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TO STUDY INDUCTION OF LABOUR USING INTRACERVICAL FOLEYS CATHETER AND COMBINED FOLEYS CATHETER WITH PGE2 SINGLE DOSE

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Abstract

Background: Various methods are employed to achieve labour induction, each with its unique advantages and considerations .This study focuses on the use of intracervical Foley's catheter, a mechanical method that has gained recognition for its effectiveness in cervical ripening and compares outcomes of induction of labour using intracervical foleys catheter and combined foleys catheter with pge2 single dose. By addressing these needs, this study aspires to contribute valuable evidence that can guide healthcare providers in making informed decisions regarding the induction of labour.

Materials and Methods: A Prospective Observational study with Study Period of Approximately One Year. Study Population of 100 antenatal patients admitted to the labor room of KCGMC and meeting the inclusion criteria were enrolled in the study, undergoing induction of labour using intracervical Foley's catheter and a combined method of Foley's catheter with a single dose of PGE2.

Results: There was a significant difference in the distribution of Bishop's scores recorded 12 hours post- induction, suggesting that PGE2 addition may influence Bishop's score outcomes, potentially affecting labor progression.Furthermore, while the average Bishop's score was slightly higher in the Foley's+PGE2 group,indicating enhanced cervical ripening with PGE2, the clinical significance of this difference requires further investigation. Additionally, the duration between induction and delivery was significantly shorter in the Foley's+PGE2 group, indicating more efficient induction progress with the combined method.However, the Foley's+PGE2 group showed a higher rate of augmentation requirement, suggesting the need for additional interventions with combined induction methods.

Conclusion: Overall, while PGE2 addition to Foley's catheter induction may offer certain benefits such as shorter induction delivery intervals and potentially improved cervical ripening, its impact on clinical outcomes and safety requires further investigation and consideration.

Key Words: Induction Of Labour, Intracervical Foleys Catheter, PGE2

INTRODUCTION

The initiation of labour, commonly known as induction of labour (IOL), is a prevalent obstetric procedure aimed at triggering the commencement of labour through artificial means [1]. Induction of labour is a crucial aspect of obstetric management employed to initiate uterine contractions when continuation of the pregnancy poses potential risks to the well-being of both the mother and the fetus. Various methods are employed to achieve labour induction, each with its unique advantages and considerations [2].This study focuses on the use of intracervical Foley's catheter, a mechanical method that has gained recognition for its effectiveness in cervical ripening and induction of labour.

The intracervical Foley's catheter, originally designed for bladder drainage, has found widespread application in obstetrics due to its ability to mechanically dilate the cervix, thus initiating the cascade of events leading to labour[3]. Its non-pharmacological nature and minimal side effects make it a preferred option in certain clinical scenarios. In recent years, a combination approach involving the use of Foley's catheter along with a single dose of prostaglandin E2 (PGE2) has emerged as a promising strategy for labour induction[4].

This study addresses the need for a comprehensive evaluation of induction methods by focusing on both intracervical Foley's catheter alone and its combination with a single dose of prostaglandin E2 (PGE2). The rationale for this research lies in the potential synergistic effects of combining mechanical and pharmacological approaches to induce labour.

Understanding the dynamics of this combined approach is crucial for healthcare practitioners who seek evidence-based strategies to ensure the safety and optimal outcomes for mothers and newborns. Furthermore, the study aims to fill existing knowledge gaps in the literature, providing insights into the comparative efficacy, safety, and feasibility of these induction methods.

The emphasis on key parameters such as changes in Bishop score, the interval from induction-to-delivery interval, and maternal and fetal outcomes reflects the commitment to a comprehensive understanding of these methods' impact on obstetric care. In summary, the need for this research stems from the ongoing quest to enhance and individualize obstetric care, taking into account the diverse clinical scenarios and patient profiles encountered in everyday practice. By addressing these needs, this study aspires to contribute valuable evidence that can guide healthcare providers in making informed decisions regarding the induction of labour, ultimately improving outcomes for both mothers and infants.

