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RESEARCH ARTICLE

EFFECT OF VAGINAL WASH BEFORE INTRAVAGINAL MISOPROSTOL (PGE1) INSERTION FOR INDUCTION OF LABOUR

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ABSTRACT

Aim: The aim of the study is to observe the effectiveness of saline vaginal wash just before insertion of intravaginal Misoprostol for the induction of labour. Background: Saline vaginal wash removes the secretions of the vagina, enhances the bioavailability of Misoprostol. Prostaglandin E1 analogue has dual role for cervical ripening and induction and initiation of labour.

Methods: A prospective randomized control trail conducted with 2 groups of pregnant women at term with and without saline vaginal wash before insertion of intpra vaginal Misoprostol. Cases consisted of 50 pregnant women with vaginal wash before intra vaginal Misoprostol. Controls consisted of 50 pregnant women with no vaginal wash before Misoprostol insertion.

Results: The total number of pregnant women 100 divided in to two groups has similar mean age, body mass index, gestational age, gravidity, parity and Bishop score before drug insertion. Time, frequency and number of doses of Misoprostol kept intravaginally, time from the beginning of Misoprostol 25mcg insert vaginally to the active phase of labour and time of the delivery were significantly longer in the control group ($p<0.05$).

Conclusion: Simple easy method with good outcome without or minimal side effects. Results of our study are comparable to other studies with saline wash before insertion of Misoprostol . So can be considered as routine practice. Limitations of our study are vaginal pH is not estimated and vaginal cultures are not done before and after saline vaginal wash.

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INTRODUCTION

Induction of labour [1]is artificial method of initiating uterine contractions beyond the age of fetal viability aiming vaginal delivery. The various methods are mechanical, medical and surgical. The indications of these methods are maternal and fetal by which safe delivery can be accomplished. To name few fetal and maternal indications[2] like post maturity pregnancy, Diabetes complicating pregnancy, Rh incompatibility, IUGR, malformations, and IUFD. Renal diseases like Nephrotic Syndrome, liver disease, Autoimmune diseases. Maternal and fetal diseases like PIH, Accidental hemorrhage, PROM etc.. Our study included mostly past dates and term gestation. We selected medical induction of labour in our study as it is simple, well tolerated, well accepted, low cost and easy to follow. There are number of studies recorded in the literature with Misoprostol (PGE1). Misoprostol is a synthetic prostaglandin E1 analogue which was originally used for non obstetrics causes for prevention and treatment of gastric ulcer diseases.

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Later, Misoprostol is found to be useful in obstetrics and Gynaecology for induction of labour and abortions. It has been shown that Misoprostol increases Myometrial contraction and decreases cervical resistance. Misoprostol has been extensively researched for its use in obstetrics and has proved to be a very effective which improves the Bishop score by cervical softening before termination of pregnancy. The beneficial effects on cervical ripening may make Misoprostol a desirable agent for helping cervical dilatation on non pregnant women also. A few studies are available on the use of Misoprostol as cervical priming agent before Gynaecological procedures on non pregnant women. After oral administration, Misoprostol is rapidly absorbed and converted to its pharmacologically active metabolite – Misoprostol acid. Plasma concentration of Misoprostol acid reaches its peak in about 30 minutes and decline rapidly thereafter. Misoprostol is primarily metabolized in liver and less than 1% of its active metabolite is excreted in urine. Most common adverse effects of Misoprostol after oral administration are nausea vomiting diarrhea, abdominal cramps and fever which are dose dependent. The effects of Misoprostol on the reproductive tract are increased and gastrointestinal side effects are decreased if the tablets are administered vaginally. After vaginal

application the peak plasma concentration of Misoprostol acid is reached in one to two hours and then declines slowly. Though vaginal application of Misoprostol results in slower increase and lower peak plasma concentration as compared to oral administration, the overall exposure to the drug is increased, so repetition of the drug can be minimized. Method of application of different ways and forms of drugs, effect the pharmacokinetics and dynamics of the molecule one of them is vaginal pH which is effected by hormones and infections. Normal vaginal pH is 3.8-4.5 because of Doderlein's bacilli[5]. These organisms produce lactic acid through glycogen fermentation, so alkaline pH causes growth of pathogenic bacteria species. Some of the studies proved that the release of PGE2[4] is reduced in lower pH. Vaginal wash reduces normal vaginal flora and turn the vaginal pH to alkaline so we used the method of saline wash before insertion of Misoprostol for effective induction.

MATERIALS AND METHODS

Study design: This parallel, randomized controlled trial was conducted with an allocation ratio of 1:1 (50 study and 50 control groups). This to compare the outcome of delivery with and without saline vaginal wash[4] before Misoprostol 25mcg insertion. The study was conducted in February 2020 to March 2021 at Anil Neerukonda institute of medical sciences (NRIIMS) Sangivalsa, vizag, Andhra Pradesh .This study protocol was approved by the ethical committee (030/2019), NRIIMS. The study protocol was explained and informed consent was obtained from all the voluntary participants before admission to the labor room. They were given option to withdraw from the study at any time.

