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RESEARCH ARTICLE

COMPARATIVE ANALYSIS OF SAFETY, EFFICACY and FETO MATERNAL OUTCOME WITH INDUCTION OF LABOUR IN TERM LIVE PREGNANCY WITH ORAL MIFEPRISTONE AND INTRACERVICAL DINOPROSTONE GEL

Dr. Sweety P. K. Pradhan, Dr. Sumanta Kumar Mondal, Dr. Debarshi Jana and *Dr. Sambhunath Bandyopadhyay

Department of Gynecology and Obstetrics, Institute of Post Graduate Medical Education and Research (IPGME and R) and Seth Sukhlal Karnani Memorial Hospital (SSKM), Kolkata-700020, West Bengal, India

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ABSTRACT

Introduction: The rapid increase in cesarean birth rates from 1996 to 2011 in US without clear evidence of concomitant decreases in maternal or neonatal morbidity or mortality raises significant concern that cesarean delivery is overused. Increasing women's access to nonmedical interventions during labor, such as continuous labor and delivery support, also has been shown to reduce cesarean birth rates. Several examples of interventions that can contribute to the safe lowering of the primary cesarean delivery rate is by induction of labour by various modes where indicated. In the present study focused on medical method of induction of labour where potential risk of continuing pregnancy is more than terminating.

Materials and methods: This study is a parallel group open labeled randomized control trial conducted in the Institute of post graduate medical education and Seth Sukhlal Karnani Memorial Hospital (SSKM), a tertiary care hospital in West Bengal for a period of 1 year and 6 months from April 2016 to October 2017 in the department of obstetrics and gynaecology. During the study period a total of 90 pregnant women, 45 women in mifepristone group and 45 in the dinoprostone group, scheduled for induction of labour. Safety, efficacy and fetomaternal outcome of both the drugs were compared in the study population.

Results: The following observations were made: Baseline characteristics like Parity, obesity were comparable in both the groups. Multigravida women had successful induction and vaginal delivery more than primigravida, obese women had less successful induction and vaginal delivery than nonobese with both mifepristone and dinoprostone. Successful induction of labour and postinduction improvement of bishop's score were more with mifepristone group than dinoprostone (p value=0.0038). Requirement of augmentation with oxytocics were more in the dinoprostone group than mifepristone (p value =0.0567). Uterine hyper stimulation during the period of induction noted in dinoprostone group is more than mifepristone (p value= 0.0112)Vaginal deliveries were more with mifepristone and less with dinoprostone whereas caeserian section rates were more in dinoprostone group than the mifepristone group (p value=0.020). Fetal outcomes were observed with 2 variables NICU admission and APGAR score at 5 minutes after birth which showed that less NICU admission and good APGAR score is noted with mifepristone than dinoprostone group.

Discussion and conclusion: Main advantage of mifepristone is that it can be given on outpatient basis and the patient is asked to report after 24hrs or with onset of labour whichever is earlier provided that the patients were thoroughly explained about the outcomes. Whereas with dinoprostone, patient must be hospitalized on induction with first gel of dinoprostone itself. Thus the total duration of hospital stay in mifepristone group is much lesser than in dinoprostone group.

**Corresponding author*

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INTRODUCTION

Induction of labor is an important and most common clinical procedure in obstetrics today, but was also practiced in obstetrical history. In 1993, approximately 640,000 births (16% of all live births) in the United States were a result of labor induction (Ventura *et al.,* 1995).

Induction of labor is carried out in over 20% of pregnancies on an average in developed countries, indicated to be advantageous for the mother and baby, decrease perinatal morbidity and mortality. Induction between 37-41 weeks has the potential to improve neonatal outcomes. Induction of labor is associated with a doubling in the caesarean delivery rate compared with spontaneous labour.

