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A Randomised Controlled Trial Comparing Intracervical Pge2gel Alone Versus Combination of Intracervical Foleys Catheter and Intravaginal Misoprostol for Induction of Labour

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Background and objectives: *Induction of labour is commonly performed in the obstetric department. Around 20% of deliveries are initiated using induction methods. When the risk of continuing the pregnancy is more than benefits of delivery an induction for labour is preferred. Common indication for induction of labour include maternal medical conditions like hypertension or diabetes mellitus, premature rupture of membranes, chorioamnionitis, placental abruption or foetal conditions like foetal growth restriction or oligohydramnios and post term pregnancy& post-dated Cervical ripening has a major in successful induction of labour and vaginal delivery. It is the first component of induction of labour where in cervix is softened in preparation of labour. Mechanical methods like Foley's catheter or pharmacologic methods are used for the cervical ripening. Cervical ripening takes place with a series of biochemical processes which cause many changes in cervix like collagen fibril rearrangement and realignment, glycosaminoglycan composition changes. Balloon catheters and hygroscopic dilators are mechanical methods of cervical ripening. Foley's catheter induces changes in biochemical mediators resulting in cervical ripening.*

Study Design: *It is a randomised controlled trail conducted on Primigravida at term gestation who are admitted in labour ward for induction of labour in GOVERNMENT MATERNITY HOSPITAL,HANAMKONDA during the study period.*

Materials and Methods: *200 pregnant women included in the study. They were alternatively divided into 2 groups (combined group and PGE2 gel group).In combined group , 16F foleys catheter inserted aseptically into cervix with concurrent intravaginal administration of 25 microgram misoprostol 6th hourly for a maximum of 4 doses. In PGE2 gel group 0.5g of gel applied intracervically and repeated after 6hours for a maximum of 3 doses until the cervix was favourable(Bishop score >/- 6). Progress of labour is monitored by a partogram and in all cases fetal heart was monitored by continuos CTG. Outcome measures such as rate of vaginal delivery , induction to active stage interval , induction to delivery interval, NICU admissions , maternal complications were recorded.*

Results: *Two hundred women were included in the final analysis. The combined group and PGE2gel group showed a mean age of 24.85 ± 4.93 and 24.55 ± 4.35 years. Preinduction modified bishop score 2, 3, 4 and 5 were identified in the combined group with 34%, 31%, 29% and 6% whereas, in PGE2 gel group with 33%, 46%, 12% and 9% respectively. In the combined group, APGAR at 1 minutes were >=7 and <7 in 83% and 17% of participants whereas, in PGE2 gel group identified with 71% and 29%. Similarly, APGAR at 5 minutes in combined group were >=9 in in 84% and<9 in 16% of participants whereas, in PGE2 gel group identified with 72% and 28%.*

Interpretation and Conclusion: *The combined use of foleys catheter plus misoprostol is associated with shorter duration of cervical ripening , shorter induction to delivery interval . The combined use of foleys catheter and misoprostol also appears to cause less hyperstimulation and tachysystole. Perinatal outcome was better in combined group than PGE2 gel group.*

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I. Introduction

Induction implies stimulation of contractions before the spontaneous onset of labor, with or without ruptured membranes.When the cervix is closed and uneffaced,labor induction will often commence with cervical ripening.[1] Induction methods are used in 20% of deliveries . When the risk of continuing the pregnancy is more than benefits of delivery an induction for labour is preferred. Common indication for induction of labour include maternal medical conditions like hypertension or diabetes mellitus, premature rupture of membranes, chorioamnionitis, placental abruption or foetal conditions like foetal growth restriction

or oligohydramnios and post term & post dated pregnancy.[2]

Cervical ripening has a major role in successful induction of labour and vaginal delivery.[3] It is the first component of induction of labour where in cervix is softened in preparation of labour. Mechanical methods like Foley's catheter or pharmacologic methods are used for the cervical ripening.[2] Cervical ripening takes place with a series of biochemical processes which cause many changes in cervix like collagen fibril rearrangement and realignment, glycosaminoglycan composition changes, increased production of cytokine and infiltration of white blood cells. All these changes together result in thinning and softening of cervix. Cervical ripening is determined as favourable or unfavourable depending on the extent of modifications occurring and is given by Bishop's score. Favourable cervical ripening is important to be achieved to enhance the efficacy of exogenous oxytocin used to stimulate uterine contractions.[2] Cervical ripening method is usually selected depending on patient's medical and obstetric history, clinical findings and risk of adverse effects like tachysystole. Sometimes even combination methods are used for cervical ripening.[2]

