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Original research article

To compare the efficacy and safety of intravaginal misoprostol, intracervical dinoprostone and transcervical foley's catheter for induction of Labour

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Abstract

Background: The labour induction involves the initiation of nonspontaneous contractions of the uterus prior to spontaneous onset leading to progressive effacement and dilation of the cervix and delivery of the baby. Labour is commonly induced in case of post-term pregnancy, pre-eclampsia, premature rupture of membranes etc. Induction is indicated in situations where pregnancy continuation is dangerous to the life of the pregnant women or well-being of the mother or the fetus. The aim of labour induction is to complete the process of labour within defined time frame in good condition and minimum discomfort and complications to the pregnant women.

Objective:

1. To compare the efficacy of intravaginal misoprostol, intracervical dinoprostone and Foley's catheter for induction of labour in terms of induction-delivery interval, oxytocin augmentation and mode of delivery.
2. To compare the neonatal outcome in terms of APGAR score. METHODS: Prospective study was conducted on 180 pregnant women at Vani Vilas Hospital and Bowring & Lady Curzon Hospital, BMCRI, Bangalore after taking full informed consent.

They were randomly assigned into 3 groups:
Group 1: Intravaginal misoprostol.
Group 2: Intracervical dinoprostone.
Group 3: Transcervical Foley's catheter.
Each group containing 60 pregnant women.
Results: The mean (± SD) induction delivery interval was 11.50±2.19 hours in misoprostol group and 13.92±1.80 hours in dinoprostone group and 12.18±1.53 in foley's group. About 76.7% of misoprostol group, 68.3% of dinoprostone group and 83.3% of foley's group delivered vaginally. About 16.7% of misoprostol group, 10% of dinoprostone group and 6.7% of foley's group had NICU admission.
Conclusion: This study shows that induction delivery interval was less, rate of caesarean section was less and number of NICU admission was less with foley's group. Hence transcervical Foley's catheter can be used to achieve effective and safe induction of labour. The sample size is small and hence the results cannot be generalized.
Keywords: Vaginal misoprostol, dinoprostone, foley's catheter

Introduction

Induction of labour is defined as stimulation of regular uterine contractions before spontaneous onset of labour. It can be done either by pharmacologic or mechanical methods. The prostaglandin E2 dinoprostone gel are effective in inducing labour in patients with unripe cervix but is unstable at room temperature, requires refrigeration and is expensive.

Vaginal misoprostol [PG E1] has both myometrial stimulating and cervical ripening properties. It has been reported in over 9000 women worldwide and seems to have safety profile similar to that of dinoprostone [1]. American College of Obstetricians and Gynaecologists recommends the use of low dose 25 microgm vaginal misoprostol every 3 to 6 hrs. Misoprostol can be administered vaginally, orally or rectally, vaginal route appears to offer most benefits in terms of efficacy and minimising side effects [3].

Foley's catheter appears to induce labour through direct mechanical dilatation of cervix and also by stimulating endogenous release of prostaglandin [2]. It has been reported to be more effective than

intracervical or intravaginal administration of PG E2 but associated with a lower rate of caesarean section [5]. It has been reported to be more effective than intracervical or intravaginal administration of PG E2 but associated with a lower rate of caesarean section [5].
The labour induction involves the initiation of nonspontaneous contractions of the uterus prior to spontaneous onset leading to progressive effacement and dilation of the cervix and delivery of the baby [2].

Aims and Objectives

1. To compare the efficacy of intravaginal misoprostol, intracervical dinoprostone and foley's catheter for induction of labour in terms of induction-delivery interval, oxytocin augmentation and mode of delivery.
2. To compare the neonatal outcome in terms of APGAR score.

Materials and Methods

Study design: A Prospective study
The study will be conducted on 180 pregnant women at term. Full informed consent will be taken from the subjects. They are randomly assigned into 3 groups.
Group 1: Intravaginal misoprostol.
Group 2: Intracervical dinoprostone.
Group 3: Transcervical foley's catheter.

Each group containing 60 subjects.