AIM: To study induction of labour using intracervical foley’s catheter and combined foley’s catheter with PGE2 single dose

OBJECTIVES: To study the following parameters in patients undergoing induction of labour using intracervical Foley’s catheter and combined foley’s catheter with PGE2 single dose

1. To study changes in Bishop score.
2. To study induction delivery interval.

METHODOLOGY

Study Location: Department of Obstetrics and Gynecology, KCGMC Karnal, Haryana Study Design: Prospective Observational study

Study Period: Approximately One Year

Study Population: Antenatal Women Admitted to the Labor Room of KCGMC Karnal Induction Methods: Foley's Catheter and Foley's Catheter Combined with PGE2 Gel Sample Size: 100 Women Undergoing Labor Induction

Ethical Approval: Obtained from the Ethical Committee Inclusion and exclusion criteria:

Inclusion Criteria:

Singleton pregnancy • Primipara • >=37 weeks of gestation • Cephalic presentation • Bishop score ≤6 • Intact fetal membranes • Reactive fetal heart rate • Post-term pregnancy

Exclusion Criteria:
Multiple pregnancies • Malpresentation • Ruptured membranes • Active genital infection • Antepartum hemorrhage/Placenta previa • Medical disease- Heart disease or renal disease • Cephalopelvic disproportion/contracted pelvis • Twin pregnancy • Polyhydramnios • Sepsis • Any evidence of fetal distress • Patient refusing to participate in the study

Methods of induction of labour:
1. Intracervical Foley's catheter
2. PGE2 Gel instillation

MEASUREMENT OF OUTCOMES: Socio demographic and obstetric details were noted from the participants' case sheets. The Bishop score was recorded at the time of induction of labor and 12 hours after induction. The induction delivery interval was noted and results analysed.
Primary Outcome. ● Induction delivery interval-it is the interval between the induction and the end of the second stage of labour.
Secondary Outcome ●Changes in bishop score
Ethical Clearance - Informed written consent was obtained from the study participants or their legal guardians. - Confidentiality of all provided information was ensured. - The study did not cause any harm to the respondents.
Sample size: Sample size calculation was done using the formula n = (Zα/2+Zβ) 2 *2*σ2 / d2 , where Zα/2 is the critical value of the Normal distribution at α/2 (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Zβ is the critical value of the Normal distribution at β (e.g. for a power of 85%, β is 0.15 and the critical value is 1.03), σ2 is the population variance, and d is the difference you would like to detect. Power and Sample Size 16 Alpha = 0.05 Assumed standard deviation = 6.5 Mean Difference =4.24 Sample Size = 50 Power = .85. The sample size is for each group 50 & Total Sample Size =100 (approximately)
Statistical Analysis: The statistical analysis was conducted using IBM SPSS (Statistical Package for Social Sciences) statistical version 20.

RESULTS

Table 1: Age distribution of study participants.

Group			Foley's	Foley's+ PGE2	Total	p value
Age (years)	20-25	Count	22	23	45	0.90
		% within Group	44.0%	46.0%	45.0%	
	25-35	Count	22	20	42	
		% within Group	44.0%	40.0%	42.0%	
	35-40	Count	6	7	13	
		% within Group	12.0%	14.0%	13.0%	
Age (Mean+-sd)			27.14±4.9	27.16 ± 5.0	27.15±4.9	0.98

Regarding age distribution, participants were fairly evenly distributed across age groups (p=0.98).

Table 2: Literacy level of study participants among two groups

Group			Foley's	Foley's+ PGE2	Total	p value
Literacy status	Illiterate	Count	17	14	31	0.79
		% within Group	34.00%	28.00%	31.00%	
	Primary	Count	15	15	30	
		% within Group	30.00%	30.00%	30.00%	
	Secondary	Count	10	14	24	
		% within Group	20.00%	28.00%	24.00%	
	Graduate and above	Count	8	7	15	
		% within Group	16.00%	14.00%	15.00%	

In terms of literacy status, the majority of participants were either primary literate or illiterate, with no significant differences observed between the Foley's and Foley's+PGE2 groups (p=0.79).