Prostaglandins cause collagenase activation, remodelling of extracellular matrix and initiation of uterine contractions. Prostaglandins used for exogenous administration are available in two forms misoprostol (PGE1) in tablet form and dinoprostone(PGE2) in gel form. Misoprostol can be given through different routes of administration including oral, sublingual or vaginal.[4] Misoprostol is synthetic analog of PGE 1 approved by FDA mainly for prevention and treatment of gastrointestinal ulcers and peptic ulcer disease. But it is also widely used for cervical ripening & induction of labour.[2] The disadvantage associated with misoprostol is the hyper stimulation of uterus. It can avoided with the use of low doses in every 4-6 hours.[5]

Safe and timely vaginal delivery is the main goal of induction of labour and it is believed that combination method of used of mechanical device and administration of chemical agent is more advantageous than using either of the methods in isolation. This study aims to compare efficacy of use of intravaginal misoprostol alone and combination of use of cervical Foley's catheter along with intravaginal PGE2 gel for induction of labour.

II. Aim And Objectives

To compare the efficacy of use of intracervical PGE2 gel alone and combination of use of intracervical Foley's catheter along with intravaginal misoprostol for induction of labour and to reduce side effects of PGE2 gel with combined method.

III. Methodology

The study was conducted on Primigravida at term gestation who were admitted in labour ward requiring induction of labour for any medical or obstetric indication at GMH ,Hanamkondaduring the study period July 2019-December 2020

STUDY DESIGN: RANDOMISED CONTROLLED TRIAL

STUDY PERIOD: JULY 2019-DECEMBER 2020

SOURCE OF DATA: This study was done from the Department of Obstetrics & Gynecology, KAKATIYA MEDICAL COLLEGE ,Warangal under Government Maternity hospital ,Hanamkonda.

INCLUSION CRITERIA:

Age between 19-35 years

1. Primigravida
2. Gestational age between 38 to 42 weeks
3. Singleton foetus
4. Cephalic presentation
5. Intact Membranes & adequate pelvis
6. Bishop score less than 6
7. Reactive Non stress test

EXCLUSION CRITERA:

1. Multigravida
2. Intrauterine fetal death
3. Scarred uterus
4. Prelabour rupture of membranes
5. Malpresentations
6. Placenta previa(grade 2 posterior,grade 3 & grade 4) Vasa previa, active genital herpes
7. Any contraindication to vaginal deliveries

SAMPLE SIZE: 200 cases (100 in combined group and 100 in intracervical PGE2 gel group), was estimated based on induction delivery interval between two groups as 20+/-8.4 and 22.09+/-7 hours respectively from the

study by levineld et al .considering these values at 10% alpha error and 85% power a sample size of 100 in each group was obtained from open epi software.

CONFIDENCE INTERVAL: 90%
POWER: 85%

	INTRACERVICAL PGE2 GEL GROUP	COMBINED GROUP
MEAN	22.09	20
SD	7	8.4

SAMPLE SIZE OF COMBINED GROUP - 100
SAMPLE SIZE OF INTRACERVICAL PGE2 GEL GROUP - 100
THE SAMPLE SIZE WAS CALCULATED BY THE FORMULA

$$\text{Sample size} = \frac{2SD^2(Z_{\alpha/2} + Z_{\beta})^2}{d^2}$$

SD – Standard deviation = From previous studies or pilot study
$Z_{\alpha/2} = Z_{0.05/2} = Z_{0.025} = 1.96$ (From Z table) at type 1 error of 5%
$Z_{\beta} = Z_{0.20} = 0.842$ (From Z table) at 80% power
d = effect size = difference between mean values

So now formula will be

$$\text{Sample size} = \frac{2SD^2(1.96 + 0.84)^2}{d^2}$$

METHOD OF COLLECTION OF DATA

A total of 200 primigravida(100 in combined group and 100 in intracervical PGE2 gel group) fullfilling the inclusion criteria for induction of labour were included into the study after explaining the method of study and obtaining an informed consent. Detailed history regarding age, parity, period of gestation, menstrual history, obstetric history, past history and any complications in present pregnancy were taken Indication for induction of labour was recorded.

