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Original Research Article

A comparative study of vaginal misoprostol, dinoprostone gel, foley catheter, extra amniotic saline infusion along with vaginal misoprostol for induction of labor at term

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ABSTRACT

Background: Objective of this study was to study the effect of vaginal misoprostol, dinoprostone gel, foley catheter, extra amniotic saline infusion along with vaginal misoprostol for induction of labor at term on maternal and fetal outcome.
Methods: A one-year prospective observational study was conducted in the department of obstetrics and gynecology, SDM College of Medical Science and Hospital, Dharwad. Totally 100 postdated primigravida women with singleton gestation, vertex presentation and intact membrane who were induced with any four methods of induction 1) Tab. misoprostol 25 µg vaginally, 2) Intracervical dinoprostone gel, 3) Foley catheter and 4) Extra amniotic saline infusion along with tab. misoprostol 25 µg vaginally with 25 patients selected in each group, by random allocation technique and included in the study. Outcome measures analysed were the demographic profile, bishop score, induction to delivery interval, mode of delivery, maternal and fetal complications. Statistical analysis was done using SPSS 17 software.
Results: Mean induction delivery interval was significant between PGE1 versus foley group (p=0.0034). In this study, 60% patients in dinoprostone group had Vaginal delivery and 72% in the EASI + misoprostol group underwent cesarean section (p=0.0372). NICU admission was maximum with EASI + vaginal misoprostol group and minimum with vaginal misoprostol alone.
Conclusions: The groups were comparable with respect to maternal age, bishop score and fetal weight. The vaginal misoprostol group had shortest induction delivery interval. The maximum number of patients in dinoprostone gel group underwent vaginal delivery with a highest cesarean section and NICU admission with the EASI + misoprostol group.

Keywords: Bishop score, Dinoprostone gel, Extra amniotic saline infusion, Foley catheter, Induction of labor, Misoprostol

INTRODUCTION

The history of labor induction dates back to Hippocrates' description of cervical canal dilation by mammary stimulation and mechanical techniques.[1] Induction of Labor is the stimulation of contraction before the spontaneous labor onset, with or without ruptured membranes.[2] During the second century AD, soranus

used a combination of procedures to induce labor, including artificial rupture of the membranes (ARM). Other methods of labor induction had been introduced during this period. In the 17th century, mechanical methods to induce labor came into more common use. In 1810, James was the first in the United States to use amniotomy to induce premature labor.[3] Until 20th century amniotomy and other mechanical methods remained the techniques of labor induction. In 1943, page suggested that the pituitary extract oxytocin be in the form of an intravenous infusion, and in 1955 synthetic oxytocin has been in use.[4] In 1968, Karim and colleagues were the first to report the use of prostaglandins for induction of labor.[5] Since then, prostaglandins, in different varieties and forms of administration, became a common method of labor induction.[6] Both mechanical dilator and pharmacological procedures have been found successful in Induction of labor. Misoprostol, a synthetic PGE1 analogue, safely and effectively ripens the cervix and induces labor in patients with unfavourable cervix.[7] Intravaginal doses of 25-50 µg have shown to shorten the induction to vaginal delivery interval and to lower the caesarean delivery rate. Dinoprostone (PGE2) is the prostaglandin most commonly employed in obstetrics. This prostaglandin plays an important role in the cervical ripening process and in initiating and maintaining labor. The intracervical route has been used in around two thirds of reported clinical trials. The commercial dinoprostone gel contains 0.5 mg of dinoprostone is available in a prefilled applicator. Active labor and vaginal delivery are more likely to occur within this 12-hour period, reducing the need for oxytocin infusion.

