



## A Comparative Study on Use of Intracervical Dinoprostone Gel and Intravaginal Misoprostol for Cervical Ripening and Induction of Labour

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### Abstract

Generally labour induction is indicated when the benefits of delivery to the mother or fetus outweigh the potential risk of continuing the pregnancy. Labour is commonly induced in response to a number of fetal and maternal situations, including post term pregnancy, premature rupture of membranes without the onset of spontaneous contraction within the next 24 hours. Induction of labour has become a common intervention with induction rate ranging from 16% to 44%. The aim of our study is to compare the dinoprostone gel and misoprostol 25µg tab in ripening and induction of labour. The improvement of Bishop's score was more in misoprostol THAN dinoprostone gel.

The rate of vaginal delivery is 78% in dinoprostone gel and 84% in misoprostol group respectively. Three patients in dinoprostone gel groups had Forceps delivery (6%). The rate of caesarean section in group A was 20% & Group B was 16%. The interval from recruitment to ripening of cervix was shorter in misoprostol group than dinoprostone gel [Misoprostol ( $4.98 \pm 1.86$ ), dinoprostone gel ( $8.06 \pm 2.93$ ),  $p < 0.001$ ].

The time from ripening to active labour was almost equal between these two groups.

The interval from active phase of labour to full dilation in group A ( $4.85 \pm 1.13$ ) group B ( $4.11 \pm 1.32$ ).

**Key Words:** Dinoprostone, Misoprostol, Intracervical, Intravaginal, Cervix, Ripening, Induction, Labour.

### INTRODUCTION

The process of induction of labour considered when vaginal delivery is felt to be the appropriate route of delivery<sup>1,2</sup>. Generally labour induction is indicated when the benefits of delivery to the

mother or fetus outweigh the potential risk of Continuing the pregnancy. The most appropriate timing for labour induction is the point at which the maternal or perinatal benefits are greater if the

pregnancy is interrupted than if the pregnancy is continued.

Induction of labour has become a common intervention with induction rate ranging from 16% (Calder et al)<sup>3</sup> to 44% (Yeast et al)<sup>4</sup>.

Labour is commonly induced in response to a number of fetal and maternal situations, including post term pregnancy, premature rupture of membranes without the onset of spontaneous contraction within the next 24 hours<sup>5</sup>. Hypertensive disorders of pregnancy, intrauterine growth restriction, abruption placenta, intraamniotic infection (chorioamnionitis), IUFD and major congenital anomaly etc.

Induction of labour is contraindicated in few circumstances like contracted pelvis and cephalopelvic disproportion, malpresentation.

There are lots of pharmacological and surgical methods for induction of labour intracervical Foley's catheterization, intravaginal misoprostol 25µg tabs and intracervical dinoprostone gel are the most commonly used technique

## MATERIALS AND METHODS

The study was conducted in the Department of Obstetrics and Gynaecology, Calcutta National Medical College & Hospital, Kolkata

**Study population:** All antenatal mothers at term with decision of induction of labour were admitted in the labour room in the O&G Department of Calcutta National Medical College & Hospital. All high and low risk populations were recruited for study.

**Study period:** 8<sup>th</sup> May 2013 to 30<sup>th</sup> November 2014

**Sample size:** Using statistical protocols, a sample size of minimum 50 cases were randomly recruited in each of these two groups. Misoprostol 25 µg (group A, n =50) and dinoprostone gel (group B, n = 50).

**Sample design:** Randomized prospective study

### Inclusion criteria:

1. Primigravida
2. > 37 weeks of gestation
3. Singleton pregnancy
4. Cephalic presentation
5. Bishop's score  $\leq$  3
6. Intact membrane

**Parameters study:**

1. Demographic profile
2. Gestational age
3. Improvement of Bishop's score
4. Induction delivery interval
5. Mode of delivery, 6) Foetomaternal outcome