Therefore; successful labor induction is clearly related to state of the cervix. Pregnant lady with unfavorable cervix, who have not experienced cervical ripening phase prior to labor, present a great challenge with regard to induction of labor. So Bishop's scoring is done to see whether the cervix is favorable or not. In an unfavorable cervix, if induction is done chances of prolonged labor and chance of having cesarean section will be increased. To reduce cesarean section rate cervical priming is done prior to induction. Numerous methods for cervical ripening and labor induction have been employed (Cunninghams *et al.,* 2010). Concomitant use of balloon-tipped catheters and pharmacologic agents has been effective in labor induction; however, the cost of combination therapy is markedly increased (Atad *et al.,* 1991). Natural and synthetic laminaria have been shown to be effective in cervical ripening, but a high incidence of infection is associated with the use of laminaria during the third trimester of pregnancy (Krammer *et al.,* 1995). Because the most common adverse effect of oxytocin infusion is fetal heart rate (FHR) deceleration associated with increased uterine activity, it is essential that FHR and uterine contractions be continuously monitored to observe any tachysystole or hyperstimulation requiring intervention. Dinoprostone (PGE2) is the prostaglandin most commonly employed in obstetrics. Prior to FDA approval of the intracervical and vaginal insert dinoprostone preparations, hospital-prepared gel was frequently utilized (Sanchez-Ramos *et al.,* 1995; Stempel *et al.,* 1997).

The most common complications observed with PGE2 for cervical ripening and labor induction have been tachysystole and hyperstimulation of the uterus. These results appear to be dose related and are rarely seen in patients receiving small doses (0.5 mg). Other complications resulting from PGE2 induction include uterine rupture, amniotic fluid embolism, and myocardial infarction though rare but serious complications. Mifepristone has been used with some success for the induction of labor in cases of intrauterine fetal demise of at least 16 weeks' gestation. Still not popularly used in induction of labour in live pregnancy because of less number of studies. A randomized double-blind trial employing 200 mg of mifepristone daily for 2 days resulted in a shorter interval to the onset of labor, and less oxytocin was required for those achieving vaginal delivery. In the mifepristone group, 58% went into spontaneous labor, compared with 22.6% in the placebo group. The cesarean delivery rate did not differ between the two groups, and no side effects were encountered in the treatment group (Frydman *et al.,* 1992). Induction of labour is required when the risk of continuation of pregnancy either to the mother or to the fetus is more than termination of pregnancy. This study has been taken in the department of obstetrics and gynecology of a tertiary care hospital in West Bengal, IPGMEandR (S.S.K.M), aims at comparing the efficacy, safety and fetomaternal outcome of Mifepristone as cervical ripening and labor inducing agent versus Dinoprostone intracervical gel. The study also aims to observe the improvement in pre induction Bishop's score, proportion of patients going in labor and induction–delivery interval.

MATERIALS AND METHODS

This is a hospital based prospective study with comparison groups. Pregnant women attended at Antenatal Clinic or admitted at Obstetrics ward of SSKM Hospital, Kolkata. All patient with indication of induction of labour, age >18 years presenting to our hospital is the population during April 2016 to October 2017. Data would be collected through clinical observation for a period upto 48hrs following intervention and reviewing the subject's medical records. The data would be recorded in a structured case report form.

Inclusion criteria

- Singleton pregnancy with cephalic presentation and intact membranes if labour induction was indicated and delivery could be postponed for 24 hrs.
- Women with unfavorable cervix (Bishop score less than 6).
- Antenatal patients in third trimester (37-41 wks).
- Patients with reactive NST.
- Pregnancy induced hypertension.
- Gestational Diabetes Mellitus.
- Post dated pregnancy.

Exclusion criteria

- Parity more than 4.
- Previous Caesarean section.
- Major cephalopelvic disproportion, macrosomia.
- Malpresentation.
- Known hypersensitivity to prostaglandins or mifepristone.
- Medical problems like impaired renal, hepatic or adrenal function.
- Antenatal hemorrhage.
- Premature rupture of membrane.
- IUGR, IUFD.
- Major congenital malformation of fetus causing obstructed labour.