Study participants: Patients were admitted for induction of labour. Selected cases as per inclusion criteria are included in the study. Inclusion criteria: singleton pregnancy, cephalic presentation, term gestation (defined as >38 weeks), reactive fetal heart rate in cardiotocography, no contraindication to vaginal delivery, absence of spontaneous uterine contractions, cervical modified Bishop's score not less than 5 were enrolled for the study. Exclusion criteria: multiple pregnancies, less than 38 weeks, non-cephalic presentation, ruptured membranes, non-reassuring fetal heart rate, fetal anomaly and fetal demise, suspected chorio -amnionitis, who are already in labour High risk pregnancies, known hypersensitivity to prostaglandins, previous cesarean delivery or other uterine surgery.

Procedure: Initial cervical assessment of women for induction is done by Bishop score .Vaginal wash with sterile 0.9% NaCl (saline) with 20 cc syringe was give just before inserting Misoprostol 25mcg , followed with the interval of 4 hours between each dose in the study group. Misoprostol 25mcg was inserted with the interval of 4 hours between each dose directly without wash in the control group. Progress is recorded on partogram with onset of active labour till full dilatation. Follow up was done from full dilatation to baby delivery. Time of Misoprostol insertion to full dilation noted and insertion to delivery time recorded. Progress and outcome of labor were recorded.

Statistical analysis: Evaluation of this study results done by, the IBM SPSS STATISTICS 22.0 program. Student's t-test was used for the comparison of two groups of normal distribution parameters in comparison of descriptive statistical methods. Chi-square test, Fisher's exact test and continuity correction test were used for the comparison of qualitative data. P less than 0.05 level is significant.

RESULTS

The patient flow chart is listed in detail in Figure 1. Out of 112 eligible patients, 12 patients were excluded because they did not meet the inclusion criteria. Hundred participants were randomly assigned to the study (n = 50) and control groups (n = 50). The baseline characteristics of participants in each group were shown in Table 1. The ages of the patients ranged from 20 to 30 years with an average of 28.35 +/- 4.45 years. There was no statistically significant difference in the Misoprostol usage indications between the groups ($P > 0.05$). The mean pre- induction Bishop score was 1.82+/- 0.82 in the study group and 1.87 +/- 0.80 in the control group. There was no statistically significant difference between groups in terms of birth weight ($P > 0.05$). Table -1 Evaluation of demographic parameters by the two groups. The most common indication of labor induction was post-term pregnancy in both groups (Table 2).

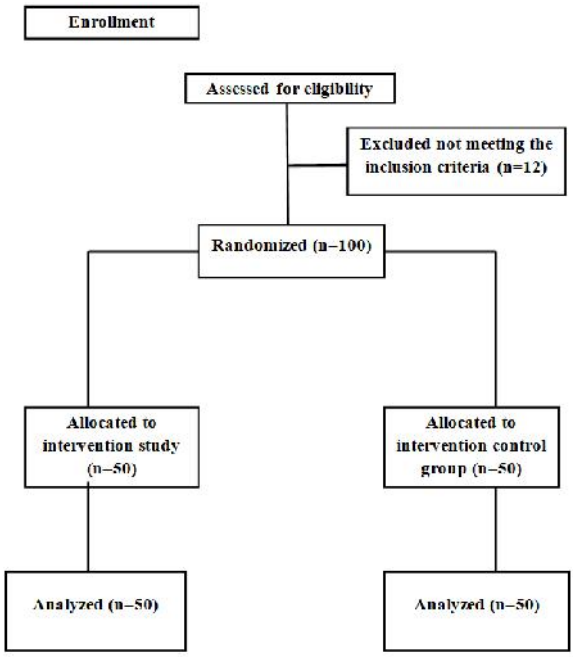

Figure 1. Flow chat of the Study population

In the study group, Time of Misoprostol insertion to full dilation noted and insertion to delivery time recorded. Progress and outcome of labor were recorded were statistically significantly shorter than in the control group ($P < 0.05$, Table 2). There was no statistically significant difference of cases of failed induction between the groups ($P > 0.05$, Table 2). There was no statistically significant difference between the groups in terms of the rate of labor arrest ($P > 0.05$). There was no statistically significant difference in fetal distress cases between the groups ($P > 0.05$). Comparing the groups, the mean Apgar 1 and Apgar 5 scores did not differ statistically ($P > 0.05$). In the control group, the Neonatal intensive care unit (NICU) admission rate was significantly higher than the study group ($P < 0.01$).