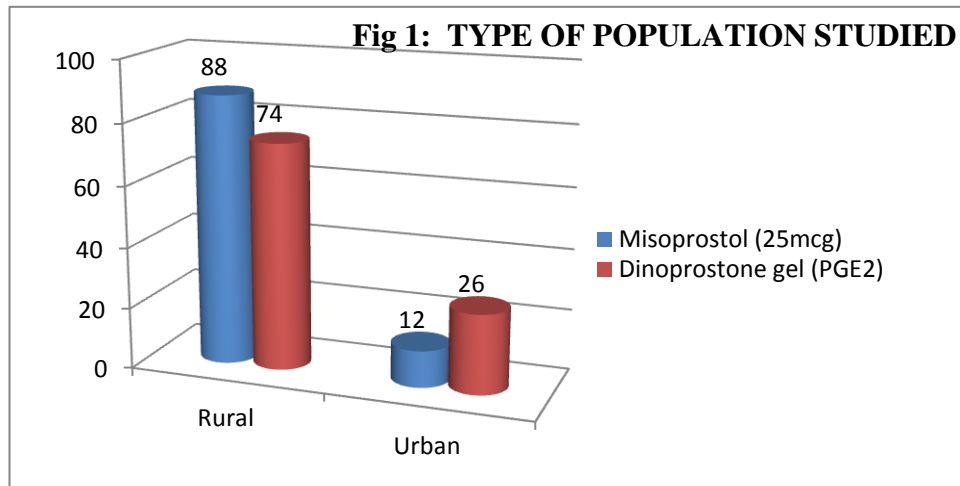
### Study technique:

Includes detailed history taking and clinical examination followed by relevant investigation. The patients were randomly allocated to misoprostol 25µg (group A, n = 50) and dinoprostone gel (group B, n = 50). Gestational age was confirmed by LMP, past records of clinical examination and 1<sup>st</sup> trimester USG if possible. Bishop's score was determined and those patients, who have score  $\leq$  3, were randomly allocated to one of these two groups. Demographic profile and gestational age were noted. Intracervical dinoprostone gel 0.5 mg was applied and reassessed after 12 hours if Bishop's score found less than 6, dose was repeated and again

reassessment done after 12 hours. Intravaginal misoprostol 25 $\mu$ g was given 6 hourly for a maximum of four doses. All patients were evaluated for improvement of Bishop's score, induction delivery interval, mode of delivery and foetomaternal outcome. Need of augmentation

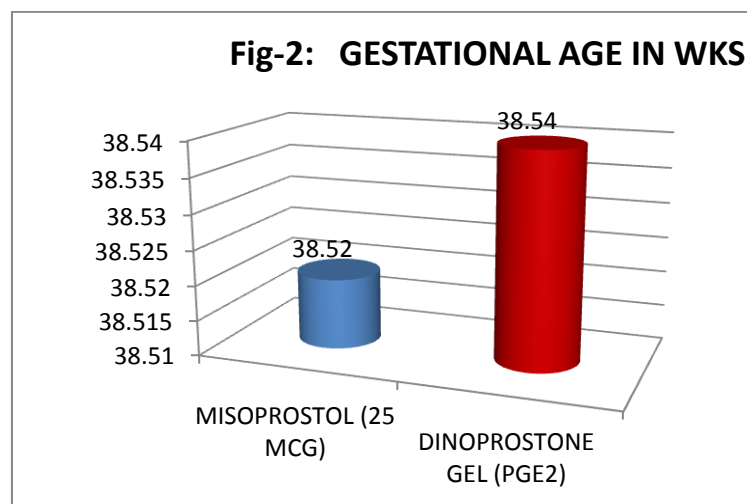
was assessed and implemented done by other methods such as artificial rupture of membranes and oxytocin administration. Failure of ripening and induction was declared if patient fails to go to active phase of labour within 48 hrs of onset of induction.

