Section: Obstetrics and Gynaecology

Original Research Article

A COMPARATIVE STUDY OF EFFICACY OF DINOPROSTONE GEL AND MISOPROSTOL IN INDUCTION OF LABOUR IN PREECLAMPSIA COMPLICATING PREGNANCY

Shobha Rani P[1], T. Suchetha Lakshmi[2], P. Rammohan[3]

[1]Assistant Professor, Department of Obstetrics and Gynaecology, Government Medical College, Siddipet, Telangana, India.
[2]Associate professor, Department of Obstetrics and Gynaecology, Government Medical College, Rajanna Sircilla, Telangana, India.
[3]Associate Professor, Department of Pathology ,Government Medical College, Rajanna Sircilla, Telangana, India.

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Corresponding Author:
Dr. P. Rammohan,
Associate Professor, Department of Pathology, Government Medical College, Rajanna Sircilla, Telangana, India.
Email: drpeddiram@gmail.com

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ABSTRACT

Background: The aim is to compare the efficacy of dinoprostone gel 0.5mg intracervical application and misoprostol 25 mcg intra vaginal application in induction of labour in preeclampsia complicating pregnancy, by comparing their.

Materials and Methods: In the present study 100 preeclampsia patients who gave consent for the study were studied and 50 patients induced with dinoprostone 0.5mg intra cervically and 50 patients induced with misoprostol 25mcg intra vaginally.

Results: Mean change in modified bishop score with dinoprostone and misoprostol is at 0 hours 1.94+/-0.97 and 2.5+/-1.16 respectively. At 6 hours 3.3+/-2.02 and 4.3+/- 2.31. In dinoprostone 20% cases need single dose,46% needed maximum 3 doses. In misoprostol 14% cases need single dose, 18% needed maximum 6 doses. Mean induction to active phase interval in dinoprostone is 13.65+/-5.44 hours, in misoprostol is 13.3+/-7.05 hours. Mean induction to delivery interval in dinoprostone is 22.84+/-8.41 hours, in misoprostol is 19.03+/-9.2 hours. Chi square value 8.16, p=0.0426 which is statistically significant. Vaginal delivery in dinoprostone group is 66%, misoprostol is 76%. Caesarean section rate in dinoprostone 34%, misoprostol is 24%. P value for mode of delivery is 0.7496, statistically not significant. Maternal complications comparable in both groups. Meconium stained liquor and tachysystole more in misoprostol but p=0.0941, statistically not significant. Neonatal complications, outcome, NICU admissions comparable in both groups, statistically not significant.

Conclusion: In conclusion, low dose misoprostol (25 mcg) is a cheap and effective drug for cervical ripening and labour induction in preeclampsia complicating pregnancy.

Keywords: Dinoprostone, Misoprostol, Preeclampsia, Cervical Ripening.

INTRODUCTION

Induction of labour is an intervention that artificially initiates uterine contractions leading to progressive dilatation and effacement of cervix and expulsion of fetus prior to spontaneous onset of labour. Ideally, most pregnancies should be allowed to reach term, with the onset of spontaneous labour being sign of physiological termination of pregnancy. According to WHO guidelines, labour induction should be performed at a center, where qualified staff and Operation Theatre facilities are available for caesarean section. Uterine activity and electronic fetal monitoring should be done for all patients undergoing labour induction. Cervical assessment (Bishop Score) at the time of initiation is the best independent predict of induction success. Although multiple agents are available for labour induction, the most commonly used methods are mechanical methods, prostaglandins and oxytocin. The goal of

labour induction must always be to ensure the best possible outcome for mother and newborn.[1,2] Favorable factors for labour induction include younger age, multi parity, body mass index (BMI) <30, favorable cervix and birth weight <3500 gr.

Hypertensive disorders complicate 5-10% of pregnancies, and together they are one of the deadly triad –along with hemorrhage and infection, that contribute greatly to maternal morbidity and mortality rates. Of Hypertensive disorders preeclampsia syndrome is the most dangerous. Severe preeclampsia is a major cause of severe maternal morbidity (e.g. stroke and liver ruptures) and adverse perinatal outcomes, such as prematurity and intrauterine growth restriction. Preeclampsia is one of the dreaded complications in obstetrics & due to its associated adverse maternal & neonatal outcome. Incidence range from 5-15%, in primi it is 10%, multi 5%, there is significant association of preeclampsia in maternal & neonatal mortality & morbidity.[3,4] It has to be terminated at 37 weeks or before depending on the severity of preeclampsia, for that labour has to be induced. Limited knowledge is available on the efficacy of misoprostol and dinoprostone gel in induction of labour in preeclampsia complicating pregnancy. Hence this study was designed to bridge this lacuna comparing effectiveness of misoprostol and dinoprostone gel in terms of maternal and fetal outcome.