Study period: December 2014 to May 2016

Study population: Vani Vilas Hospital and Bowring & Lady Curzon Hospital, BMCRI, Bangalore.

Sample size: 180 patients

Inclusion criteria

Primi and 2nd gravida with single live fetus with cephalic presentation.
Gestational age 37 to 42 weeks.
Bishops score of < 6.
Reassuring FHS.

Exclusion criteria

Previous uterine surgery.
Non reassuring FHS.
Oligohydramnios.
Placenta praevia.
Multifetal pregnancy.
Fetal malpresentation.
Cord prolapse.
Chorioamnionitis, herpes.
EFW =>4 kgs.
Renal and hepatic disease.

Methodology of data collection

A detailed history followed by general physical examination is done Obstetrical examination is done to assess fundal height, lie, presentation and FHR. Per vaginal examination is done to assess modified Bishop score and adequacy of pelvis. Gestational age was evaluated by last menstrual period. Ultrasound examination was conducted for assessing the gestational age, liquor volume and fetal well-being. The fetal condition was assessed by NST tracings. Samples were collected for baseline laboratory tests. Maternal and fetal parameters monitored by partogram.
NST is done to rule out non-reactive FHR before inducing labour.
In Group 1: Intravaginal misoprostol was repeated every 4 hrs to a maximum 6 doses until patient goes into active labour
In Group 2: Intracervical dinoprostone was repeated every 6-8 hrs to a maximum of 3 doses in 24 hrs, until patient goes into active labour by reassessing FHR before each dose.
In Group 3: Transcervical foley's catheter was inflated with 30 to 50 ml normal saline until it was spontaneously extruded or taken out after 12 hrs.

Procedure

Pregnant women between 37-42 weeks of gestation included in the study were randomly divided into three groups. Group A included pregnant women who were induced with 25 µg of Misoprostol intravaginally in posterior fornix, 4th hourly to a maximum of 6 doses and patients were kept in recumbent position for one hour, Group B included pregnant women induced with 0.5 g of Dinoprostone gel available in 2.5ml syringe with an applicator intracervically,6th hourly to a maximum of 3 doses with or without oxytocin augmentation and Group C were induced with foley's transcervically with or without oxytocin augmentation.

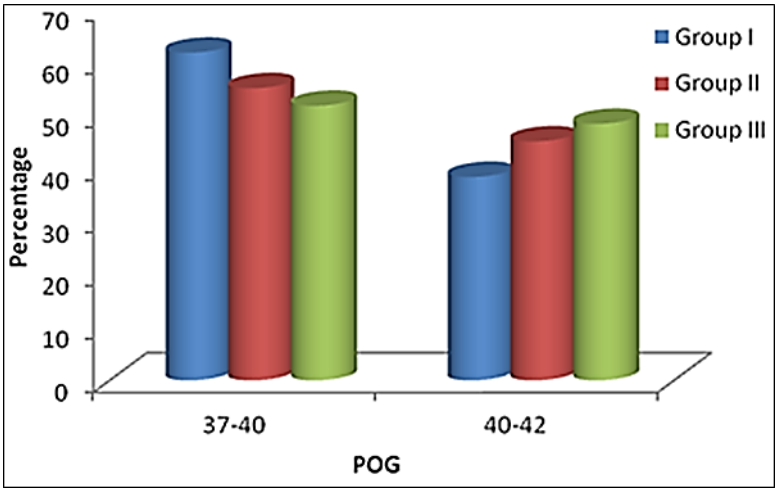
Bishop score was assessed every 6 hours in dinoprostone group, every 4 hours in misoprostol group and after 12 hours in foley's group. Artificial rupture of the membranes was conducted in active labour to hasten the process of delivery and to note down the colour of liquor. If the contractions were not adequate after 1hr of artificial rupture of membranes, in active phase of labour oxytocin drip was started with 2.5 U in 500 ml ringer lactate with 2 mU/min and increased in geometric fashion every 30 min till 3 contractions were observed in 10 min period each lasting for 45 –60 seconds up to a maximum of 40 mU/min. Labour and delivery parameters including interval from start of induction to delivery, number of patients requiring oxytocin augmentation, mode of delivery were compared. Fetal criteria including presence of thick meconium in the amniotic fluid, fetal distress as defined by abnormal cardiotocography prompting emergency delivery, APGAR scores at one and five minutes, meconium stained amniotic fluid and transfer to NICU were noted.