Table 3: Religion of study participants among two groups

Group			Foley's	Foley's+ PGE2	Total	p value
Religion	Hindu	Count	26	31	57	0.57
		% within Group	52.00%	62.00%	57.00%	
	Muslims	Count	15	11	26	
		% within Group	30.00%	22.00%	26.00%	
	Other	Count	9	8	17	
		% within Group	18.00%	16.00%	17.00%	

The majority of participants identified as Hindu, with no significant difference in religious distribution between the two groups (p=0.57).

Table 4: Area of residence of study participants among two groups.

Group			Foley's	Foley's+ PGE2	Total	p value
Locality	Urban	Count	39	42	81	0.44
		% within Group	78.00%	84.00%	81.00%	
	Rural	Count	11	8	19	
		% within Group	22.00%	16.00%	19.00%	

A higher proportion of urban residents in the Foley's+PGE2 group compared to the Foley's group however it was not statistically significant (p=0.44).

Table 5: Registration status of pregnancy of participants among two groups

Group			Foley's	Foley's+ PGE2	Total	p value
Registration of pregnancy	Booked	Count	45	44	89	0.75
		% within Group	90.00%	88.00%	89.00%	
	Unbooked	Count	5	6	11	
		% within Group	10.00%	12.00%	11.00%	
		% within Group	44.00%	22.00%	33.00%	

Registration of pregnancy was similar in both groups (p=0.75).

Table 6: Socio-economic status of study participants among two groups.

Group			Foley's	Foley's+ PGE2	Total	p value
Socio-economic status	Class I	Count	4	9	13	0.075
		% within Group	8.00%	18.00%	13.00%	
	Class II	Count	16	23	39	
		% within Group	32.00%	46.00%	39.00%	
	Class III	Count	22	11	33	
		% within Group	44.00%	22.00%	33.00%	
	Class IV	Count	8	7	15	
		% within Group	16.00%	14.00%	15.00%	

In terms of socio-economic status, there was a trend towards a higher proportion of participants from Class II in the Foley's+PGE2 group compared to the Foley's group(p=0.075).

Table 7: Comparison of period of gestation among two groups

Group	Foley's	Foley's+ PGE2	Total	p value
POG	38.96 ± 0.90	39.00 ± 0.86	38.98 ± 0.87	0.82

Additionally, the periods of gestation are similar among the two groups.

Table 8: Indicators of induction among two groups.

Indications for induction		Group		Total
		Foley's	Foley's+ PGE2	
Post-term	Count	16	13	29
	% within Group	32.00%	26.00%	29.00%
Pre-eclampsia	Count	9	12	21
	% within Group	18.00%	24.00%	21.00%
Oligohydramnios	Count	7	7	14
	% within Group	14.00%	14.00%	14.00%
IUGR	Count	5	4	9
	% within Group	10.00%	8.00%	9.00%
Congenital malformations	Count	3	4	7
	% within Group	6.00%	8.00%	7.00%
Other	Count	10	10	20
	% within Group	20.00%	20.00%	20.00%
Chi square: 0.99		**p value: 0.96**		

In the post-term category, there were 16 cases in the Foley's group and 13 in the Foley's + PGE2 group, representing 32.00% and 26.00% respectively within their respective groups, with a total of 29 cases. The chi-square value of 0.99 with a p-value of 0.96 indicates similarities in indications for induction.

Table 9: Bishop's score at the start of induction among two groups.

Bishop's score at start of induction		Group		Total
		Foley's	Foley's+ PGE2	
1-2	Count	12	7	19
	% within Group	24.0%	14.0%	19.0%
3-4	Count	19	24	43
	% within Group	38.0%	48.0%	43.0%
5-6	Count	19	19	38
	% within Group	38.0%	38.0%	38.0%
p value: 0.38				

The p-value associated with the comparison between the two groups is 0.38, Bishop's scores between the two groups at the start of induction were similar.