Procedure of study technique: After selecting the patients for study who met the inclusion and exclusion criteria in the OPD, randomization is done by computer generated method of randomization into two groups-experimental group (Mifepristone) and control group (dinoprostone gel). USG (FPP, AFI, Doppler study),baseline blood tests parameters, bishop's score were noted. After getting an informed consent, the pregnant woman in Mifepristone group- who met the inclusion criteria are given 1 tablet of Tab. MIFEPRISTONE (200 mg) orally and are asked to report to labour room if pain started or reassessed after 24 hours. If Bishop's score >/=8 any time during reassessment, they are transferred to labour room. Regular CTG monitoring to monitor fetal status and uterine action were done. Once the cervical dilatation crossed 4cm pantograph is maintained and labour is proceeding as per requirement. If Bishops score is < 8 even after 24hrs of induction, the induction is categorized as failed. The women in dinoprostone gel group after proper informed consent who met the inclusion criteria are induced with intracervical dinoprostone gel (0.5 mg) and reassessed whenever labour pain starts or after 24 hours. If the bishop's score is less than 8 even after 24 hrs then the induction is categorized as failed. If any time during the reassessments the bishop's score is >/= 8 then labour is proceed as previously stated.

Definition of outcomes: Labour progression (Bishop score improvement, induction delivery interval, oxytocin augmentation),

- Maternal outcome (mode of delivery, indications for Caesarean section, number of failed inductions, incidence of hyperstimulation associated with meconium stained liquor),
- Fetal outcome (healthy baby, NICU admission, APGAR score at 5 mins).
- Requirement for augmentation.

Statistical analysis plan: For statistical analysis data were entered into a Microsoft excel spreadsheet and then analysed by SPSS 20.0.1. Data have been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. The median and the interquartile range have been stated for numerical variables that are not normally distributed. Student's independent sample's t-test was applied to compare normally distributed numerical variables between groups; Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. p-value ≤ 0.05 was considered for statistically significant.

RESULTS AND ANALYSIS

A detailed analysis was carried out in both the groups regarding the efficacy of the drugs in terms of Age, Religion, Obesity, Parity, Mode of induction, Result of induction, Requirement of augmentation with Oxytocin, Improvement in Bishop's score, Induction to delivery interval, Mode of delivery: normal vaginal/ caesarean section, Fetal outcome: NICU admission required or not required, Uterine Hyperstimulation, APGAR score recording in both group babies. As per table-1, we found that the mean age (mean± s.d.) of patients was 24.2667 ±3.1580 years with range 19.00-30.00 years and the median age was 25.00 years in Dinoprostone group. In Mifepristone group, the mean age (mean± s.d.) of patients was 23.6000 ±3.1508 years with range 18.00-29.00 years and the median age was 23.00 years. Difference of mean age in two groups was not statistically significant. Thus age was matched in two groups (p=0.3188).

We found that the mean Bishop's-Score-Improvement (mean± s.d.) of patients was 3.9556 ±.9034 with range 2.00-5.00 and the median Bishop's-Score-Improvement was 4.00 in Dinoprostone group. In Mifepristone group, the mean Bishop's-Score-Improvement (mean± s.d.) of patients was 4.5778 ±1.0764 with range 1.00-6.00 and the median Bishop's-Score-Improvement was 5.00. Difference of mean Bishop's-Score-Improvement in two groups was statistically significant (p=0.0038). It was found that the mean induction to delivery interval (mean± s.d.) of patients was 18.4222 ±5.5206 mins with range 11.00-30.00 mins and the median induction to delivery interval was 18.00 mins in Dinoprostone group. In Mifepristone group, the mean induction to delivery interval (mean± s.d.) of patients was 19.1333 ±3.9057 mins with range 14.00-30.00 mins and the median induction to delivery interval was 20.00 mins. Difference of mean induction to delivery interval in two groups was not statistically significant (p=0.4824). We found that the mean APGAR score at 5 min (mean± s.d.) of patients was 6.8444 ±2.4583 with range 2.00-10.00 and the median APGAR score at 5 min was 4.00 in Dinoprostone group. In Mifepristone group, the mean APGAR score at 5 min (mean± s.d.) of patients was 7.4889 ±2.1911 with range 1.00-10.00 and the median APGAR score at 5 min was 8.00. Difference of mean APGAR score at 5 min in two groups was not statistically significant (p=0.1927).