MATERIALS AND METHODS

Cross sectional study in all the 100 women with preeclampsia attended for OPD or admitted from December 2017 to September 2019 as per inclusion and exclusion criteria, and give informed consent for study are selected. Patients fulfilling the inclusion criteria were randomly allocated to

Group A: Receiving tablet misoprostol 25 mcg intra vaginally 4 hourly in primi,6 hourly in multi, to a maximum of 6 doses.

Group B: Receiving dinoprostone gel 0.5 mg intracervically 8 hourly in primi,12 hourly in multi, to a maximum of 3 doses.

Patients will be monitored by intermittent auscultation, electronic fetal monitoring for development of fetal complications. The entire drug profile including its side effects, success rate and failure rate will be explained to the patient and her attendants in detail. It will be explained that refusal to participation in the study will not affect the management of the patient.

The patient was considered in the active phase when there was cervical dilatation of at least 4 cm. Women in labour when they entered active phase, depending on the pattern of uterine contractility, oxytocin will be used for augmentation. If women failure to achieve regular uterine contractions (every 3 minutes) within 24 hours of induction, caesarean section will be done for failed induction. No augmentation was done when uterine contractions reached a frequency of 3 in 10 minutes, each contraction lasting for 45 sec.

Inclusion criteria: Women with preeclampsia in third trimester of Singleton pregnancy with Cephalic presentation, Pre induction cervical score less than 5 by bishop's scoring system, Intact membranes, Reactive Non stress test, Clinically adequate pelvis.

Exclusion criteria: Women with previous uterine scar, Placenta / vasa previa, Abnormal fetal lie / malpresentations, PROM, EFW > 4500 grams, Eclampia, Cephalo pelvic disproportion, Multiple gestation, Severe oligohydramnios, Antepartum haemorrhage, Intrauterine fetal demise, Non-reactive Non stress test, with asthma, allergy to prostaglandins.

Complete blood picture, complete urine examination, screening for HIV (Human immuno deficiency virus), HBsAg (Hepatitis B surface antigen), VDRL (Venereal disease research laboratory), Thyroid stimulating hormone, Liver function tests, Renal function tests, Random Blood Sugar, Blood Grouping & Typing, Bleeding Time, Clotting Time, Expert ultrasound with biophysical profile and doppler study.

The statistical significance among all parameters will be derived by student t-test & chi-square test. The results observed, subjected to statistical analysis by independent 't' test and chi- square test, a p value <0.05 is considered statistically significant.

RESULTS

Total number of preeclampsia cases studied was 100. 50 patients were induced with 25mcg intravaginal misoprostol tablets and the other 50 patients induced with 0.5mg intracervical dinoprostone gel.

Table 1: Patient particulars in present study

Particulars	Dinoprostone		Misoprostol	
	No. of Patients	Percentage	No. of Patients	Percentage
Booked	28	56	33	66
Unbooked	22	44	17	34
Total	50	100	50	100
Gestational age in weeks				
28w – 31w	0	0	1	2
31w 1 day – 34w	7	14	1	2
34w 1 day – 37w	12	24	11	22
37w 1 day – 40w	22	44	31	62
40w 1 day – 42w	9	18	6	12
>42w	0	0	0	0
Bishop Score				
1	23	46	14	28

2	9	18	10	20
3	16	32	13	26
4	2	4	13	26
5	0	0	0	0

In the dinoprostone group out of 50 patients 28 cases were booked and 22 cases were unbooked giving an incidence of 56% and 44% respectively.