## RESULTS AND ANALYSIS



There was actually no difference in between these two groups and therefore neonatal outcome in

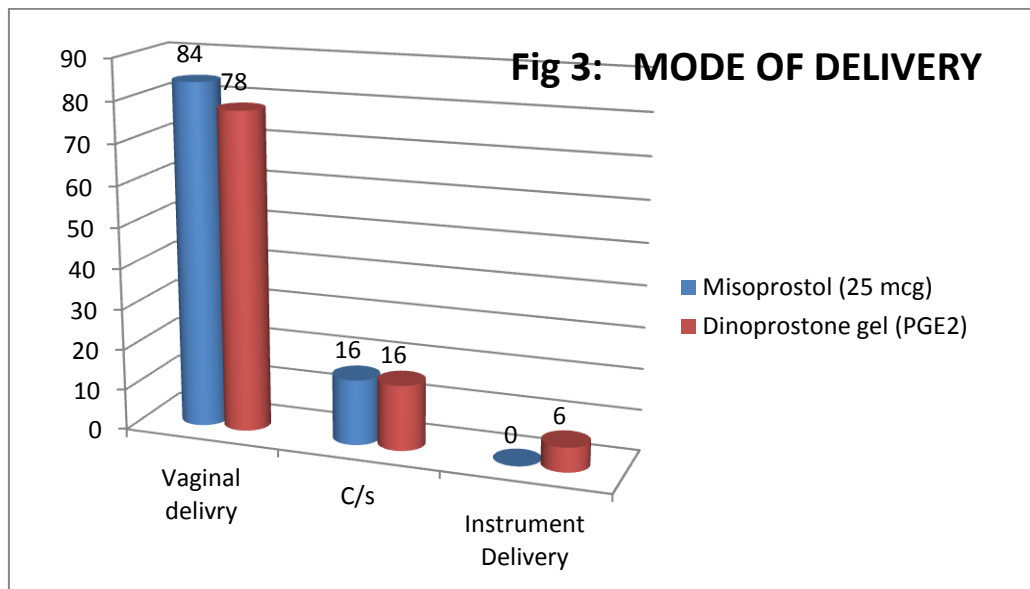
term of Apgar score at 1 min is very similar in two groups.



The distribution of mean gestational age in completed weeks in term pregnant women with induction in two different groups. Values are in completed weeks. Here the p value is greater than

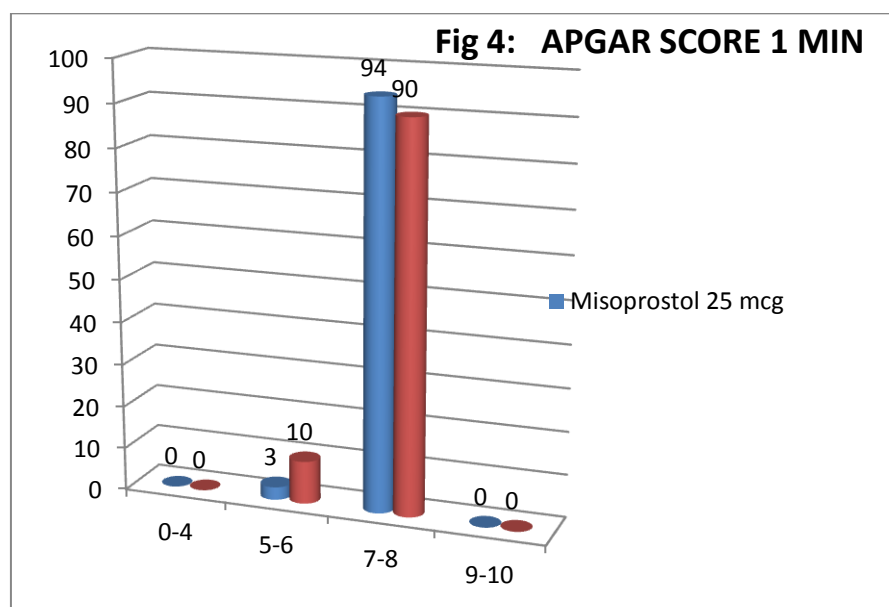
0.05, therefore the difference in these two groups is not significant.