General clinical examination and complete obstetric examination was performed. Abdominal examination was done to find out presentation, fetal heart rate and uterine contractions. Per-vaginal examination was done to assess adequacy of pelvis and modified bishop score.

Obstetric scan and NST was done to find out fetal well-being. Following reactive NST and confirmation of modified bishop score </=5, patients were alternatively divided into 2 groups (combined group and misoprostol group).

Combined group (100 patients)- The participants assigned to this group had a 16F foleys catheter inserted aseptically into cervix. Patient was placed in lithotomy position, a sterile cusco's speculum was introduced into vagina to visualise cervix.The anterior lip of cervix was held with sponge holding forceps and the foleys catheter which is held with another sponge holding forceps was advanced upto endocervical canal. The ballon of catheter was inflated with 40ml of sterile normal saline and then the catheter is tapped with traction to inner thighs until it is expelled spontaneously or removed after 12 hours with concurrently intravaginal administration of 25 microgram misoprostol 6th hourly inserted for a maximum of 4 doses.

Intracervical PGE2 GEL group (100 patients)- The participants assigned to this group received 0.5g intracervical application of PGE2 gel every 6 hours until the cervix was favourable (Bishop score >/- 6) or to a maximum 3 doses.)

ANALYSIS OF PROGRESSION

The cervix was assessed every 6 hours to determine the bishop score. Progress of labour was monitored by a Partogram in active stage of labour .

In all cases fetal heart rate was monitored by continuous CTG and oxytocin infusion was given for augmentation of labour if needed.

Outcome measures that were observed was Rate of vaginal delivery, Induction to active phase interval. Others include induction to delivery interval, need for oxytocin augmentation, mode of delivery, APGAR SCORES at 1 and 5 min, admission into NICU, indication of NICU admission, occurrence of maternal complications which includes hyperstimulation.1. Tachysystole- 6 contractions in 10 minutes. 2.Uterine hypertonus- single contraction more than 60 seconds, fetal heart rate abnormalities.

Failed induction is defined as if the modified bishop score remains unfavorable / no adequate uterine contractions were initiated even after 4 doses of misoprostol in both the groups. In such cases , further patient was considered for augmentation with oxytocin / decision for caesarean section was made.

Non progression of labour includes prolonged latent phase and protracted active phase dilatation and descent.

IV. Results And Discussion:

Induction of labour is being increasingly used to prevent many complications of pregnancy including perinatal death. Various factors like fetal size and presentation, gestational age, membrane status, cervical favorability influence successful vaginal delivery through induction. Some studies have established biological efficacy of use of combination of mechanical and pharmacologic agents which include administration of synthetic prostaglandin along with use of catheter. Hence, the present study was conducted to compare the efficacy of use of intracervical PGE2 gel alone and combination of use of intracervical Foley's catheter along with intravaginal misoprostol for induction of labour.

A total of 200 women were enrolled in the study. The subjects were divided in to two equal groups of 100, with the one where intracervical PGE2 gel alone was used and the other where combination of use of cervical Foley's catheter along with intracervical PGE2 gel for induction of labour was used. Baseline demographic and obstetric characteristics of study participants

AGE RATIO:

In the present study, 24.85 ± 4.93 years was the mean age of participants in combined group and 24.55 ± 4.35 years in PGE2 gel group. In a prospective, randomized controlled trial conducted by Chung JH, et al. in 146 patients the mean of age in the combined and PGE2 gel group were 26.4 ± 6.61 and 26.3 ± 6.82 respectively which is similar to our study results.[7]

Table 1: Comparison of mean of age in various studies.