In the Misoprostol group, out of 50 patients 33 were booked and 17 were unbooked giving an incidence of 66% and 34% respectively In the present study, maximum number of patients are having 37 to 40 weeks of gestational age, in both dinoprostone and misoprostol groups,22 (44%) and 31 (62%) respectively. In the dinoprostone group majority of patients were found to have a modified Bishop score of 1 (23cases 46%). In the misoprostol group majority of patients were found to have a modified Bishop's score of 1 (14cases28%)

In the present study, In the dinoprostone group 66% and 26 % patients were found to have a modified Bishop's score at 6 hours between 1 to 3 and 4 to 6 at 6 hours respectively. In the misoprostol group 42% patients were found to have a modified Bishop's score at 6 hours between 1 to 3 and 4 to 6 at 6 hours each respectively.

Table 2: Total Dosage Required

Misoprostol			**Dinoprostone**		
Dosage Required In mcg (N)	**Number**	**Percentage**	**Dosage Required in mgs (N)**	**Number**	**Percentage**
25 (1)	7	14	0.5 (1)	10	20
50 (2)	9	18	1.0 (2)	17	34
75 (3)	7	14	1.50 (3)	23	46
100 (4)	6	12			
125 (5)	12	24			
150 (6)	9	18			

In misoprostol group, majority of patients12 (24%) required 5 doses of misoprostol. In the dinoprostone group, majority of patients 23(46%) required 3 doses of dinoprostone.

Table 3: Induction to active phase

Interval (Hours)	**Dinoprostone**		**Misoprostol**	
	Number	**Percentage**	**Number**	**Percentage**
</=10	8	16	14	28
10.01-20	25	50	20	40
20.01-30	3	6	7	14
30.01-40	0	0	0	0
>40	0	0	0	0

χ 2 =4.50 P=0.212. "p" value > 0.05, so it is statistically not significant.

In the dinoprostone group total 36 (72%) cases went into active phase. Majority of cases, that is 25 (50%) cases went into active phase in 10.01 to 20 hours.

In the misoprostol group total 41 (82%) cases went into active phase. Majority of cases, that is 20 (40%) cases went into active phase in 10.01 to 20hrs

Table 4: Induction to delivery interval

Interval (Hours)	**Dinoprostone**		**Misoprostol**	
	Number	**Percentage**	**Number**	**Percentage**
</=10	6	12	15	30
10.01-20	9	18	11	22
20.01-30	27	54	22	44
30.01-40	8	16	2	4
>40	0	0	0	0

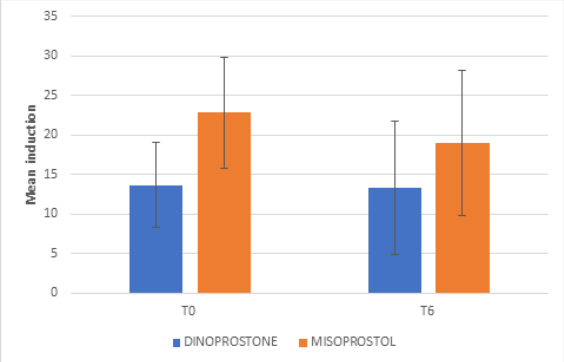

Figure 1: Mean induction to active phase and delivery interval

In the dinoprostone goup, majority of cases 27 (54%) cases delivered within 20.01to 30 hours interval. In misoprostol group, majority of cases, that is 22(44%) cases delivered within 20.01 to 30 hours interval.

The mean induction delivery interval was lower in misoprostol group when compared to dinoprostone group (19.03+/-9.2 vs 22.84+/-8.41.). For induction to delivery interval chi square value 8.16 and p value 0.0426, less than 0.05, statistically significant.

In the misoprostol group 76% patients delivered vaginally and 24% patients underwent.

Table 5: Mode of delivery and indications of caesarean section

	Dinoprostone		Misoprostol	
	Number	%	Number	%
Vaginal	33	66	38	76
Low Forceps	2	4	2	4
Outlet Forceps	1	2	1	2
Caesarean Section	17	34	12	24
Indications of caesarean section				
Failed Induction	12	24	4	8
Meconium Stained Liquor	2	4	5	10
Dystocia	2	4	1	2
Uncontrolled B.P. Recordings	1	2	1	2
Tachysystole	0	0	1	2
Total	17	34	12	24
Need for oxytocin	15	30	8	16

Caesarean delivery. In the dinoprostone group 66% patients delivered vaginally and 34% patients underwent caesarean delivery. The rate of instrumental delivery was same in both groups so it is statistically not significant

In dinoprstone group 15(30%) cases need oxytocin for augmentation where as in misoprostol less number of cases that is 8(16%) need oxytocin for augmentation.