Apgar score at 5 min shows no difference among these three groups. So it is statistically not significant



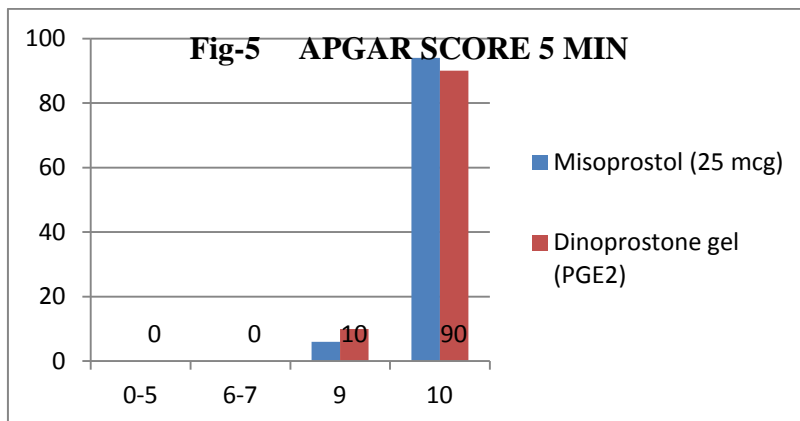
It is clear that the percentage of vaginal delivery is almost equal between these two groups and also the rate of caesarian section (c/s) is also equal between these while vaginal delivery (84%) is more common in misoprostol group and c/s rate is

equal as we can see from these figure. And rate of instrumental delivery like Forceps was common in dinoprostone gel group. So there is no significant difference ( $p > 0.05$ ) regarding mode of delivery among these two groups.

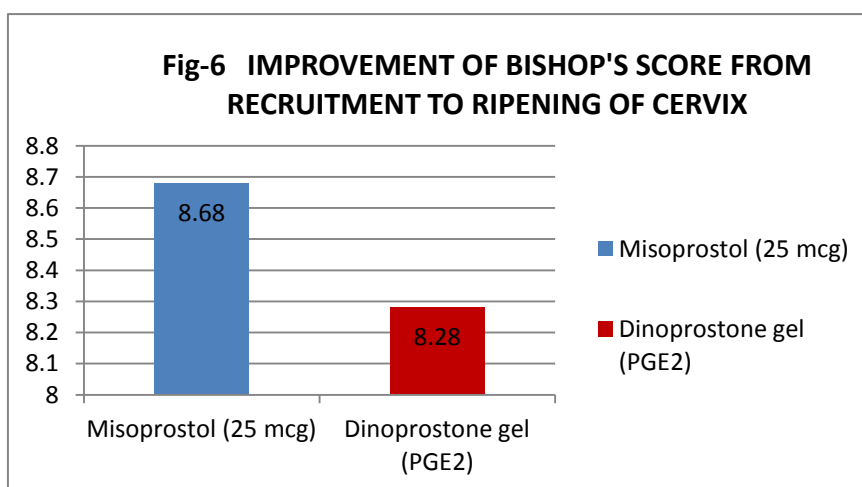


Distribution of the neonatal outcome at birth according to Apgar score in 1 min after birth in two groups. Values are in n (%). There was actually no difference in between these two

groups and therefore neonatal outcome in term of Apgar score at 1 min is very similar in two groups.

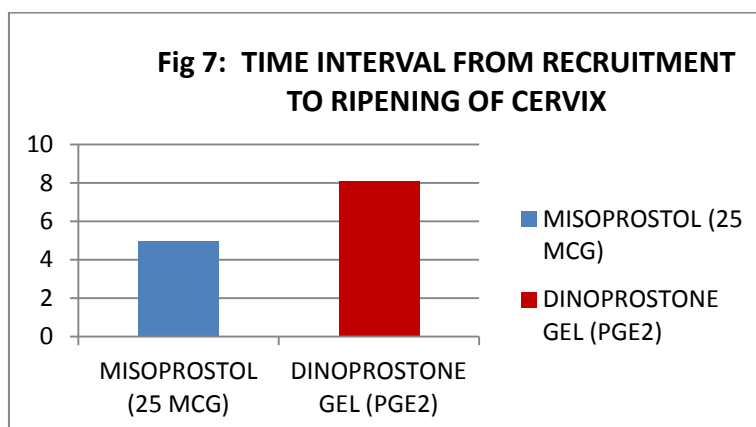


Apgar score at 5 min shows no difference among these three groups. So it is statistically not significant.