Results

Table 1: Distribution of study group according to period of gestation

POG	Group I	Group II	Group III	Total
37-40	37(61.7%)	33(55%)	31(51.7%)	101(56.1%)
40-42	23(38.3%)	27(45%)	29(48.3%)	79(43.9%)
Total	60(100%)	60(100%)	60(100%)	180(100%)

P=0.532, not significant, Chi-Square test.

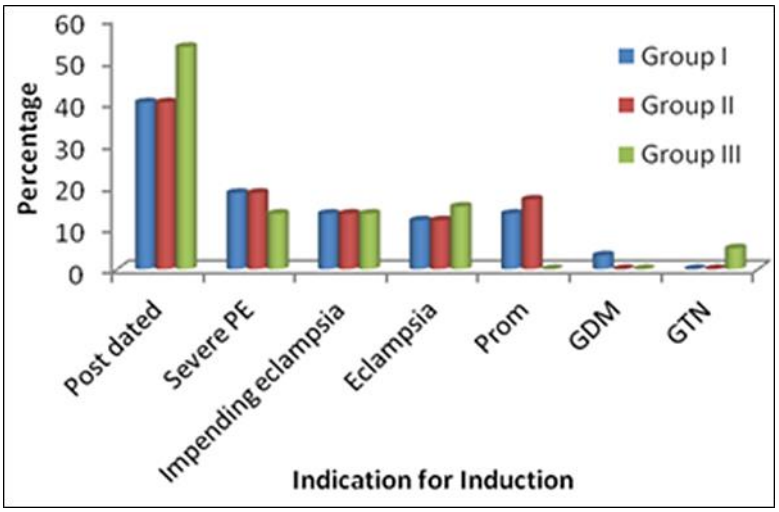


About 61.7% of misoprostol group, 55% of dinoprostone group and 51.7% of foley's group belong to 37-40 period of gestation. About 38.3% of misoprostol group, 45% of dinoprostone group and 48.9% of foley's group belong to 40-42 POG.

Table 2: Distribution of study group according to indication for induction

Indication for Induction	Group I	Group II	Group III	Total
Post-dated	24(40%)	24(40%)	32(53.3%)	80(44.4%)
Severe PE	11(18.3%)	11(18.3%)	8(13.3%)	30(16.7%)
Impending eclampsia	8(13.3%)	8(13.3%)	8(13.3%)	24(13.3%)
Eclampsia	7(11.7%)	7(11.7%)	9(15%)	23(12.8%)
Prom	8(13.3%)	10(16.7%)	0(0%)	18(10%)
GDM with prom	2(3.3%)	0(0%)	0(0%)	2(1.1%)
GTN	0(0%)	0(0%)	3(5%)	3(1.7%)
Total	60(100%)	60(100%)	60(100%)	180(100%)