Table 6: Effects on the mother

Adverse effects and complications	Dinoprostone		Misoprostol	
	Number	%	Number	%
Abruptio Placenta	1	2	0	0
Fever	1	2	2	4
Vomiting	2	4	2	4
Diarrhea	1	2	2	4
Tachysystole	0	0	1	2
PPH-Traumatic	1	2	1	2
PPH-Atonic	1	2	1	2
Total	7	14	9	18

In the dinoprostone group, the major maternal adverse effect is vomiting (4%). Other adverse effects are fever (2%) diarrhea (2%). Complications are PPH (4%) in which traumatic PPH (2%) and atonic PPH (2%), abruptio placenta (2%).

In the misoprostol group, the major adverse effects are fever (4%) vomiting (4%) and diarrhea (4%). Complications are PPH (4%) in which traumatic PPH (2%) and atonic PPH (2%) Tachysystole (2%).

χ 2 =2.95, P=0.08. “p” value > 0.05, so it is statistically not significant.

Table 7: Neonatal outcome in present study

Birth Weight (Kgs)	Dinoprostone		Misoprostol	
	Number	%	Number	%
1-1.5	6	12	3	6
>1.5 to 2	3	6	4	8
>2 to 2.5	10	20	11	22
>2.5 to 3	15	30	11	22
>3	16	32	21	42
APGAR score				
1 MIN APGAR >6 </=6	44 6	88 12	46 4	92 8
5 MIN APGAR >8 </=8	44 6	88 12	46 4	92 8

In the present study, It is observed that, there is no major difference, in the fetal outcome, in both groups, with regards to the birth weight.

χ 2 =1.597, P=0.66. “p” value > 0.05, so it is statistically not significant

In the present study, It is observed that, there is no major difference, in the fetal outcome, in both groups, with regards to the APGAR SCORE at 1 minute and at 5 minutes. Mean APGAR for dinoprostone 7.34+/-1.8 and for misoprostol is 7.56+/-1.5.

Table 8: Neonatal Complications

Complications	Dinoprostone		Misoprostol	
	Number	%	Number	%
MSL	7	14	11	22
BA	2	4	2	4
MSL [NICU]	4	8	5	10
BA [NICU]	2	4	2	4

In the present study, meconium staining of liquor is higher in the misoprostol group (22%) than dinoprostone group (14%). The NICU admission rates slightly more in misoprostol group7 (14%), than dinoprostone group 6 (12%).

For NICU Admissions $\chi 2 = 0.03$, P=0.852. "p" value > 0.05, so it is statistically not significant. For neonatal complications chi square=0.1671. p value 0.682, statistically not significant.

DISCUSSION

In the present study only 6 cases present in less than 20 years,4 cases induced with misoprostol and 2 cases induced with dinoprostone. In the misoprostol group 4 had vaginal delivery, 2 cases had fever, 1 case had diarrhea after induction. In the dinoprostone group in 2 cases 1 had vaginal delivery, 1 had caesarean section for failed induction. None of the cases in the present study more than 35 years. Most of the cases 20-30 age group. There is no difference in the success of induction in misoprostol and dinoprostone group according to age criteria in the present study.

Body mass index (BMI) more than or equal to 35 is the moderate risk factor for preeclampsia. In the present study most of the cases in 25-29.9 range that is overweight. None of the cases have more than 35 body mass index. More than or equal to 30 body mass index that is obesity present in 8 cases.1 case induced with misoprostol delivered vaginally by using outlet forceps in view of meconium-stained liquor.7 cases induced with dinoprostone gel in that 3 cases delivered vaginally,4 cases delivered by caesarean section. In the vaginal delivery group 2 cases need 3 doses of dinoprostone,1 case need 2 doses of dinoprostone gel. In 4 cases of cesarean section 3 cases due to failed induction,1 case due to meconium stained liquor. This is consistent with the hypothesis that less chance of successful induction in obesity cases.