The commonly used mechanical method of induction includes the foley catheter and extra amniotic saline infusion. For a single balloon catheter, a number 18 foley is introduced under sterile technique in the intracervical canal past the internal OS. The bulb is inflated with 30 to 60 ml of water. The catheter is left in place until either it falls out spontaneously or 24 hours have elapsed. Foley catheters have shown to be efficacious with a shorter induction to-delivery interval than prostaglandin in patients with unfavourable cervix. Both agents have similar caesarean section rates, but foley catheter may require increased need for oxytocin stimulation and there is more tachysystole with prostaglandin.[8] Extra amniotic saline infusion (EASI) involves infusion of isotonic fluid into extra-amniotic space. It is an effective method of cervical ripening than labor prostaglandin, however, it does not improve the outcome of induction when compared with Foley catheter alone. A 2001 Cochrane review reported mechanical methods to have less tachysystole with fetal heart changes than prostaglandin's but no difference in caesarean section rates.[8]

A 2009 RCT of 330 nulliparous women with term pregnancies with an unfavourable cervix (bishop 0 to 4) compared single (16F foley) and double balloon catheter and vaginal PGE2, showed that the single balloon catheter had the shortest induction to delivery interval (single balloon=25.8 hours). Heinemann et al systematic review of 30 RCTs showed an increased risk of both, maternal and neonatal infection when all (foley catheters, hygroscopic dilators, Laminaria) mechanical methods were analysed.[8]

Limited studies are available which compare the various, pharmacological and mechanical method of inducing labor within the same population. Hence the main objective of this study was to compare the four different methods of inducing labor: vaginal misoprostol, intracervical dinoprostone gel, foley catheter, extra amniotic saline infusion (EASI) along with vaginal misoprostol, in terms of efficacy, safety, maternal and fetal complications.

METHODS

This prospective, observational study was conducted on hundred patients admitted to labor ward of Sri Dharmasthala Manjunatheshwara College of Medical Sciences and Hospital, Dharwad for induction of labor during one-year period, from 1st November 2016 to 30th October 2017.

Inclusion criteria

The inclusion criteria were all primigravida with alive singleton pregnancy with cephalic presentation with poor bishops score and pregnancy (>/=40 weeks) who were not in labor.

Exclusion criteria

Pregnancy with complications such as IUGR, diabetes, hypertension, oligohydramnios and premature rupture of membrane were excluded from the study.

A total of hundred patients who fulfilled the inclusion criteria were selected from the four different methods of induction, with twenty-five in each group. The methods of induction being tab. misoprostol 25 µg vaginally (PGE1) every 4 hours with maximum of 4 doses, intracervical dinoprostone gel (PGE2) every 6 hours with maximum of 3 doses, foley catheter intracervical until there was a spontaneous expulsion of the catheter or no longer than 24 hours and extra amniotic saline infusion along with tab. misoprostol 25 µg vaginally every 4 hours with maximum of 4 doses. The catheter was kept in situ until there is spontaneous expulsion or no longer than 24 hours. Augmentation with oxytocin was done as per labor ward protocol. At first, the study method was completely explained to them and if the written consent was obtained, they were entered for the study. There were no interventions done in the study. The ethics committee of authors institution approved the study. The detailed history, examination, confirmation of diagnosis and investigations were recorded for all the participants. The groups were compared with respect to maternal age, bishops score, induction delivery interval, mode of

delivery, post-delivery complications, Apgar score and NICU admission. Data was presented as mean and standard deviation and association among the study groups was done using one-way anova test chi-square test. Pair wise comparison was done using Tukeys multiple posthoc procedures.

Statistical analysis

Data was statistically analysed using SPSS 17 software. P values of less than 0.05 was taken as statistically significant.

RESULTS

There were 100 primigravida patients with Postdated pregnancy involved in this study with twenty-five in each method of induction, tab. misoprostol 25 µg (PGE1) vaginally, dinoprostone gel (PGE2), Foley catheter and extra amniotic saline infusion (EASI) along with vaginal tab. misoprostol 25 µg. The groups were comparable with respect to the maternal age, bishops score, fetal weight. The mean maternal age was 25 years in PGE1 group, 26 years in PGE2 group, 23 years in foley group and 24 years in the EASI +misoprostol group. The mean bishop's score was 5.4 in misoprostol group, 5.3 in dinoprostone gel group, 5.5 in foley group and 5.4 in EASI +misoprostol group. With respect to the fetal weight in misoprostol group it was 2.66 kg, while dinoprostone gel group it was 2.7 kg, foley group was 2.71 kg and the EASI +misoprostol group had a weight of 2.77 kg (Table 1).