P=0.039*, significant, Fisher Exact test

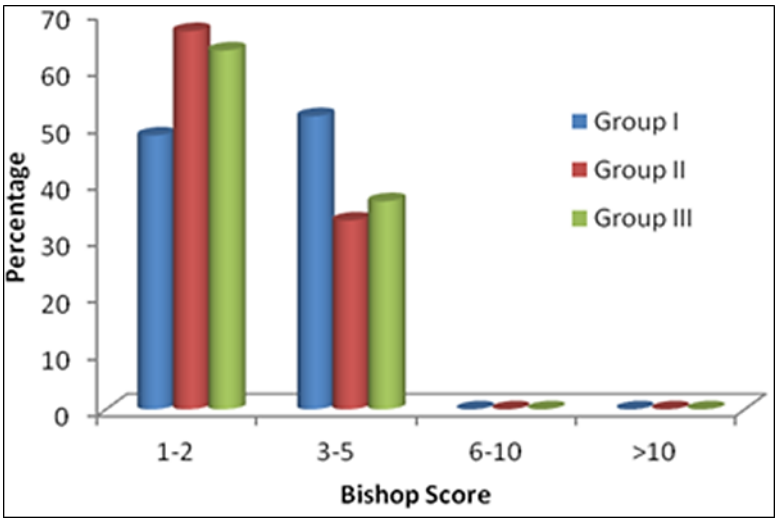


About 40% of dinoprostone group and misoprostol group, 53.3% of foley's group were postdated. 18.3% of dinoprostone group and misoprostol group, 13.3% of foley's group had severe pre-eclampsia. 13.3% of dinoprostone, misoprostol group and foley's group had impending eclampsia. 11.7% of misoprostol and dinoprostone group, 15% of foley's group had eclampsia. 3.3% of misoprostol group had GDM with PROM.

Table 3: Distribution of study group according to modified Bishop score

Bishop Score	Group I	Group II	Group III	Total
1-2	29(48.3%)	40(66.7%)	38(63.3%)	107(59.4%)
3-5	31(51.7%)	20(33.3%)	22(36.7%)	73(40.6%)
6-10	0(0%)	0(0%)	0(0%)	0(0%)
>10	0(0%)	0(0%)	0(0%)	0(0%)
Total	60(100%)	60(100%)	60(100%)	180(100%)
Mean ± SD	2.65±0.78	2.25±0.60	2.33±0.66	2.41±0.70

P=0.004**, significant, ANOVA test

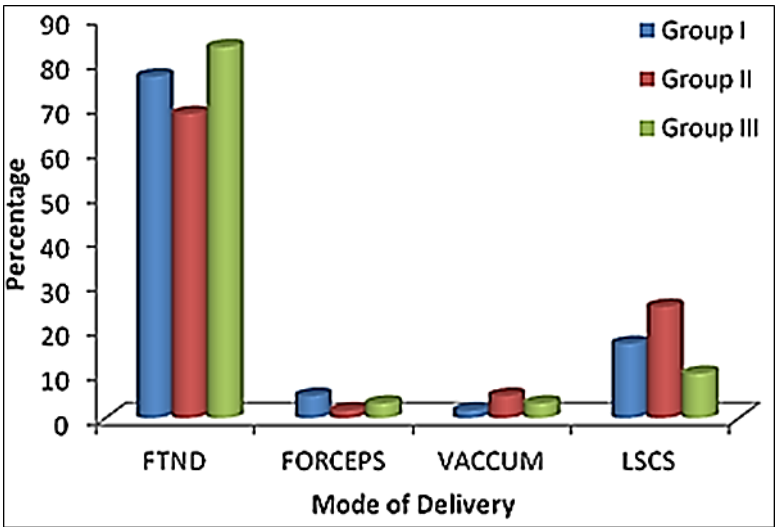


The mean (± SD) Bishop Score was 2.25±0.60 in Dinoprostone, 2.65±0.78 in Misoprostol groups and 2.33±0.66 in foley's group.

Table 4: Distribution of study group according to mode of delivery

Mode of Delivery	Group I	Group II	Group III	Total
FTND	46(76.7%)	41(68.3%)	50(83.3%)	137(76.1%)
FORCEPS	3(5%)	1(1.7%)	2(3.3%)	6(3.3%)
VACCUM	1(1.7%)	3(5%)	2(3.3%)	6(3.3%)
LSCS	10(16.7%)	15(25%)	6(10%)	31(17.2%)
Total	60(100%)	60(100%)	60(100%)	180(100%)