In the present study in total 100 patients 77 patients are primigravida,5 cases are G2A1,15 cases are G2P1L1,3 cases are gravida3.First pregnancy is a moderate risk factor for preeclampsia. In 15 cases of gravida 2,7 cases induced with dinoprostone, 8 cases induced with misoprostol. In dinoprostone group 5 had vaginal delivery,2 had cesarean section 1 for meconium stained liquor,1 for uncontrolled BP recordings ,these 2 patients had bishop score at 0 hour is 1.In 8 cases of misoprostol group 7 patients delivered vaginally,1 patient had caesarean section for failed induction, this patient had bishop score 1 at 0 hour and 34 weeks1day to 37 weeks gestation, this gestational age and bishop score are less favorable factors for induction of labour. In 3 cases of gravida3 all cases delivered vaginally.

Table 9: Drug dosage

Name And Year	Drug Dosage	
	Misoprostol [Micrograms/Mcg]	**Dinoprostone [Milligrams/Mgs]**
Van Gemund N 2004,[5]	50 mcg, 6 hourly Max doses 4	0.50 mg 6th hourly, Intracervical Max doses 4
S. Kulshreshtha. P. Sharma, 2006,[6]	100 mcg 4 hourly, Intra vaginal	0.50 mg, Intracervical, 12 hourly
Lapaire O, Zanetti- Dällenbach R 2007,[7]	25 mcg 6th hourly Intra vaginal Max 100 mcg/24 hour	3 mg suppositories 6 hourly Max 6 mg/24 hours
N S Chitrakar et al 2012,[8]	25 mcg 6th hourly	0.50 mg 6th hourly
Dr. Pooja Patil and Dr. Abhijit 2013,[9]	50 mcg Intra vaginal	0.50 mg Intracervical
Monica Parmar, Rupa Aherwar, Ishrat Jahan 2014,[10]	25 mcg 6 hourly, Intra vaginal Max 5 doses	0.50 mg Intracervical
Shikha Yadav, Nootan Chandwaskar, 2017,[11]	25 mcg Sub lingual	0.50 mg Intracervical
Present Study	25 mcg 4th hourly in primi, 6th hourly in gravida 2 and3, maximum 6 doses	0.5 mg 8th hourly 3 doses in primi, 12th hourly 3 doses in gravida 2 and 3, maximum 3 doses

Different drug dosages were used in different studies, In the present study, The dose of misoprostol is 25 mcg 4th hourly in primi, and 6th hourly in gravida 2 and3 used. The dose of dinoprostone is 0.5 mg 8th hourly 3 doses in primi, and 12th hourly 3 doses in gravida 2 and 3. Most of the studies used misoprostol 25mcg 6th hourly, but in the present study for primi used 4th hourly, in multi 6th hourly used as the dosage recommended is every 3 to 6 hours.

Oral misoprostol causes peak plasma concentration of misoprostol higher and achieved earlier. Vaginal misoprostol plasma concentration of misoprostol will last for longer duration. On this basis in the present study misoprostol used by vaginal route, this is consistent with most of the studies.

Systemic bioavailability of vaginal misoprostol is 3 times higher than that of oral route and first effect is uterine tonus.

A 2014 cochrane review reported 37 trial (6417 women) compare oral and vaginal route of misoprostol concluded that -no statistically significant difference in primary outcome of serious neonatal or maternal morbidity or mortality. Hyperstimulation rate primarily relate to dosage. Meconium-stained liquor increased with oral route.

A systematic review with meta-analysis of 13 randomized trials concluded that- Intra vaginal misoprostol at 50mcg for cervical ripening and induction of labour more efficacious but safety concerns make 25mcg dose is preferable. Large dose

of misoprostol causes greater incidence of tachysystole.[12] 2014 meta-analysis reported 10 studies including total 1061 women compared dinoprostone and misoprostol - dinoprostone safer because of lower incidence of hyperstimulation and tachysystole (2.3% vs 7.7%), dinoprostone and misoprostol both acceptably safe and effective for routine use of induction of labour.

In the present study in 28-31weeks only 1 case present, due to severe preeclampsia and imminent symptoms and signs of eclampsia. After giving corticosteroids for pulmonary maturity and magnesium sulfate for prophylaxis of eclampsia patient induced with 5 doses of misoprostol. Bishop score at 0 hour is 1. Patient did not go to active phase and had meconium-stained liquor so caesarean section done.