Study	Number of cases	Mean of age
Present study	200	Combined group (24.85 ± 4.93) PGE2 GEL group (24.55 ± 4.35)
Chung JH, et al., [7]	146	Combined group (26.4 ± 6.61) PGE2 GEL group (26.3 ± 6.82)

In the present study, prolonged pregnancy, pre-eclampsia-eclampsia and oligohydramnious were the indication for induction of labour identified in the combined group with 49%, 20% and 31% whereas, in PGE2 gel group with 61%, 12% and 27% respectively. In both the groups the major indication of the induction of the labour was prolonged pregnancy and no statistically significant difference was observed between the groups regarding the indications of the induction[10]

The observations of our study are contradicting the study conducted by BhatiyaniBR, et al., in which postdatism, PIH, IUGR and oligohydramnios are the indications identified for induction in combined group with 40.7%, 44.4%, 11.1% and 3.7% while in PGE2 gel group with 49%, 27.5%, 9.8% and 13.7% [11].

NUMBER OF DOSES

Table 2: Comparison of number of doses of doses of misoprostol used between study groups (N=200)

Number of Doses of misoprostol	Study Group		Chi square	P value
	Combined Group (N=100)	PGE2 gel Group (N=100)		
U3	18 (18%)	29 (29%)		
4	4 (4%)	22 (22%)		

In combined group, 39 (39%) cases required 1 dose ,39(39%) cases required 2 doses ,18(18%) cases required 3 doses and 4(4%) cases required 4 doses. In PGE2 gel group, 22 (22%) cases required 1 dose, 27 (27%) cases required 2 doses, 29 (29%) cases required 3 doses and 22 (22%) cases required 4 doses. The difference in the proportion of number of doses between study group was statistically significant (p value<0.001) (Table 2&Figure 1)

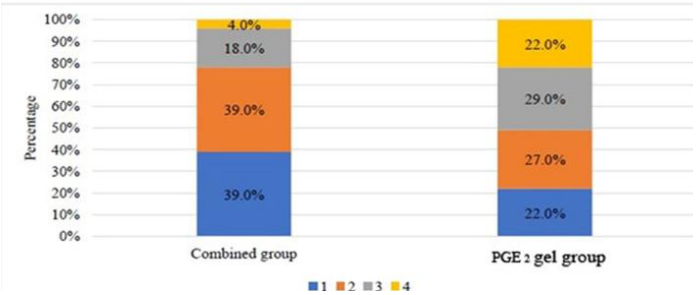


Fig 1: Stacked bar chart of comparison of number of doses between study groups (N=200)

In the present study, most women (39%) in the combined group achieved a favourable Bishop's score with one dose; while in the PGE2 gel group, 22 % cases achieved favourable bishops with one dose.
In a study of 237 pregnant women done by Osoti A, et al. 1, 2, 3 and 4 doses were administered with 100%, 66.7%, 26.7% and 8.9% whereas, in PGE2 gel group with 100%, 88.9%, 46.7% and 17.6% respectively which is contrasting to our study results[12]

Table 3: Comparison of pre induction modified bishop score between study groups (N=200)

Pre-Induction Modified Bishop Score	Study Group		Chi square	P value
	Combined group (N=100)	PGE2 GEL group (N=100)		
2	34 (34%)	33 (33%)	0.967	0.809
3	40 (40%)	46 (46%)		
4	15 (15%)	12 (12%)		
5	11 (11%)	9 (9%)		

Among the cases in combined group, 34 (34%) cases had a pre-induction modified bishop score 2, 40 (40%) had a score of 3, 15 (15%) had a score of 4 and 11 (11%) had a score of 5.Among the cases in PGE2 gel group, 33 (33%) had a score of 2,46 (46%) had a score of 3, 12 (12%) had a score of 4 and 9 (9%) had a score of 5. The difference in the proportion of pre-induction modified bishop score between study group was statistically not significant (p value 0.809) (Table 3 &Figure 2)