It was found that the mean induction to delivery interval (mean± s.d.) of patients was 21.0526 ±6.2581 mins with range 11.00-30.00 mins and the median induction to delivery interval was 24.00 mins in caesarean section. In Vaginal delivery, the mean induction to delivery interval (mean± s.d.) of patients was 18.1690 ±4.1300 mins with range 12.00-30.00 mins and the median induction to delivery interval was 18.00 mins. Difference of mean induction to delivery interval in two mode of delivery groups was statistically significant (p=0.0183). As per Table 2, among dinoprostone group 8 patients were obese and among mifepristone group 9 were obese. Among 17 obese patient induction was successful in 10 patients (59%) and among 73 non-obese patients induction was successful in 63 patients (86%). In dinoprostone group 25 patients were multigravida and among mifepristone group 22 patients were multigravida.

There is only 4 induction failure (8.9%) among mifepristone group compared to 13 induction failure (28.9%) among dinoprostone group. By applying Fisher's exact test the two-tailed P value equals 0.0153which is considered to be statistically significant. The above table shows that among dinoprostone group 29 (64.4%) required augmentation whereas among mifepristone group 20 (44.4%) required augmentation out of 45 patients of each group. By applying Fisher's exact test the two-tailed P value equals 0.0567which is considered to be not quite statistically significant. The above table shows that with dinoprostone the caesarean section were 14 (31.1%) and vaginal delivery were 31 (68.9%). With mifepristone induction there were 5(11.1%) caesarean section and 40 (88.9%) were vaginal delivery. By applying Fisher exact test the two tailed p value, which is considered to be statistically significant. The above table shows that NICU admission with dinoprostone was 5 and mifepristone (Atad *et al.,* 1991). By applying Fisher exact test the two tailed p value 0.4588, which is not considered to be statistically significant. The above table shows that among the patients induced with dinoprostone 6 developed uterine hyperstimulation and meconium stained liquor noted during delivery while none among the mifepristone group developed uterine hyperstimulation. By applying Fisher's exact test the p value is 0.0112 which is statistically significant.

DISCUSSION

The present study is a parallel group open labeled randomized control trial done in the Institute of post graduate medical education and Seth Sukhlal Karnani Memorial Hospital (SSKM), a tertiary care hospital in West Bengal for a period of 1 year and 6 months from April 2016 to October 2017 in the department of obstetrics and gynecology. During the study period a total of 90 pregnant women, 45 women in mifepristone group and 45 in the dinoprostone group, scheduled for induction of labour were selected for the study by computer generated method of randomization. In the present study it is observed that most of the population was in the mean age group in the dinoprstone group was 24.2667 years and that of mifepristone group was 23.6 years (Table 1). Table 2 shows distribution of study population on the basis of religion. Majority of my study populations are muslims (55.5%). Among dinoprostone group 8 patients were obese and among mifepristone group 9 were obese. Among 17 obese patient induction was successful in 10 patients and among 73 non-obese patients induction was successful in 63 patients.

Table 1. Distribution of Mean age, bishop's score improvement, induction to delivery interval, apgar score at 5 mins and induction to delivery interval

Table-1		Number	Mean	SD	Minimum	Maximum	Median	p-value
AGE	Dinoprostone	45	24.2667	3.1580	19.0000	30.0000	25.0000	0.3188
	Mifepristone	45	23.6000	3.1508	18.0000	29.0000	23.0000	
Bishop's score improvement	Dinoprostone	45	3.9556	.9034	2.0000	5.0000	4.0000	0.0038
	Mifepristone	45	4.5778	1.0764	1.0000	6.0000	5.0000	
Induction to delivery interval	Dinoprostone	45	18.4222	5.5206	11.0000	30.0000	18.0000	0.4824
	Mifepristone	45	19.1333	3.9057	14.0000	30.0000	20.0000	
Apgar score at 5 min	Dinoprostone	45	6.8444	2.4583	2.0000	10.0000	8.0000	0.1927
	Mifepristone	45	7.4889	2.1911	2.0000	10.0000	8.0000	
Induction to delivery interval	Caesarean section	19	21.0526	6.2581	11.0000	30.0000	24.0000	0.0183
	Vaginal delivery	71	18.1690	4.1300	12.0000	30.0000	18.0000	