In 31weeks1day-34weeks 8 cases present.7 cases induced with dinoprostone, all have bishop score 1 at 0 hours.4 cases need 3 doses in that 3 cases delivered vaginally,1 case caesarean section done for failed induction.2 cases need 2 doses delivered vaginally.1 case gravida2 after 1 dose of dinoprostone induction patient did not went to active phase was interrupted due to uncontrolled BP recordings caesarean section done to decrease maternal morbidity and mortality.1 case had bishop score at 0 hour is 4 induced with misoprostol needed 1 dose only delivered vaginally.

In 34weeks1day-37weeks total 23 cases present. In that 12 cases induced with dinoprostone gel ,5 (10%) cases delivered vaginally, 7 (14%) cases delivered by caesarean section in that 5 cases due to failed induction, in these 5 cases bishop score at 0 hour 1 for 4 cases and 2 for 1 case. unfavorable cervix may be the cause for failed induction. In 2 cases 1 for meconium stained liquor,1 for dystocia caesarean section done.11 cases induced with misoprostol in that 8 (16%) cases delivered vaginally, 3 (6%) cases delivered by caesarean section, 1 for failed induction, 1 for uncontrolled B.P recordings, 1 for meconium stained liquor. In these 11 cases 2 cases gravida2, 1 case gravida 3. This gravida3 case need only 1 dose as bishop score at 0 hour is 4. This concludes that failed induction rate more in dinoprostone group compared with misoprostol consistent with the 2016, Veena B, Samal R study.[8]

In the present study most of the cases are in 37weeks1day-40weeks. Total 53 cases, 22 cases induced with dinoprostone 16 (32%) cases delivered vaginally. 6 (12%) delivered by caesarean section, 5 for failed induction 1 for meconium stained liquor. 31 cases induced with misoprostol in that 25 (50%) delivered vaginally. 6 (12%) cases delivered by caesarean section, 3 for failed induction (bishop score 1 at 0 hour) and 2 for meconium stained liquor,1 for dystocia. This is consistent with the 2012, N.S. Chitrakar et al,[8] concluded that vaginal delivery rate more in misoprostol group compared to dinoprostone. This is contrast to the 2014, Monica Parmar,[10] study concluded more caesarean section in misoprostol compared to dinoprostone but statistically not significant.

In the present study 40weeks1day-42 weeks 15 cases present. 9 cases induced with dinoprostone, 7 (14%) cases delivered vaginally and 2 (4%) cases delivered by caesarean section 1 for failed induction 1 for dystocia. 6 cases induced with misoprostol in that 4 (8%) delivered vaginally and 2 (4%) cases delivered by caesarean section 1 for tachysystole, 1 for meconium stained liquor. Bishop score at 0 hour in both groups more than 1, most of the cases have 3 or 4. Due to the advanced gestational age and favorable cervix success of induction more in this group.

In the present study none of the cases are more than 42 weeks gestational age. In the present study in misoprostol group 7 (14%) cases needed only 1 dose in that 5 cases delivered vaginally (Bishop score 4 at 0 hour), 2 cases delivered by caesarean section (Bishop score 1 at 0 hour). 9 (18%) cases need maximum doses that is 6 doses in that 7 cases had bishop score 1 at 0 hour and 2 cases more than one, concludes that the importance of bishop score to determine cervix favorability and the number of dosages required. Dinoprostone 23 (46%) cases needed maximum doses that is 3 doses, most of the case had bishop score 1 at 0 hour. 10 (20%) cases needed only 1 dose as most of the case had bishop score 3 or 4 at 0 hour. This is consistent with the 2012, N.S. Chitrakar et al,[8] study concluded that 25mcg misoprostol is superior in promoting cervical ripening compared to dinoprostone significantly.

In the present study induction to active phase interval is comparable in both misoprostol and dinoprostone. In dinoprostone out of 50 cases 36 (72%) went into active phase and in misoprostol out of 50 cases 41 (82%) case went into active phase. In dinoprostone 8 (16%) cases went into active phase in less than 10 hours where as in misoprostol 14 (28%) cases went into active phase. In 10.01-20 hours 25 (50%) cases went into active phase in dinoprostone group where as in misoprostol 20 (40%) cases. In 20.01-30 hours 3 (6%) cases went into active phase in dinoprostone group where as in misoprostol 7 (14%) cases. Mean induction to active phase interval for dinoprostone is 13.65+/-5.44 hours where as in misoprostol is 13.3+/-7.05 hours. In active phase chi square value 4.50 and p value 0.212 which is >0.05, so statistically not significant. It is not consistent with any of the study, may be due to many factors like age, parity, bishop score.

