein et al included 100 nulliparous women.[4-6]

The mean gestational age in days in the Foleys group is 270.60days and in the PGE2 group is 269.64 days. The maximum numbers of patients were in the 260-280 days group in both the groups. Studies done by Jackson et al, Ekman et al all included term pregnant women like the present study.[4,5]

In our study women with bishop score ≤5 were included. Studies done by Herabutya et al and Bernstein et al included women with bishops score ≤4.[7,6] However in a study by Egarter et al, Sciscione et al and Ashrafunnessa et al included women with bishops score ≤5.[8-10]

In our study, Foleys catheter was found to increase the bishops score better then PGE2 gel. In a study by

Niromanesh et al, ninety women with a Bishop score of ≤5 were randomized to receive an intracervical Foleys catheter or prostaglandin E2 gel.[11] No difference was seen in the mean Bishop Scores between the 2 groups. In another similar study by Sciscione et al, 77 mothers were included into Foley group and 72 in PGE2 gel group.[9] Bishop score after ripening (6.5 and 5.1, P <0.001) and change in Bishop score (3.5 and 2.7, P = 0.015) was higher in Foleys group.

In our study, a significant difference in the induction delivery interval between the two groups was seen. The mean duration in Foleys group was 16.48 hours and PGE2 group was 14.66 hrs. In a study by Antonella Cromi et al, 74% of the Foleys group and 72% of the PGE2 group delivered vaginally within 24 hours with the mean induction delivery interval being 16.32 hrs in the foleys group and 15.27 hrs in the PGE2 group which was not statistically significant.[12] Zvi Vaknin et al compared the safety and efficacy of Foleys catheter and intravaginal dinoprostone for cervical ripening. The time taken for cervical ripening and the time for vaginal delivery was better in the foleys group.[13] There was no much difference between both groups in rates of cesarean sections. Prostaglandins had an increased risk of uterine hyperactivity (P = 0.001). Foleys group had more need of oxytocin in labour (P = 0.0002).

In the study done by Sciscione et al, the Foleys catheter caused a high postinduction Bishop score, a higher change in Bishop score, less time for induction, but were similar in terms of mode of delivery.[9] In Foleys and PGE2 group, with respect to nulliparas, failed induction was the commonest indication for caesarean section-56.3% (18 patients) in Foleys group and 45.8% (11 patients) in PGE2 group. 39% of patients in the PGE2 group needed regel as bishops' score was not favourable after induction with one PGE2 gel. This was statistically very significant (P<0.001).

In a similar study done by Jozwiack et al, 82 patients were randomly assigned for cervical ripening with Foleys catheter and PGE2 gel. Four cases of failed induction of labour in Foleys group were seen and 0 in the PGE2 group (P <0.05).[14] The second common indication for LSCS was fetal distress in both the groups with respect to nulliparas. 9.4% (3 patients) in the Foleys and 33.3% (8 patients) in the PGE2 group respectively which was statistically significant. In the para-1 patients in the Foleys group, out of 3 patients who delivered by caesarean section, 2 patients indication for LSCS was fetal distress (50%). In the PGE2 group, 8 para-1 patients underwent LSCS for fetal distress (72.7%) which was again statistically significant. The number of patients in the PGE2 group developing non reassuring fetal heart rate during induction and subsequently ending up in caesarean section was 9 compared to none in the Foleys group. This was statistically very significant. 7 patients in the PGE2 group developed hyperstimulation to induction but there were no adverse affects in the Foleys group which was statistically very significant. Thus PGE2 was associated with a significant occurrence of non reassuring fetal heart variabilities and maternal complications compared to the foleys group.

In the study done by Sciscione et al, no significant difference in both groups for mode of delivery, birth weight, and occurence of uterine hyperactivity, patient discomfort, use of epidural analgesia, use of oxytocin, or abnormal fetal heart rate was seen.[10]

In the study done by Jozwiack et al 3 cases hyperactivity occurred which required cesarean delivery in the PGE2 group and none in the Foleys group.[14] The outcome of pregnancy was otherwise similar in both groups.

The cost in the Foleys group was 40 rupees per catheter per patient and it was hundred rupees per patient per gel in the pge2 group thus making the Foleys group cost effective.

CONCLUSION

In the present study comparing prostaglandin E2 intracervical gel and foleys catheter as preinductional cervical ripening agents, the primary outcome, vaginal delivery within 24 hours was similar between the two groups. The study demonstrates that Foleys catheter yields similar caesarean section rates compared to prostaglandinE2 gel, making both methods equally effective. Foleys catheter was found to increase the bishops score better than prostaglandin E2 gel but the induction to delivery interval was significantly shorter in the PGE2 group. The occurrence of fetal heart abnormalities was significantly more in PGE2 group. The 5 minute APGAR and birth weight was similar between two groups. Thus Foleys catheter can be useful as a ripening agent in low-resource countries, due to low cost, easy storage, and decreased need of fetal surveillance during the ripening phase of induction. This makes Foleys catheter a superior method, with the potential for even outpatient cervical ripening.

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