Table 2. Association of religion, obesity, gravida, result of induction, requirement of augmentation, mode of delivery, NICU admission and uterine hyperstimulation

Table-2		Dinoprostone	Mifepristone	Chi-square value	p-value
Religion	Hindu (n)	19	21	0.1800	0.6713
	%	42.2	46.7		
	Muslim(n)	26	24		
	%	57.8	53.3		
Obesity	Absent(n)	37	36	0.0725	0.7876
	%	82.2	80.0		
	Present(n)	8	9		
	%	17.8	20.0		
Gravida	Multi(n)	25	22	0.4008	0.5266
	%	55.6	48.9		
	Primi(n)	20	23		
	%	44.4	51.1		
Result of induction	Failure(n)	13	4	5.8743	0.0153
	%	28.9	8.9		
	Success(n)	32	41		
	%	71.1	91.1		
Requirement of augmentation	No(n)	16	25	3.6287	0.0567
	%	35.6	55.6		
	Yes(n)	29	20		
	%	64.4	44.4		
Mode of delivery	Caesarean section(n)	14	5	5.4040	0.020
	%	31.1	11.1		
	Vaginal delivery(n)	31	40		
	%	68.9	88.9		
Nicu admission	Non-required(n)	40	42	0.5488	0.4588
	%	88.9	93.3		
	Required(n)	5	3		
	%	11.1	6.7		
Uterine hyperstimulation	Absent(n)	39	45	6.4286	0.0112
	%	86.7	100.0		
	Present (n)	6	0		
	%	13.3	0.0		

n-Number, %- Percentage

By applying the Fisher exact test the p value is 0.0153 ($p< 0.05$), which is statistically significant. Wolfe *et al.* 2011 found that their population-based cohort study compared failed induction of labor rates between obese and normal-weight women and showed that the increase rate of induction is associated with increasing body mass index from 28% in normal-weight women to 34% in class III obese women (body mass index, ≥40 kg/m2). Induction failure rates are also associated with increasing obesity class from 13% in normal-weight women to 29% in class III obese women. Arrow smith *et al.* 2011 in their Retrospective (historical) cohort study on Liverpool Women's Hospital NHS Foundation Trust, UK showed that obese women had a significantly higher rate of IOL ending in caesarean section compared with women of normal weight following IOL (38.7% versus 23.8% primiparous; 9.9% versus 7.9% multiparous women, respectively); however, length of labour, incidence of postpartum haemorrhage and third-degree tear, rate of low cord blood pH, low Apgar scores and shoulder dystocia were similar in all body mass index categories.

Vicky O'Dwyer *et al.* 2013 in their study in large university teaching hospital showed that compared with women with a normal BMI, obese primigravidas but not obese multigravidas were more likely to have labor induced. In primigravidas who had labor induced, the cesarean section rate was 20.6% (91/442) compared with 8.3% (17/206) in multigravidas who had labor induced ($p < 0.001$). In obese primigravidas, induction of labor was also more likely to be associated with other interventions such as epidural analgesia, fetal blood sampling and emergency cesarean section. In contrast, induction of labor in obese multigravidas was not only less common but also not associated with an increase in other interventions compared with multigravidas with a normal BMI. Table no 2 is showing that there is only 4 induction failure (8.9%) among mifepristone group compared to 13 induction failure (28.9%) among dinoprostone group. By applying Fisher's exact test the two-tailed P value equals 0.0153. The association between rows (groups) and columns (outcomes) is considered to be statistically significant. Vidya Gaikwad *et al.* 2014 showed that post induction improvement in Bishop's