In the present study induction to delivery interval is </=10 hours in 6(12%) cases in dinoprostone group whereas in misoprostol 15(30%). Maximum number of cases delivered in 20.01-30 hours in both groups that is 27(54%) cases in dinoprostone,22(44%) cases in misoprostol. Less number of cases that is 2(4%) delivered in 30.01-40 hours in misoprostol group whereas 8(16%) cases in dinoprostone group. Mean induction to delivery interval in dinoprostone is 22.84+/- 8.41 hours where as in misoprostol 19.03+/-9.2 hours. Chi square value 8.16 and p=0.0426 which is <0.05, so induction to delivery interval is less in misoprostol compared to dinoprostone and it is statistically significant. This is consistent with the

study of Monica Parmar,[10] 2014 that is 23.19+/-9.59 hours in dinoprostone,20.08+/- 8.24 hours in misoprostol. They concluded that misoprostol is a better inducing agent than dinoprostone. The induction delivery interval of dinoprostone and Misoprostol of present study are nearer to the study of Monica Parmar 2014.[10]

Table 10: Comparison of caesarean section and vaginal delivery rates

Caesarean Section Rates	Dinoprostone	Misoprostol
Van Gemund et al 2004,[5]	21%	16.1%
Monica 2014,[10]	6%	8%
Kumari 2016,[14]	9.6%	8%
Veena B 2016,[8]	32.6%	15.8%
Present Study	34%	24%
Vaginal Delivery		
S. Kulshreshtha 2006,[10]	85%	95%
Pooja Patil 2013,[15]	22%	06%
Monica Parmar 2014,[10]	14.8%	17.3%
Veena B 2016,[8]	61.1%	76.8%
Kumari 2016,[14]	10%	6%
Present Study	66%	76%

In the present study caesarean section in dinoprostone is 17(34%) cases, which is consistent with the study of Veena B 2016.[8] In the present study, in dinoprostone group 17(34%) cases delivered by caesarean section. In that 12(24%) cases due to failed induction, 2(4%) cases due to meconium stained liquor, 2(4%) cases due dystocia, 1(2%) case due to uncontrolled BP recordings .In misoprostol group 12(24%) cases delivered by caesarean section in that 5(10%) cases due to meconium stained liquor, 4(8%) cases due to failed induction, 1(2%) case for tachysystole, 1(2%) case due to dystocia, 1(2%) case due to fetal distress and uncontrolled BP recordings. This is consistent with the 2016, Veena B study.[8]

In the present study it has been observed that there are higher number of vaginal deliveries 38(76%) in the misoprostol group compared to dinoprostone group 33(66%). The observations are consistent with the study of the Veena 2016.[8] Maternal adverse effects in the present study are due to usage of dinoprostone and misoprostol are as follows.

In the dinoprostone group major adverse effect is vomiting (4%). Abruptio placenta (2%). This is consistent with the 2010, Martinez, Martillotti,[15] study concluded that use of misoprostol in preeclampsia women appears to be safe and is not associated with a higher risk of placental abruption when compared with dinprostone. fever (2%) diarrhea (2%) PPH (4%) in which traumatic PPH (2%) and atonic PPH (2%).

In the misoprostol group major adverse effects are fever (4%) vomiting (4%) and diarrhea (4%). Complications are PPH (4%) in which traumatic PPH (2%) and atonic PPH (2%)

Tachysystole (2%). This is consistent with the 2015, Zhang Y, Wang,[16] study, 2017, Shikha Yadav,[11] study and Denguezli,[17] study concluded that tachysystole more with misoprostol than with dinoprostone. In the present study for maternal complications the chi square value is 2.95. p value is 0.08, p>0.05, indicating that statistically not significant. The difference in the rates of tachysystole in the both groups is not significant statistically in the present study.

In the present study, rate of tachysystole in dinoprostone group is 0% and in misoprostol group is 2%. In the study of Shikha Yadav 2017,[11] the rate of tachysystole in dinoprostone group is 10% and in misoprostol group is 22%. The difference in the incidence of tachysystole in different studies is could probably be attributed to the different dosing regimens.