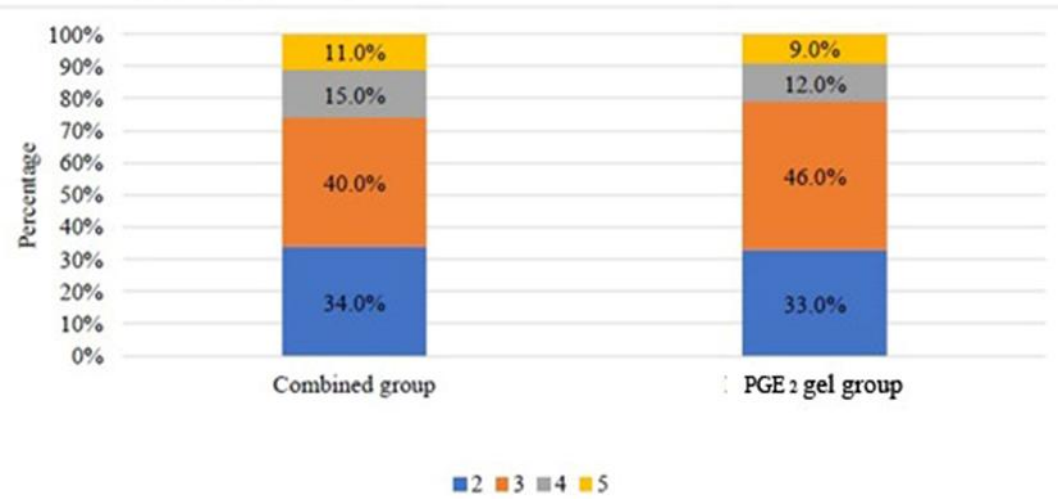


Fig 2: Stacked bar chart of comparison of pre-induction modified bishop score between study groups (N=200)

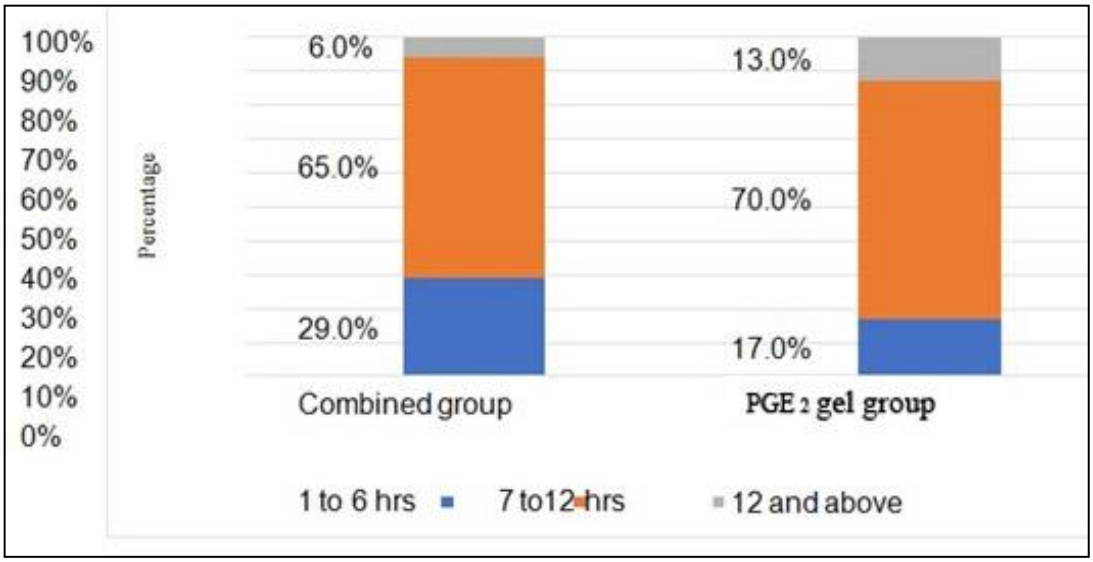
INDUCTION TO ACTIVE STAGE INTERVAL

Table 4: Comparison of Induction to active stage interval between study groups (N=200)

Induction to active stage interval	Study Group		Chi square	P value
	Combined Group (N=100)	PGE2 GEL Group (N=100)		
1 to 6 Hrs	29 (29%)	17 (17%)	5.895	0.052
7 to12 Hrs	65 (65%)	70 (70%)		
12 and above	6 (6%)	13 (13%)		

Among the cases in combined group, duration of induction to active stage was 1 to 6 hours in 29 (29%) cases, 7 to 12 hours in 65(65%) cases, 12 and above hours in 6(6%) cases. Among the cases in PGE2 gel group, duration of induction to active stage was 1 to 6 hours in 17(17%) cases, 7 to 12 hours in 70 (70%) cases, 12 and above hours in 13(13%) cases. The difference in the proportion of timing of induction to favourable bishops score between study group was statistically significant (p value0.052) (Table 4 &Figure 3)

Fig 3: Cluster bar chart of comparison of induction to active stage interval between study groups (N=200)



In the present study the induction to active phase interval in the combined group was significantly shorter than in the PGE2 gel group with a p value of 0.052.