score was seen to be significantly more in Mifepristone (96.6%) induced group than Dinoprostone (76.6%) group. Wing *et al.* 2000 found that a randomized controlled trial with tablet Mifepristone for preinduction cervical ripening beyond 41 weeks and concluded that Mifepristone had a modest effect on cervical ripening when given 24hrs before labour induction appearing to reduce the need for Misoprostol and Oxytocin compared with placebo (Wing *et al.* 2000). Stenlund *et al.* 2000 found that a prospective double blind study to evaluate efficacy of Mifepristone in induction of labour in women with unripe cervix. He found that during first 48 hrs following treatment, 79.2% of women treated with Mifepristone went in labour. The overall success rate was 83.3% for Mifepristone. The result shows that Mifepristone is a simple and effective treatment for inducing labour in post term pregnant women with an unripe cervix (Stenlund *et al.* 2000). Neilson *et al*. 2009 showed that Mifepristone for induction of labour compared to placebo observed that Mifepristone treated women were more likely to have a favourable cervix at 48 hours. Effect persisted at 96 hours. A single dose of 200 mg Mifepristone appears to be the lowest effective dose for cervical ripening (Neilson *et al*. 2009).

Table no 2 shows that among dinoprostone group 29 (64.4%) required augmentation whereas among mifepristone group 20 (44.4%) required augmentation out of 45 patients of each group. By applying Fisher's exact test the two-tailed P value equals 0.0567. The association between rows (groups) and columns (outcomes) is considered to be not quite statistically significant. Vidya Gaikwad *et al.* 2014 found that comparison of augmentation required with Oxytocin in both study groups (n= 100), 20% of patients in group A (Mifepristone) and 56% in group B (Dinoprostone) required augmentation. Thus, Mifepristone induced patients required less need for augmentation. Warke *et al.* 1999 did a study in 75 patients with unripe cervix who underwent induction of labour with PGE2 gel. 68.1% patients required augmentation of labour and 31.9% did not require augmentation of labour with Oxytocin drip. The above Table 1 shows that in the study populations those with dinoprostone gel induction average Bishop's score improvement is 3.96 compared to those with mifepristone tablet induction Bishop's score improvement is 4.58 which is significantly more than dinoprostone group. Ashtekar Archana *et al* found that mean pre-induction Bishop's score was 4.50 in Group A. It was increased by 6.80 in 6 hrs and 8.22 after 12 hrs. The mean pre induction Bishop's score was 4.72 in Group B. It was increased by 5.94 in 6 hrs and 7.81 after 12 hrs. So it is found that Bishop's score is significantly improved in Group A with T. Mifepristone with T. Misoprostol than only with T. Misoprostol in Group B which was statistically significant (Ashtekar Archana *et al.* 2014).

Since the Induction delivery time variable in this study represents a censored variable (since we do not have complete information on this variable for subjects delivered by LSCS) we have compared this variable between the two study groups. This gives median induction delivery time as 18.422 h in Dinoprostone group and 19.133 h mifepristone group which difference is not significant statistically (p = 0.4824 by). Hence mifepristone takes a little longer induction to delivery interval than dinoprostone. AshtekarArchana *et al* found that the Mean Induction delivery interval was 9.59 hrs in Group A and in Group B, it was 11.78 hrs. It means that induction delivery interval duration is less in Group A (T. Mifepristone with T. Misoprostol) than in Group B with T. Misoprostol.16 VidyaGaikwad *et al*11 found that the mean induction delivery interval in mifepristone group was 20.3 hrs and in dinoprostone group it was 11.5 hrs. The difference was statistically significant (p value 0.001) in favor of dinoprostone. But there was not much difference in the time from prostaglandin administration to vaginal delivery between the subgroup of women who required dinoprostone gel following priming with mifepristone, and dinoprostone group. The induction delivery interval in group1 is more, as it takes about 24-48 hrs for the drug to have priming effect on the cervix. Neilson JP *et al* reported that mifepristone treated women were more likely to be in labour or to have a favourable cervix at 48 hrs and this effect persists at 96 hrs(RR 3.40, 95% CI 1.96-5.92) (Neilson, 2009). Sailatha *et al.* shows labour outcome based on the improvement in Bishop score and induction delivery interval. The improvement in Bishop score was better in dinoprostone group [mean 4.7(±1.49)] when compared to mifepristone group [mean 4.0(±1.48)] which was statistically significant (p value 0.042). It has to be noted that, this result could not be achieved in dinoprostone group with one gel alone. 20 women needed 2 dinoprostone gels and 11 women needed 3 gels to improve the Bishop score. Whereas in mifepristone group, Bishop score was assessed after one dose of mifepristone (200 mg). Mean induction delivery interval was more [20.3 h (±15)] in mifepristone group while it was lesser [11.5 h (±8.7)] in dinoprostone group, which was again statistically significant (p value 0.001) (Krammer *et al.,* 1995). cases in mifepristone group and 6 cases in dinoprostone group delivered within 6 hrs of induction (Sailatha *et al.,* 2017).