In the present study, It is observed that, there is no major difference, in the fetal outcome, in both groups, with regards to the birth weight and APGAR SCORE at 1 minute and at 5 minutes. In the present study very low birth weight that is 1-1.5kg babies delivered in 6(12%) cases in dinoprostone group whereas 3(6%) cases in misoprostol group.3(6%) cases in dinoprostone group and 4(8%) cases in misoprostol group delivered babies of birth weight more than 1.5-2kg.10(20%) cases in dinoprostone group and 11(22%) cases in misoprostol group delivered babies birth weight of more than 2 to 2.5kg.15(30%) cases in dinoprostone group and 11(22%) cases in misoprostol group delivered babies of birth weight more than 2.5kg to 3kg. 16(32%) cases in dinoprostone group and 21(42%) cases in misoprostol group delivered babies of birth weight more than 3kg.

Cheng.et al studied effect of macrosomia on induction of labour concluded that lower rates of caesarean section rates in women undergoing induction of labour at 39 63 gestational weeks compared to women delivering at later gestational age with birth weight 4kg or more. In the present study only 4 patients delivered babies of birth weight of 4kg or more, in that 3 cases in the misoprostol group all delivered vaginally, 1 case in the dinoprostone group delivered by caesarean section in view of meconium stained liquor. In the present study birth weight chi square is 1.597 and p=0.66 that is statistically not significant.

NICU admission was 12% & 14% in dinoprostone and misoprostol groups respectively. The indications

for NICU admission were meconium aspiration syndrome & birth asphyxia.

There was an increased incidence of meconium aspiration syndrome and birth asphyxia in the misoprostol group. Meconium stained liquor 11(22%) in misoprostol group. In that 3(6%) delivered vaginally,3(6%) cases delivered vaginally with the help of forceps,5(10%) cases delivered by caesarean section. In the dinoprostone group 7(14%) cases had meconium stained liquor. In that 3(6%) cases delivered vaginally, 2(4%) case delivered vaginally with the help of forceps, 2(4%) cases delivered by caesarean section. This is contrast with the 2012, N.S.Chitrakar et al,[8] study concluded that meconium stained liquor more with the dinoprostone compared to misoprostol(32% vs 23%). For neonatal complications statistically not significant in the present study.

In the study of Shikha Yadav 2017,[11] the neonatal outcome was similar in both the groups (PGE1 and PGE2 groups), and there is no major difference in NICU admission rates in both groups. This is contrast with the study Lapaire,[18] concluded that NICU admission more in dinoprostone group. Lapaire,[18] concluded that misoprostol has improved efficacy and lower cost compared to dinoprostone even in cases of preeclampsia and the present study is consistent with this study.

In the present study also, there is no major difference in the NICU admission rates in both groups. It was 12% in dinoprostone group and 14% in misoprostol group. In misoprostol group 4 (8%) cases had low Apgar in that 2(4%) cases due to meconium stained liquor, 2 (4%) cases due to birth asphyxia. In dinoprostone group 6 (12%) cases had low Apgar in that 2 (4%) cases due to meconium stained liquor, 2 (4%) cases due to birth asphyxia, 2 (4%) cases due to very low birth weight that is less than 1.5kg.

A Dutch randomized controlled trial (HYPITAT-2 trial),[19] concluded that induction of labour recommended between 34-37 weeks of gestation, considering maternal and fetal wellbeing and risk of respiratory distress syndrome. The randomized HYPITAT trial reported a 13% decrease in maternal morbidity when labour was induced by 37 gestational weeks compared to expectant management in cases of preeclampsia with no severe complications. A single dose of dinoprostone costs Rs. 259/- while a single dose of misoprostol costs Rs. 18/-. Thus, misoprostol is more cost effective when compared to dinoprostone.

CONCLUSION

Misoprostol and dinoprostone both are safe and effective for cervical ripening and induction of labour in preeclampsia complicating pregnancy. Mean change in modified bishop score, induction to active phase interval, induction to delivery interval, vaginal delivery rate more in misoprostol compared to dinoprostone. Failed induction and caesarean section rate less in misoprostol. There is no significant difference in maternal and neonatal complications in both groups. In conclusion, low dose misoprostol (25 mcg) is a cheap and effective drug for cervical ripening and labour induction in preeclampsia complicating pregnancy.

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