Similar results were obtained in a study by Aduloju D et al, the induction to active phase was shorter in the combined group than in the PGE2 gel group (1 hour 57 minutes versus 4 hours 25 minutes) with a p value of 0.006[13]

These results were also comparable to a study by Leduc P et al, interval from induction of labour to onset of active labour was significantly shorter in the Combined group as compared to the PGE2 gel group (464.35 ± 253.61 minutes versus 617.57 ± 242.72 minutes, p<0.001)[10]

INDUCTION TO DELIVERY INTERVAL

In the current study, the interval from induction to delivery in combined group was upto 12 hours in 40./. whereas 13-24 hours in 57./. and 25-36 hours in 3./. While in PGE2 gelgroup , the interval from induction to delivery was upto 12 hours in 13./. while 13 - 24 hours in 35./. and 25-36 hours in 52./. of cases, which was statistically significant between the groups.

Table 5: Comparison of induction to delivery interval between various studies

Study	Population	Induction to delivery interval
Present study	200	Combined group <12 hrs (40%) 13-24 hrs (57%) 25-36 hrs (3%) PGE2 GEL group <12 hours (13%) 13-24 hrs (35%) 25-36hrs (52%)
Santosh PK, et al.,[14]	200	Combined group 6-16 hrs (50%) 12-24 hrs (41.67%) > 24 hrs (8.535) PGE2 GEL group 6-16 hrs (29.55%) 12-24 hrs (47.72%) >24 hrs (22.73%)

MODE OF DELIVERY

In the present study, the mode of delivery was vaginal in 58%whereas assisted vaginal delivery and caesarean delivery in 16% and 26% of participants and in PGE2 gel group vaginal delivery , assisted vaginal delivery and caesarean sectionwere identified with 37% , 16% and 47% respectively which was statistically significant between the groups where the majority underwent vaginal delivery in combined group, where as in PGE2 gel group it was by caesarean section.

In a prospective, randomized controlled trial conducted by Chung JH, et al., in 146 patients in which vaginal delivery, assisted delivery and caesarean section were identified in the combined group with 58.1%, 11.6% and 41.9% whereas, in PGE2 gel group with 63.3%, 6.1% and 36.7% respectively which is similar to our study results[15]

INDICATION FOR CAESAREAN SECTION

In the current study, in combined group ,38.46% had fetal distress , whereas 23.08.% had failed induction and 38.46 % had non progression of labour as indication for LSCS .Similarly in PGE2 gel group , 52.06% had fetal distress , 17.03% had failed induction and 31.91% had non progression of labour as indication. The commonest indication for caesarean section in both the groups was fetal distress, though the absolute number of cases with fetal distress was greater in the PGE2 gel group52.06% as compared to combined group 38.46%, this difference did not achieve statistical significance. Similar results were obtained in the study by El-Kelani et al, fetal distress followed by failure of induction commonest indications for caesarean section and there was no statistically significant difference between the groups[16]

OXYTOCIN AUGMENTATION

In the present study ,35% cases required oxytocin augmentation in combined group while in PGE2 gel group, 42 % cases required. Though not significant more subjects in the PGE2 gel group required oxytocin augmentation in the present study.

And e AB., et al.performed a study in 100 women in which 44% of participants in the combined group required oxytocin augmentation whereas, 64% in PGE2 gel group required oxytocin augmentation which is similar to our study results[17]

Table 6: Comparison of oxytocin augmentation in various studies.