Table 2 shows that with dinoprostone the caesarean section were 14 (31.1%) and vaginal delivery were 31 (68.9%). With mifepristone induction there were 5 (11.1%) caesarean section and 40 (88.9%) were vaginal delivery. By applying Fisher exact test the two tailed p value 0.020, which is considered to be statistically significant. In this study caesarean section rate is more with dinoprostone gel induction whereas vaginal delivery rate is more with mifepristone tablets. Table 2 shows that NICU admission with dinoprostone were 5 and mifepristone 3. By applying Fisher exact test the two tailed p value 0.4588, which is not considered to be statistically significant. Table 2 shows that among the patients induced with dianprostone 6 developed uterine hyperstimulation while none among the mifepristone group developed uterine hyperstimulation. By applying Fisher's exact test the p value is 0.0112 which is statically significant. Table 1 shows the average value of apgar score at 5 min among dianprostone is 6.84 and mifepristone group is 7.49. Thus 5 minute APGAR scores were better in mifepristone group babies, there was no statistically significant difference (p=0.1927). Sailatha R *et al* 17 in their study showed parameters of maternal outcome among the study population. Number of women who had vaginal delivery and Caesarean sections were the same in both the group 5 (41.67%) women in group II had to undergo Caesarean section for failed induction whereas only 2 (16.67%) in group I underwent Caesarean section for the same indication. Thus showing that chances of failure of induction was lesser with mifepristone than dinoprostone. 9 (75%) out of 12 cases of Caesarean section in mifepristone group was done for fetal distress (Non- reactive NST). But none of these neonates had poor APGAR score nor did they need NICU admission. 5(41.67 %) in dinoprostone group underwent Caesarean section for fetal distress and 2 neonates out of these 5 needed NICU admission. Thus showing that mifepristone does not increase the incidence of fetal distress.

The requirement of syntocinon augmentation was less with mifepristone (24%) when compared to dinoprostone (38%). Difference was not statistically significant.

Conclusion

The final conclusion after conducting this research is: Mifepristone, a progesterone antagonist, is known to cause softening and dilation of the human pregnant cervix and an increase in uterine activity. It is theoretically attractive for use as an adjunct in cervical priming and labour induction. Mifepristone is associated with an increase in the chance of vaginal delivery within 24-48 hours with decreasing incidence of LSCS. Hence mifepristone combined with or without augmentation is a safe, efficient, economical and convenient induction agent for initiation of labor in women at term. Therefore, this may justify future trials comparing mifepristone with the routine cervical ripening agents currently in use. Mifepristone is a safe and effective induction agent for cervical ripening and initiation of labour, when given at least 24 hours prior in third trimester pregnancies whenever induction of labour is indicated. Even though mifepristone is expensive, as it may be administered on outpatient basis, there might be overall savings in this group. Mifepristone and cerviprime are comparable in feto-maternal outcome. Thus, mifepristone can be a safe alternate and more effective than dinoprostone in induction of labour, especially when prostaglandins are contraindicated.

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