Among the hundred participants, patients who underwent vaginal delivery were 14 (56%) in PGE1 group 15 (60%) in PGE2 group, 13 (52%) in foley group and 5 (20%) in the EASI +misoprostol group. The mean Induction delivery interval was 19 hours in PGE1 group, 20 hours in PGE2 group, 25.79 hours in foley group and 25.14 hours in EASI +misoprostol group (p=0.0021). PGE1 group had a shorter induction delivery interval compared to foley group (p=0.0034) (Table 2). The patients requiring single dose of induction were 4% in misoprostol group in comparison to 44% in dinoprostone gel group (Table 3). On the other hand, women who underwent caesarean section were 10 (40%) in the PGE1 group, 9 (36%) in the PGE2 group 10 (40%) in the foley group 18 (72%) in the EASI +misoprostol group (Table 4). Vaginal delivery was highest in PGE2 group while caesarean section was highest in the EASI +misoprostol group (p=0.0372). The primary indication for caesarean section in misoprostol group was fetal distress (50%) while dinoprostone group it was meconium stained liquor (55%). Fetal distress was a common indication in Foley (70%) and EASI +misoprostol group. The other indication for caesarean section was failed induction, seen in 20% of patients in misoprostol group and 10% in the EASI+ vaginal misoprostol group.

Table 1: Comparison with respect to age, bishop score and fetal weight.

Variable	Misoprostol 25 µg (PGE1)	Dinoprostone gel (PGE2)	Foley catheter	EASI +misoprostol 25	P value
Age	25.40±3.86	26.88±4.96	23.88±3.36	24.48±3.64	0.0524
Bishop score	5.40	5.32	5.56	5.44	0.8005
Fetal weight	2.66	2.78	2.71	2.77	0.2439

*P value <0.05.

Table 2: Comparison with respect to induction delivery interval.

Groups	Mean	SD
M 25	19.00	3.18
Dinoprostone gel	20.94	6.38
Foley catheter	25.79	4.68
EASI +M25	25.14	5.01

*P=0.0021.

Table 3: Comparison by the number of doses used for induction of labor.

Number of doses of induction	Misoprostol 25 µg (PGE1) (%)	Dinoprostone gel (PGE2) (%)	Foley catheter	EASI +misoprostol 25 µg (%)
One	4	44	-	88
Two	8	36	-	4
Three	4	20	-	8
Four	40	0	-	0

Chi-square=22.0355, p=0.1069.

In respect to complications, PPH and blood transfusion was found to be more in the PGE1 group that is 2 (8%) and 4 (16%) respectively (Table 5). Patients with fever of 3 days duration was seen maximum with EASI +misoprostol group that is, 2 (8%). Mean Apgar values at 1 minute 7.56 in PGE1 group, 7.44 in PGE2 group, 7.4 in foley group and 7.32 in EASI + misoprostol group (p=0.8070). The scores at 5 minutes was 8.24 in PGE1 group, 8.2 in PGE2 group 8.4 in foley group, 8.2 in EASI +misoprostol group (p=0.9020). There was not much difference between the groups (Table 6). Maximum period of NICU admission was seen with EASI +misoprostol group i.e., 10 days while least period was seen with PGE1 group i.e., 1 day (Table 7).

Table 4: Comparison with respect to method of delivery.

Method of delivery	Misoprostol 25 µg (PGE1) (%)	Dinoprostone gel (PGE2) (%)	Foley catheter (%)	EASI +misoprostol 25 µg (%)
VD	56	60	52	20
CS	40	36	40	72
Instrumental	4	4	8	8

Chi-square=8.4703, p=0.0372*. *P value <0.05, CS: Caesarean section, Instrumental-vacuum /forceps, VD: Vaginal delivery.