Table 10: Bishop's score 12 hours post induction among two groups.

Bishop's score after 12 hours of induction		Group		Total
		Foley's	Foley's+ PGE2	
6-7	Count	22	9	31
	% within Group	44.0%	18.0%	31.0%
8-9	Count	8	14	22
	% within Group	16.0%	28.0%	44.0%
10-11	Count	8	12	20
	% within Group	16.0%	24.0%	20.0%
12-13	Count	12	15	27
	% within Group	24.0%	30.0%	27.0%
Chi square: 14.8		p value: 0.005*		

The p-value associated with the comparison between the two groups is 0.005, Bishop's scores between the two groups after 12 hours of induction werestatistically different.

Table 11: Interval between induction and delivery (hours)

Interval between induction and delivery (hours)		Group		Total
		Foley's	Foley's+ PGE2	
8-9	Count	0	14	14
	% within Group	0.0%	28.0%	14.0%
10-11	Count	11	5	16
	% within Group	22.0%	10.0%	16.0%
12-13	Count	10	12	22
	% within Group	20.0%	24.0%	22.0%
14-15	Count	12	10	22
	% within Group	24.0%	20.0%	22.0%
16-18	Count	17	9	26
	% within Group	34.0%	18.0%	26.0%
Chi square: 19.07		p value: 0.001*		

Table 12: Comparison of duration of Interval between induction and delivery (hours) Between Foley's and Foley's+ PGE2 Groups

Parameters	Foley's	Foley's+ PGE2	Total	p value
Interval between induction and delivery (hours)	13.98 ± 2.47	12.46 ± 2.95	13.22 ± 2.81	0.006*

In the Foley's group, the average interval between induction and delivery was reported as 13.98±2.47 hours. Conversely, in the Foley's+ PGE2 group, this interval was notably shorter, with an average duration of 12.46 ±2.95 hours. When considering both groups collectively, the total average duration of the interval between induction and delivery was calculated as 13.22 ± 2.81 hours. Statistical analysis, indicatethat the use of Foley's catheter alone versus in conjunction with PGE2 had a discernible impact on the duration of the interval between induction and delivery.

Table 13: Augmentation Requirement in Foley's and Foley's + PGE2 Groups.

Augmentation required		Group		Total
		Foley's	Foley's+ PGE2	
ARM	Count	9	16	25
	% within Group	18.0%	32.0%	25.0%
ARM + Oxytocin	Count	21	7	28
	% within Group	42.0%	14.0%	28.0%
No augmentation required	Count	20	27	47
	% within Group	40.0%	54.0%	47.0%
Chi-square: 10.1		p value: 0.007*		

Table 14: Mode of delivery conducted among two groups.

Mode of Delivery		Group		Total
		Foley's	Foley's+ PGE2	
NVD	Count	33	27	60
	% within Group	66.00%	54.00%	60.00%
Ventose	Count	6	7	13
	% within Group	12.00%	14.00%	13.00%
Forceps	Count	3	3	6
	% within Group	6.00%	6.00%	6.00%
LSCS	Count	8	13	21
	% within Group	16.00%	26.00%	21.00%
Chi square: 1.86		p value: 0.60		

DISCUSSION

The prospective observational study was carried out in the Department of Obstetrics and Gynecology at KCGMC Karnal. The study population comprised of antenatal women admitted to the labor room of KCGMC Karnal for safe confinement and meeting the inclusion criteria. Foley's catheter and a combined method (Foley's catheter with PGE2 gel single dose) were routinely used for labor induction at KCGMC,Karnal.100 women undergoing labor induction using these methods and meeting the inclusion criteria were enrolled for the study.