Study	Population	Oxytocin augmentation
Present study	200	Combined group (35%) PGE2 GEL group (65%)
Carbone JF, et al., [10]	123	Combined group (82%) PGE2 GELgroup(88.5%)
Ande AB., et al.[17]	100	Combined group (44%) PGE2 GEL group (64%)

MECONIUM STAINED LIQUOR

In the present study, 63 % in the combined group had clear liquor and 37% had meconium stainedliquor . Whereas in PGE2 gelgroup , 45% had clear liquor and 55% had meconium stained liquor. The difference was not statistically significant (P =0.078). Aduloju et al observed that the rate of meconium passage was 17.4% in PGE2 gelgroup and 13.9% in the combined group, and the difference was not statistically significant[13]

MATERNAL ADVERSE EFFECTS

In the present study, maternal side effects were identified in combined and PGE2 gel groups with 8% and 19% respectively. Hyperstimulation, PPH, precipitate labour, tachysystole and fever were the causes identified for maternal adverse effects . In PGE2 gel group ,hyperstimulation was noted in 3 cases and fever in 2 cases and no cases of hyperstimulation and fever were reported in combined group. Compared to combined group , a relatively higher frequency of precipitate labour and tachysystole is noted in PGE2 gel group which was statistically significant(p=0.023) In a study of 237 pregnant women done by Osoti A, et al.,4.4% of participants in combined group had maternal adverse effects whereas,8.9% in PGE2 gel group had maternal adverse effects which is a dissimilar to our study[9]

Table 7: Comparison of maternal adverse effects between various studies.

Study	Population	Maternal side effects
Present study	200	Combined group (9%) PGE2 GEL group (19%)
Osoti A, et al.,[12]	237	Combined group (4.4%) PGE2 GEL group (8.9%)

NEONATAL ADVERSE EFFECTS

In the present study 83% of participants were Apgar score at 1 minute = >7 in combined group and 17% were Apgar score at 1 minute <7. Whereas, in PGE2 gel group, 71% were Apgar score at 1 minute = >7 and 29% were Apgar score at 1 minute <7.There was no statistical significant difference between the groups.

Table 8: Comparison of Apgar score at 1 min between various studies.

Study	Population	Apgar at 1 minute
Present study	200	Combined group = >7 (83%) <7 (17%) PGE2 GEL group = >7 (71%) <7 (29%)
Ramchandra KR., et al.,[9]	146	Combined group <7 (20%) > 7 (80%) PGE2 GEL group <7 (20%) > 7 (80%)

In the current study, 84% had Apgar score at 5 minute = >9 in combined group and16% had Apgar score at 5 minute <9. While in PGE2 gel group, 72% had Apgar score at 5 minute = >9 and 28% had Apgar score at 5 minutes <9 which was not statistically significant between the groups.

Ramchandra KR., et al. conducted a hospital based comparative study in 200 women in which Apgar score at 5 mins <9 and > 9 were identified with 4% and 96% in combined group while in PGE2 gel group with 7% and 93% respectively which is dissimilar to our study

Table 9: Comparison of Apgar score at 5min between various studies

Study	Population	Apgar at 5 minute
Present study	200	Combined group = >9 (84%) <9 (16%) PGE2 gel group = >9 (72%)

		<9 (28%)
Ramchandra KR., et al.,[9]	200	Combined group <7 (4%) > 7 (96%) PGE2 GEL group <7 (7%) > 7 (93%)

In the present study, 8% of babies had NICU admission in combined group whereas, in PGE2 gel group, 39% had NICU admission but it is not statistically significant(p =0.009).
Bhatiyani BR, et al., performed a study in 105 participants in which NICU admission was required by 7% in combined group and 11% in PGE2 gel group which is similar to our study results[11.]

V. Conclusion

The combined use of foleys catheter plus misoprostol is associated with shorter duration for cervical ripening , shorter induction to delivery interval . The combination of foleys catheter and misoprostol also appears to cause less hyperstimulation and tachysystole when compared with PGE2 gel alone. Perinatal outcome was better in combined group. Combination of intracervical foleys catheter and intravaginal misoprostol is more economic because they are cheap & doesn't require refrigeration for storage whereas PGE2 gel is costly and need to be stored at 2-8 degree celsius.Developing countries like India use of combined intracervical foleys catheter and intravaginal misoprostol is ideal for induction of labour because its economic ,less caeserean rate ,perinatal outcome is good & less maternal complications.

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