Table 5: Distribution of patients in four study groups by complications.

Maternal complications	Misoprostol 25 µg (PGE1) (%)	Dinoprostone gel (PGE2) (%)	Foley catheter (%)	EASI +misoprostol 25 µg (%)
PPH	16	12	12	12
Fever	4	4	4	8
Blood transfusion	8	4	8	8

Table 6: Comparison according to neonatal Apgar score at 1 and 5 minutes.

Apgar score	Misoprostol 25 µg (PGE1) (%)	Dinoprostone gel (PGE2) (%)	Foley catheter (%)	EASI +misoprostol 25 µg (%)	P value
1 minute	7.56	7.44	7.40	7.32	0.8070
5 minutes	8.24	8.2	8.4	8.28	0.9020

*P value <0.05.

Table 7: Distribution of patients in four study groups by NICU status.

NICU admission	Misoprostol 25 µg (PGE1) (%)	Dinoprostone gel (PGE2) (%)	Foley catheter (%)	EASI+misoprostol 25 µg (%)
1 day	8	4	4	0
2 days	4	0	0	0
3 days	4	16	12	8
5 days	4	4	0	12
7 days	0	0	4	0
10 days	0	0	0	8

DISCUSSION

In this study, a total of 100 pregnant women with indication for pregnancy termination were evaluated. There were 4 groups that were studied that is vaginal misoprostol (PGE1), intracervical dinoprostone gel (PGE2), foley catheter, extra amniotic saline infusion (EASI) +vaginal misoprostol. This study was conducted in Sri Dharmasthala Manjunatheswara College of Medical Sciences and Hospital, Dharwad for a study period of one year. The studied groups were almost similar in the view of demographic characteristics including age, number of ANC visits, gestational age, parity, and bishop score.

Maternal outcome was assessed in terms of BIshop's score, induction delivery interval, and mode of delivery and complications. In term of Induction delivery interval significant difference was observed between groups vaginal misoprostol and foley catheter (p=0.0034) that was similar to a study done by Roudsari et al which showed that the mean time to delivery was significantly

shorter in misoprostol group rather than the Foley catheter group.[9] Misoprostol had the shortest Induction delivery interval in contrast to study by Calder et al and Reinhard et al which concluded that a single application of PGE2 gel caused favorable changes in the cervix by increasing the bishop score and shortened the induction delivery interval.[10,11]

In this study vaginal delivery was highest in the PGE2 group while cesarean section was highest in the EASI + misoprostol group, in contrast to a study by Jozwiak et al. concluded that induction of labor using mechanical methods results in similar cesarean section rates as prostaglandins.[12]

A significant difference was observed between no of doses of induction between PGE1 and PGE2 group but among others, no much difference observed, due to other induction methods that were combined with each method, which was one of the few drawbacks of the study. PPH, fever and blood transfusion were some of the complications that were seen between the groups. Post op fever was seen maximum with the EASI + misoprostol group probably due to nosocomial infection. PPH and blood transfusion was seen maximum in PGE1 group. There were no major complications in this study.

Neonatal outcome was assessed in terms of the Apgar score at 1 and 5 minutes of life and NICU admissions. Apgar score was comparable between the study populations. Neonatal complications such as meconium aspiration, grunting, weak cry, birth weight was noted and required NICU admissions. However, no mortality was observed in the study population. There was no much difference in respect to the fetal birth weight. NICU admission was seen maximum with the EASI + misoprostol group and minimum with PGE1 alone.

CONCLUSION

In the present study, characteristics such as age, parity, gestational age, bishop score were comparable between the four groups. The shortest Induction delivery interval was seen with vaginal misoprostol alone in comparison to others. Maximum number of patients under PGE2 group had vaginal delivery and highest caesarean section rate was seen with EASI + misoprostol induction group. NICU admission was maximally seen with EASI + misoprostol group mainly due to meconium stained amniotic fluid and fetal respiratory distress. There was no maternal and neonatal mortality observed in the study population.

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