In the present study the mean age of Foley's and Foley's+PGE2 groups was 27.14+_4.9 and 27.16 +_50 years respectively.In a study conducted by Shetty et al, mean age of Foley's and PGE2 group was 25.10 ± 4.59 and 25.50 ± 3.27 years respectively which is comparable to the present

study [5]. Deshmukh et al had also recruited cohorts with comparable age,the mean age being 22.27±2.97 and 22.00 ± 2.79 years in the foley's and PGE2 groups respectively [6] .The Kanada's study, had mean age of 22.59±3.38 and 22.32±3 in the Foley's and PGE2 groups respectively which was comparable to our study[7] . In present study , mean gestational age of the Foley's and Foley's+PGE2 groups was 38.96 ± 0.90 and 39.00 ± 0.86 respectively .Similar to present study , Shetty's study had mean gestational age of 39.72±0.93 and 39.05±1.16 in Foley's and PGE2 group respectively[5] . The mean pre induction bishop scores in Foley's and Fole's+PGE2 group in present study were 1.72 ± 0.57 and 1.66 ± 0.52 respectively. In a study done by Verma et al the mean pre-induction scores was 1.74 ± 0.27 in Foley's group and 1.62 ±
0.82 in PGE2 group respectively which is similar to our study[8] ·Alam's study mean pre-induction bishop scores was 1.91 ± 0.70 in Foley's group and 1.90 ± 0.77 in PGE2 group respectively[9] Deshmukh et al, study mean preinduction score was 1.48 ± 0.67 in foley's group and 1.59 ± 0.78 in PGE2 groupwhich is lower compared to our study[6] . In a study done by Shetty S et al, higher mean pre-induction Bishop scores were noted,score being 2.82±1.44 and 2.88±1.58 in Foley's and PGE2 gel group, respectively, with P=0.84[5] . In present study, post-term pregnancies was found to be the commonest indication for induction of labour. 16 cases were induced using Foley's catheter alone, while 13 cases underwent induction with Foley's catheter combined with PGE2, totaling 29(29%) cases. Similar to present study ,the Kanada's study observed postdated pregnancy as the commonest indication for induction of labour [7] .Similar observation was made by Gonsalves H et al[10] .
In present study The mean bishop score at 12 hrs in Foley's and Foley's+PGE2 group were 8.62
± 1.78, and 9.26 ± 1.48. The overall average Bishop's score across both groups was 8.94 ± 1.66. A statistical analysis using a p-value of 0.05 there was statically significant difference between the two groups with respect to bishop score at 12 hrs(P=0.005).Foley's +pge2 group was found to have significantly higher bishop score at 12 hrs, Similar to present study, Verma's study found Mean post-induction score of 8.04 ± 1.01 in Foley's group and 8.34-+_1.02in PGE2 group respectively, which is similar to our study[8] . In Deshmukh's study, lower mean post induction scores were noted 7.04 ± 1.72 in Foley's group and 7.08+_1.87 in PGE2 group respectively[6] This could be due to lower preinduction scores in their study. Reshme et al. compared Foley's catheter to Dinoprostone gel for labor induction. They found that Dinoprostone gel resulted in a significant change in Bishop's score after 12 hours, indicating better cervical ripening outcomes with pge2 gel compared to foley's catheter[10] .Their results are in concurrence to our study. Dalui et al. conducted a randomized prospective study on 100 patients,the pre induction scores in Foley's and PGE2 were 2.38=0.94 and 2.72 = 0.90 respectively and the post-induction score at 12 hrs in foley's and PGE2 groups were found to be 7.62=1.49 and 5.16=1.34 respectively[11]. In our study dalui et al findings underscored the superior efficacy of the Foley catheter balloon method in cervical ripening[11] . In the Foley's group in the present study, the average interval between induction and delivery was reported as 13.98 ±2.47 hours. Conversely, in the Foley's+ PGE2 group, this interval was notably shorter (12.46 ±2.95 hours). Statistical analysis, indicate that the use of Foley's catheter alone versus in conjunction with PGE2 had a discernible impact on the duration of the interval between induction and delivery. Rajeswari et al [12] observed a significant difference Rajeswari et al[12] observed a significant difference (p <0.001*) in the induction to delivery interval with the Foley's catheter alone group having a slightly longer interval compared to the Foley's catheter combined with PGE2 group.Their study is in concurrence to our study.
Deshmukh et al also observed that induction to delivery interval with Foley catheterization and PGE2 gel was not statistically significant (P = 0.291)[6] .Ziyauddin et al[13] found comparable effects on Bishop's score after 12 hours between Foley catheterization and PGE2 gel groups with a slightly shorter induction to delivery interval in the Foley catheter group 18.15 hours vs. 21.06 hours with PGE2 gel. Their results are also in contrast to our study In shetty et al[5] the mean induction to delivery was 15.65+_5.65 and 15.66±6.62 hrs in Foley's and dinoprostone gel group respectively. The difference was not statistically significant. (P=0.991) They had used only PGE2gel instead of Foley's+PGE2 and this may be due to the fact that they had used only dinoprostone gel instead of