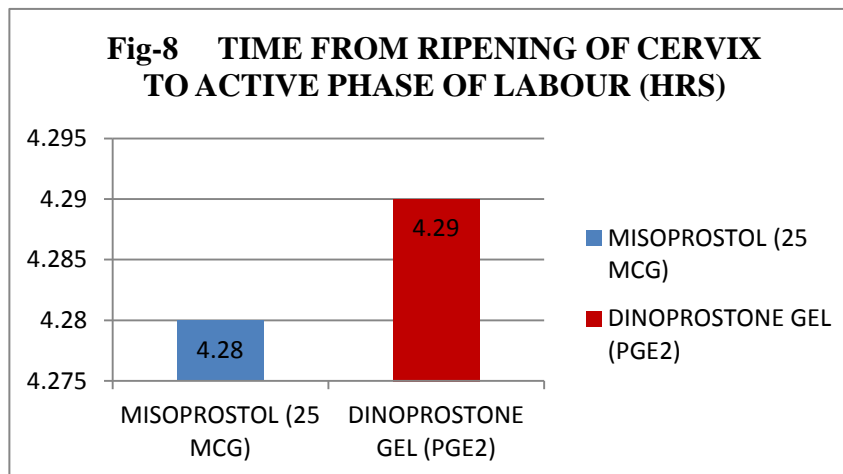
The improvement of Bishop's score is more in misoprostol (8.68 ± 1.65) group than Dinoprostone (8.28 ± 2.01) group. Here (p =

0.037) so this is **statistical significant as (p < 0.05)**.



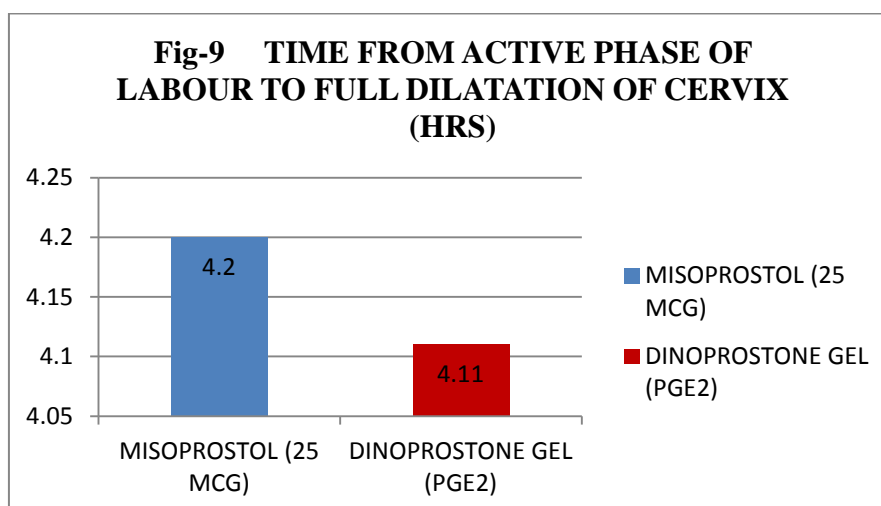
The time interval from recruitment to ripening of cervix is significantly short in these two groups. But it is shorter in misoprostol groups. P value is

very low, **p = < 0.001** between misoprostol & dinoprostone gel. So the study is **statistically significant**.



time interval from ripening to active phase of labour is almost equal in between these three

group. So the study is statistically not significant ( $p > 0.05$ ).



The time interval from active phase of labour to full dilatation in dioprostone gel is very low in comparison to misoprostol group [  $p = 0.009$  ( $p < 0.05$ )]. So this result is also found to be statistically significant.