P=0.321, Not significant, Fisher Exact test

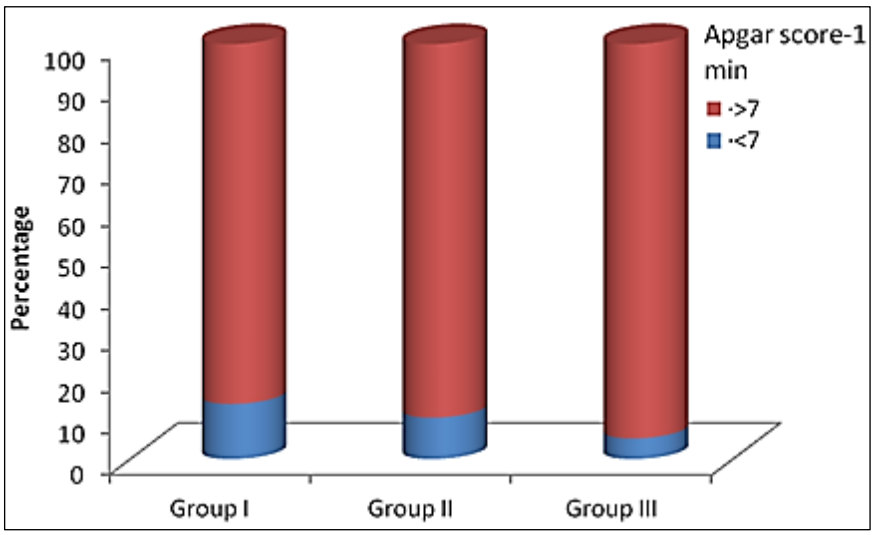


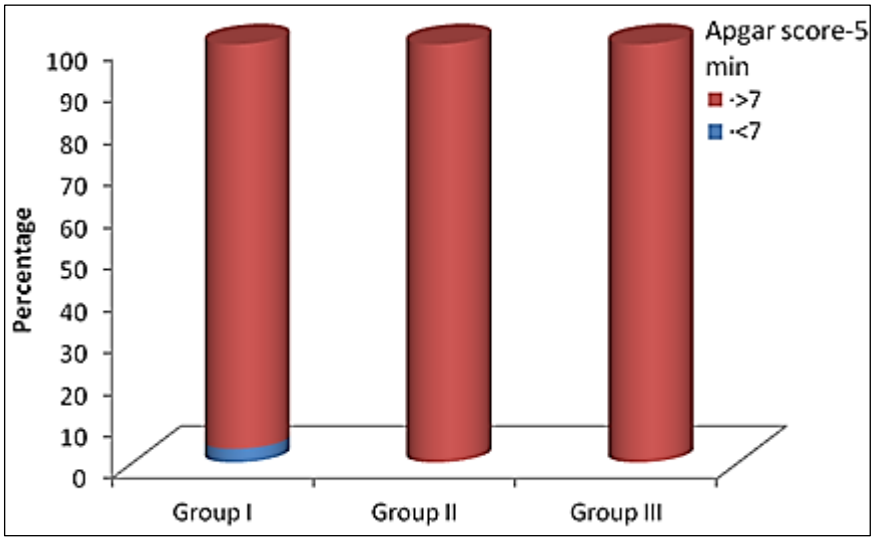
About 76.7% of misoprostol group, 68.3% of dinoprostone group and 83.3% of foley's group delivered vaginally. 5% of misoprostol group, 1.7% of dinoprostone group and 3.3% of foley's group were delivered by forceps.1.7% of misoprostol group, 5% of dinoprostone group and 3.3% of foley's group delivered by vaccum. 16.7% of misoprostol group, 25% of dinoprostone group and 10% of foley's group delivered by caesarean section.

Table 5: Distribution of study group according to Apgar score

Apgar score	Group I (n=60)	Group II (n=60)	Group III (n=60)	Total (n=180)	P value
1 min					
▪ <7	8(13.3%)	6(10%)	3(5%)	17(9.4%)	0.291
▪ >7	52(86.7%)	54(90%)	57(95%)	163(90.6%)	
5 min					
▪ <7	2(3.3%)	0(0%)	0(0%)	2(1.1%)	0.330
▪ >7	58(96.7%)	60(100%)	60(100%)	178(98.9%)	