Foley's +PGE2 in their study.

The Kanada's study found higher induction to delivery interval , 16.01±5.50 hours in Foley's and 16.85 ± 3.81 hours in PGE2 group (p=0.073)[7] .The induction delievery interval showed no significant difference in the two groups. However they had not combined PGE2 with Foley's in their study[7].

Labour started spontaneously in 40.0% patients induced with Foley's catheter alone and 54% induced with Foley's catheter with PGE2.There was a statistically significant difference between the 2 groups with respect to requirement for augmentation,p = 0.007suggesting that method of induction influences likelihood of requiring additional intervention during labour.

In Deshmukh's study spontaneous labor ensued in 50 patients in Foley's group (25%) compared with 58 patients in PGE2 group (29%). In Foley's catheter group, need for augmentation of labor was required by doing ARM 8%and both ARM + oxytocin was done in(30%) respectively. In PGE2 group augmentation with ARM and ARM+oxytocin was10% and 21%. There was no significant difference in need for augmentation in both groups.(p=0.21)[6]

Compared to present study ,Alam Study reported that Alam et al showed spontaneous labor ensued in 23 patients in Group Foley's (23%) compared with 27 patients in Group PGE2 (27%).Their results are in contrast to the present study and thid could be due to the fact that PGE2 was used alone and was not combined with Foley's catheter[9]

In present study, 66.00% and 54.00% underwent NVD done in Foley's group and in the Foley's + PGE2 group respectively. Similarly, Ventose deliveries account for 12.00% and 14.00% in the Foley's and Foley's + PGE2 groups respectively. Forceps deliveries are observed in 6.00% of both groups, with counts of 3 each. Lastly, LSCS deliveries are 16.00% and 26.00% in the Foley's and Foley's + PGE2 groups. The difference was not statistically significant indicating similarities in mode of delivery between the two groups.Compared to present study, the Alam study [9] had higher vaginal deliveries in Foley's group 76% (n=76) and where as group PGE2 had 77% (n=77) NVD.

Similar to present study, Shetty's study found vaginal delivery as most common mode of delivery followed by LSCS, they found no significant difference in mode of delivery in two groups with P=0.688[5]. Onge &Sciscione et al. also found no significant difference in LSCS rates between PGE2 and Foley's group (P = 0.438)[14,15]. Our results are similar to Kadu et al.'s[16] study,who reported no significant difference in LSCS rates between Foley's catheter alone and Foley's + PGE2 groups (p = 0.2236)

CONCLUSION

The study comparing Foley's catheter induction alone with Foley's catheter induction combined with PGE2 yielded several noteworthy findings. There was a significant difference in the distribution of Bishop's scores recorded 12 hours post-induction, suggesting that PGE2 addition may influence Bishop's score outcomes, potentially affecting labor progression. Furthermore, while the average Bishop's score was slightly higher in the Foley's+PGE2 group, indicating enhanced cervical ripening with PGE2, the clinical significance of this difference requires further investigation. Additionally, the duration between induction and delivery was significantly shorter in the Foley's+PGE2 group, indicating more efficient induction progress with the combined method. The study also found no significant difference in the mode of delivery or the occurrence of maternal complications between the two groups. However, the Foley's+PGE2 group showed a higher rate of augmentation requirement, suggesting the need for additional interventions with combined induction methods.

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