### SUMMARY

A randomized control study was performed between two groups of nulliparous pregnant mother admitted in labour room of, Obstetrics and Gynecology department in our hospital at CNMC&H for induction of labour for a span of one year from 1<sup>st</sup> July 2013 to 30<sup>th</sup> June 2014.

1. All the patient went into labour within 20-22 hrs except 2 one in group A and one in group B
2. The improvement of Bishop's score was more in misoprostol THAN dinoprostone gel.
3. The rate of vaginal delivery is 78% in dinoprostone gel and 84% in misoprostol group respectively. Three patient in dinoprostone gel groups had Forceps delivery (6%). The rate of caesarean section in group A was 20% & Group B was 16% The indication of caesarean

section was induction failure. Fetal distress and prolonged or non progress of labour. There were total 10 cases of induction failure, 5 in group A and 5 in group.

4. The interval from recruitment to ripening of cervix was shorter in misoprostol group than dinoprostone gel [Misoprostol ( $4.98 \pm 1.86$ ), dinoprostone gel ( $8.06 \pm 2.93$ ),  $p < 0.001$ ]
5. The time from ripening to active labour was almost equal between these two groups.
6. The interval from active phase of labour to full dilation in group A ( $4.85 \pm 1.13$ ) group B ( $4.11 \pm 1.32$ ).
7. Maternal outcome was measured in term of PPH, blood transfusion, trauma to genital tract, febrile episode and numbers of days of stay at hospital. There was no evidence of febrile episode. 4 cases had PPH and received blood transfusion, 2 in dinoprostone gel group and 2 in misoprostol group. Maximum numbers of days of hospital stay of mother was 2 days in all of three groups. With 4 days in three cases of dinoprostone gel group.
8. Neonatal outcome was measured in term of Apgar score at 1 min and 5 min. NICU admission, birth weight and still birth

There were no cases of still birth. Birth weight was almost equal in two group and common birth weight was (2.6-3) kg between these two groups and maximum no. of successful vaginal delivery was in dinoprostone gel group but the data was insignificant. Apgar score in 1 min was  $> 7$  in 137

cases and 6 in 12 and 5 in only 1 case. Apgar score in 5 min was 10 in 138 cases and 9 in 12 cases.

There was no significant difference found in term of maternal and neonatal outcome. With regard to safety misoprostol was similar to dinoprostone gel in our study.

## CONCLUSION

Induction of labour with Dinoprostone gel and vaginal misoprostol tablet (25 mcg) in all primigravida at term pregnancy lead to similar maternal and neonatal outcome in regard to safety, success of cervical ripening and labour induction and patient satisfaction.

Vaginal misoprostol (25 mcg) was not only safe and effective as dinoprostone gel and intracervical Foley's catheter but it reduced significantly the duration of labour in primigravida at term and no increase in the rate of caesarean section.

## REFERENCES

1. RCOG. Induction of labour: Royal College of Obstetrician and Gynecologists, RCOG Evidence based Clinical Guidelines Number 9. June 2001
2. Brindley BA, Sokal RJ. Induction and management of labour. Basis and methods for current practice. *Obstet Gynecol Surv* 1988; 43: 730
3. Calder AA. Review of prostaglandin in use in labour induction. *Br. J Obstet Gynecol* 1997; Oct 104 suppl 15: 2-7: 20-5
4. Yeast JD, Jones A, Poskin M. Induction of labour and the relationship to caesarean

- delivery: A review of 7001 consecutive inductions. *American Journal of Obst Gynae* 1999; Mar 180 (3 Pt 1): 628-33.
5. ACOG. Induction of Labour. Washington DC, USA: The American College of Obstetrician and Gynecologists, ACOG Practice Bulletin Number 10. 1999
  6. Barnes R. On the indication and operations for the induction of premature labour and for the acceleration of labour. *Trans Obstet Soc Lond* 1861; 3: 132-139.
  7. Champetier de Ribes CLA. De l'accouchement provoqué. Dilatation du canal génital (col de l'utérus vagin et vulve) à l'aide de ballons introduits dans la cavité utérine pendant la grossesse. *Ann Gynae* 1888; 30: 401-438