Table 1. Evaluation of demographic parameters by the two groups

		Study(n=50) Mean ± SD	Control (n = 50) Mean ± SD	P-value*
Age (years)		28.35 +/- 4.5 yrs	28.25+/- 4.4 yrs	0.12
Gestational age		38 -41 weeks	38-41 weeks	0.95
BMI (kg/m2)		28.67 +/- 5.6	27.8+/- 7.6	0.50
Gravidity	1	26	24	0.7
	2	16	18	
	3+	8	8	
Parity	0	28	26	0.13
	1	15	16	
	2+	7	8	

Table 2. Evaluation of some labour characteristics by the two groups

		Study (n=50) Mean+/- SD(median)	Control (n=50) Mean+/- SD(median)	P-value*
No.of doses of Misoprostol kept vaginally		3 +/- 1	4 +/- 2	<0.05*
Time taken from the beginning of Misoprostol inserted vaginally to active phase of labour(hours)		10.59 +/- 7.12	15.11 +/- 12.66	<0.05*
Time taken from the time at intravaginal Misoprostol insertion to total cervical dilatation (hours)		13.77 +/- 8.43	18.25 +/- 13.17	<0.05*
Prelabor Bishop score		1.82 +/- 0.82	1.87 +/- 0.80	0.61
Route of delivery	C/S NVD	7 43	12 38	0.07
Failure of labour induction	(+) (-)	3 47	5 45	0.07
Labour arrest	(+) (-)	2 48	3 47	0.11
Fetal distress	(+) (-)	2 48	2 48	0.49

Table 3. Evaluation of some neonatal characteristics by two groups

		Study(*n*=50) Mean ± SD	control (n=50) Mean ± SD	P-value*
Birth weight (grams) Apgar 1 Apgar 5		3378.02 +/- 492.9 7.94 +/- 0.59 9.0 +/- 0.39	3467.47 ± 443.4 7.65 +/- 1.09 8.80 +/- 0.77	0.18 0.06 0.08
NICU admission	(+) (-)	3 47	11 39	<0.01
Gender	Male Female	26 24	27 23	0.71
Meconium passage	(+) (-)	2 48	7 43	<0.05
Fetal infection	(+) (-)	0 50	5 45	<0.01

The meconium passage rate in the control group was significantly higher than in the study group ($P < 0.05$). There was a statistically significant difference in fetal infection between the groups ($P < 0.01$). The fetal infection rate in the control group was significantly higher than in the study group (Table-3).

DISCUSSION

This prospective randomized controlled trail to compare the efficacy of intra vaginal Misoprostol for labour induction with or without saline douche prior to insertion. The two groups of women are divided in to one with and another without saline vaginal wash before drug insertion. Our data analysis showed that the frequency and number of doses of Misoprostol kept in the vagina are less in study group (3+/-1), Time from the beginning of Misoprostol insertion to the active phase of labor is less in study group (10.59+/- 7.12), Time taken from the of Misoprostol insertion to the total cervical dilatation were significantly longer in the control group than the study group (13.77+/-8.43). The time taken for progress of labour is less in study group when compared to control group (<0.05).The NICU admissions were significantly lesser in the study group (3 in 50 cases) than in control group (7 in 50 cases).

Some studies have shown a significantly higher rate of caesarean delivery (12 in 50 cases) and Chorio-amnionitis in cases with a prolonged first stage of labor. As there is no prolonged first stage of labour in our study caesarean section rate is less when compared to control group and less NICU admissions (<0.01). Some researches has recommended that the moistening with acetic acid[3] before induction proved to be more effective in some of the studies. As acetic acid is irritant and have pungent odour acceptance is less. As same group used saline wash for induction by Misoprostol. So we selected saline wash with Misoprostol for induction. Vaginal douching may reduce the density of normal vaginal flora, excessive secretions and vaginal pH is balanced, which enhances the bioavailability of Misoprostol. So it is proved to be efficient procedure which reduces delivery time and comfort to the delivering women.

CONCLUSION

In this randomized clinical study in which it was observed that the use of vaginal wash before Misoprostol insertion may reduce the density of normal vaginal flora, excessive secretions and balances the vaginal pH, thus enhances the bioavailability

and efficacy of Misoprostol (PGE1). This is also useful and easy applicable method for the obstetricians to get better results about induction of labour. One of the limitation in this study is assessment of vaginal pH was not done before and after vaginal wash. The sample of study is small as NRIIMS is COVID hospital due to which there is pause in continuing the study. However, as this is prospective study which will be continued. In another same type of study the sample size is only 41 which is smaller than our study. In future research, pH assessment for each patient will be included before and after the procedure to get optimal results by maintaining vaginal pH. Vaginal infections will change pH. Response to Misoprostol varies with pH . So use of Litmus paper to check the pH and culture and sensitivity by vaginal swab before starting the procedure will be added in our future further studies.

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Effect of vaginal washing before intra vaginal Dinoprostone insertion for labor induction: A randomized clinical trial ÇigdemYayla Abide1

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