Chi-Square test/Fisher Exact test



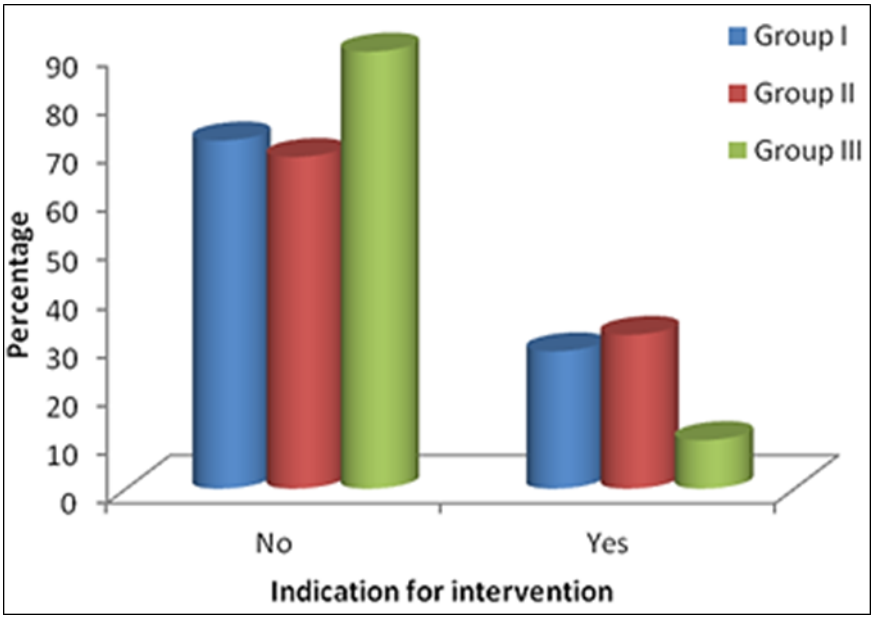


The APGAR score at 1 min was more than 7 in 86.7% of misoprostol, 90% of the dinoprostone group and 95% in foley's group. The APGAR score at 5 minute was more than 7 in 96.7% in misoprostol group and more than 98% in dinoprostone and foley's group.

Table 6: Distribution of study group according to indication for intervention

Indication for intervention	Group I (n=60)	Group II (n=60)	Group III (n=60)	Total (n=180)
No	43(71.7%)	41(68.3%)	54(90%)	138(76.7%)
Yes	17(28.3%)	19(31.7%)	6(10%)	42(23.3%)
• MSAF	7(11.7%)	7(11.7%)	3(5%)	17(9.4%)
• Non-reactive NST	4(6.7%)	4(6.7%)	2(3.3%)	10(5.6%)
• Failed induction	3(5%)	4(6.7%)	0(0%)	7(3.9%)
• DTA	2(3.3%)	3(5%)	1(1.7%)	6(3.3%)
• Cervical dystocia	1(1.7%)	1(1.7%)	0(0%)	2(1.1%)

P=0.010**, significant, Chi-Square test



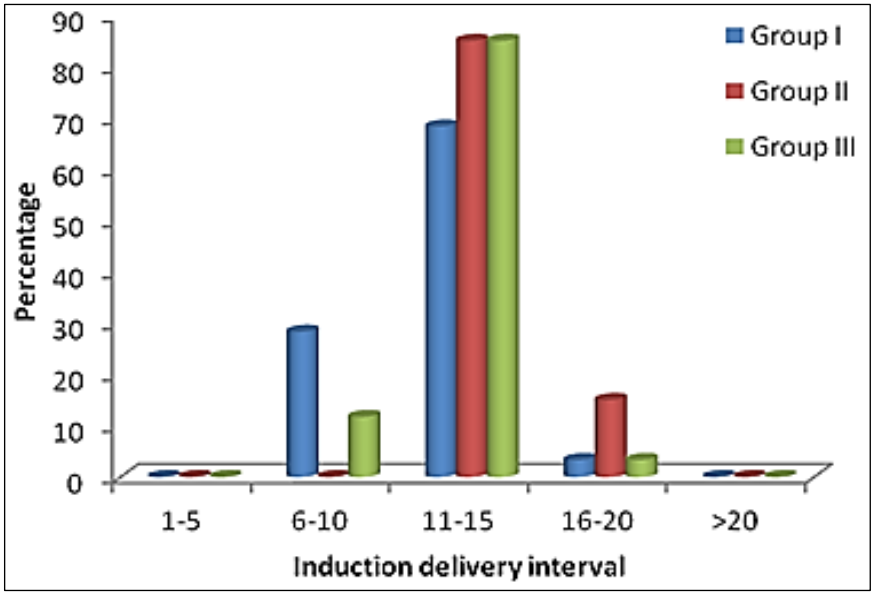
Indication for intervention in misoprostol group was 11.7% MSAF, 6.7% non-reactive NST, 5% failed induction, 3.3% DTA, 1.7% cervical dystocia. In dinoprostone group mainly MSAF, Non-reactive NST and failed induction. In foley's group mainly MSAF 5%.

Table 7: Distribution of study group according to induction delivery interval

Induction delivery interval(hours)	Group I	Group II	Group III	Total
1-5	0(0%)	0(0%)	0(0%)	0(0%)
6-10	17(28.3%)	0(0%)	7(11.7%)	24(13.3%)

11-15	41(68.3%)	51(85%)	51(85%)	143(79.4%)
16-20	2(3.3%)	9(15%)	2(3.3%)	13(7.2%)
>20	0(0%)	0(0%)	0(0%)	0(0%)
Total	60(100%)	60(100%)	60(100%)	180(100%)
Mean ± SD	11.50±2.19	13.92±1.80	12.18±1.53	12.53±2.11

P<0.001**, significant, ANOVA test

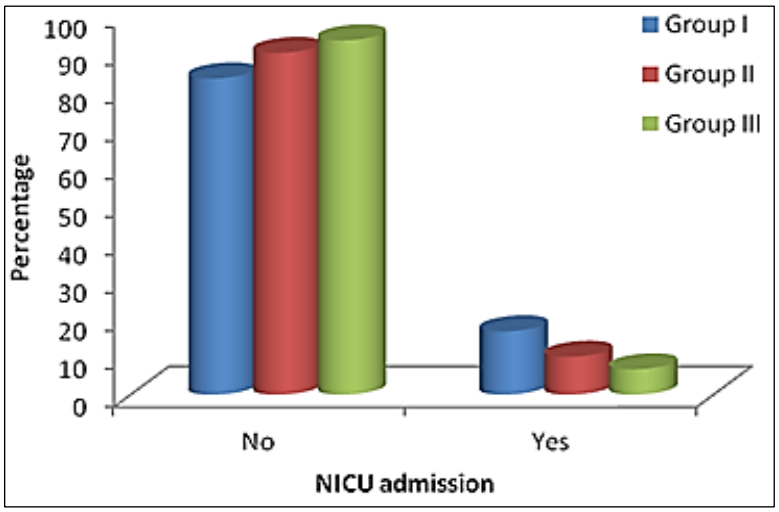


The mean (± SD) induction delivery interval was 11.50±2.19 hours in misoprostol group and13.92±1.80 hours in dinoprostone group and 12.18±1.53 in foley's group.

Table 8: Distribution of study group according to NICU admission

Baby Shifted	Group I (n=60)	Group II (n=60)	Group III (n=60)	Total (n=180)
No	50(83.3%)	54(90%)	56(93.3%)	50(83.3%)
Yes	10(16.7%)	6(10%)	4(6.7%)	10(16.7%)
NICU	10(16.7%)	6(10%)	4(6.7%)	10(16.7%)

P=0.207, Not significant, Chi-Square test



About 16.7% of misoprostol group, 10% of dinoprostone group and 6.7% of foley's group had NICU admission.

Discussion

The induction of the labour reduces the chance of cesarean section and helps in vaginal delivery and thus decreasing the chances of prolongation of labour which may be potentially dangerous for the pregnant women or baby. The induction of labour plays a vital role in this regard [1]. The induction involves the start of non-spontaneous contractions of the uterus leading to progressive effacement and dilation of the

cervix and subsequent delivery of the baby [2].

The failed induction of labour results in prolonged hospitalization, increased caesarean delivery rate up to 60% when the bishop score is less than 4 and increased stress to the patients even if the cesarean delivery is immediately performed [4].

Post-dated pregnancy, severe pre-eclampsia, impending eclampsia, eclampsia, gestational diabetes mellitus and PROM was the main reasons for induction of labour by using dinoprostone, misoprostol and foley's in this study. Chowdhury *et al*. also reported the same.

The main reason for induction of delivery in their study were post-dated pregnancy in both Dinoprostone, Misoprostol groups [6]. The results of this study are also in corroboration with Prager *et al*., Radhika *et al*. [8] and Kudagi *et al*. [9].

The mean (± SD) Bishop Score was 2.25±0.60 in Dinoprostone, 2.65±0.78 in Misoprostol groups and 2.33±0.66 in foley's group at the time of induction of the delivery. The mean bishop scores were higher in misoprostol group compared to dinoprostone group in this study. The mean bishop score was almost similar to Kulshreshtha *et al*. [7] and lower compared to Chowdhury *et al*. [6] and Radhika *et al*. [8].

The mean (± SD) induction delivery interval was 11.50±2.19 hours in misoprostol Group, 13.92±1.80 hours in dinoprostone group and 12.18±1.53 in foley's group. The mean induction delivery interval was lesser in misoprostol group compared to dinoprostone and foley's group. Similar results were obtained in Ramsey *et al*. [11], Neelu *et al*. [10], Chowdhury *et al*. [6], Kulshrshtha *et al*. [7] and Kudago *et al*. [9]. The induction delivery interval was same in Dinoprostone and Misoprostol study groups in a study by Radhika *et al*. [8]. But with study conducted by Prager *et al*. induction delivery interval was shorter with catheter.

Indication for intervention in misoprostol group was 11.7% MSAF, 6.7% non-reactive NST, 5% failed induction, 3.3% DTA, 1.7% cervical dystocia. In dinoprostone group mainly MSAF, Non-reactive NST and failed induction. In foley's group mainly MSAF 5%. Caesarean section rate was higher in dinoprostone group in this study, but did not find any statistical significance. Radhika *et al*. [8] have reported lower cesarean section rates in Dinoproston group compared to Misoprostol group. However, Chowdhury *et al*. [6] and Kudagi *et al*. [9] have reported higher cesarean section rates in dinoprostone group compared to this study.

The indication for cesarean delivery was failed induction in dinoprostone group and fetal distress misoprostol group in study by Neelu *et al*. [10]. Similar results were also reported by Chowdhury [6] and Kulshreshtha *et al*. [7]. The weight of baby was between 2.5-3.5 Kg in 95% of the misoprostol group, 100% in dinoprostone group and 98.3% of foley's group.

The APGAR score at 1 min was more than 7 in babies of 90% Dinoprostone group, 86.7% of misoprostol group and 95% of foley's group. The APGAR score at 5 minute was more than 7 in 95% in all three groups. The APGAR score was almost similar in all three groups at 1 minute and 5 minute in this study. In contrary the these results, the APGAR core was less than 7 in 13.5% of the misoprostol and 27% of dinoprostone group in a study by Chowdhury *et al*. [6]. In a similar study by Kulshreshtha *et al*. [7], the APGAR score at 1 minute was higher in both the groups [12]. Similar results were also obtained by Kudagi *et al*. [9].

Conclusion

This study shows that induction delivery interval was less, rate of caesarean section was less and number of NICU admission was less with foley's group. Hence transcervical foley's catheter can be used to achieve effective and safe induction of labour. The sample size is small and hence the results cannot be generalized. Hence, further research with larger sample size is required to study the effect with misoprostol group induction delivery interval was less, rate of caesarean section was less but the number of NICU admission was more when compared to dinoprostone group.

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