e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(6); 1605-1608

Original Research Article

Comparative Study of Misoprostol Alone Versus a Combination of Dinoprostone and Oxytocin for Induction of Labor at Obstetrics and Gynaecology Department of SKMCH, Muzaffarpur, Bihar

Chetna[1], Abha Rani Sinha[2], Abha Sinha[3]

[1]Senior Resident, Department of Obstetrics and Gynaecology, Sri Krishna Medical College & Hospital, Muzaffarpur, Bihar

[2]Professor, Department of Obstetrics and Gynaecology, Sri Krishna Medical College & Hospital, Muzaffarpur, Bihar

[3]Professor and Head of Department, Department of Obstetrics and Gynaecology, Sri Krishna Medical College & Hospital, Muzaffarpur, Bihar

Received: 25-01-2024 / Revised: 23-02-2024 / Accepted: 26-03-2024

Corresponding Author: Dr. Chetna

Conflict of interest: Nil

Abstract:

Objective: To compare the safety, efficacy, cost and fetal outcome of misoprostol with that of combination of dinoprostone and oxytocin for induction of labor.

Methods: All eligible women admitted for induction of labor during the period from June 2019 to May 2020 were included in the study (n=72). They were randomized to receive either misoprostol 25 µg intravaginally every 4 hours for a maximum of 8 doses (study group n=37) or dinoprostone 0.5 mg intracervically 6 hourly for a maximum of 3 doses followed by oxytocin if necessary (control group n=35).

Results: Induction delivery interval was significantly shorter in the study group (10.20 ± 13.50 hours vs 14.27 ± 5.51hours; P<0.001). Cesarean section rate in the study group was lower than that in the control group but not significantly so (21.62% vs 37.14%; P>0.05) Failure to progress was the main indication for cesarean section in the control group. Fetal distress was more common in the study group than in the control group but not significantly so. Neonatal outcome was comparable in the two groups. The cost of therapy was significantly less in the study group. (P<0.001).

Conclusion: Misoprostol alone was more effective and highly inexpensive alternative to the combination of dinoprostone and oxytocin for labor induction.

Keywords: Labor Induction, Misoprostol, Dinoprostone And Oxytocin.

Introduction

For majority of women, labor starts spontaneously and results in vaginal delivery at or near term. However because of medical and obstetric complications during pregnancy, cervical ripening and labor induction are often required. The only medical method of proven efficacy for preinduction cervical ripening and labor induction currently is combination of PGE_2 gel given intracervically for cervical ripening and intravenous oxytocin infusion for labor induction. PGE_2 gel preparation specially prepared commercially has to be administered by intracervical route, which is invasive. It has to be refrigerated during storage and warmed before use. For succeeding induction of labor by oxytocin, a minimum time gap of 6 hours has to elapse after the last dose of PGE_2. [1] Misoprostol is a synthetic prostaglandin E_1 analogue, widely used for treatment of peptic ulcer in patients taking nonsteroidal antiinflammatory drugs for a long time. It has uterotonic action and recently has been shown to be an effective agent for preinduction cervical ripening and labor induction in many clinical trials. These trials have confirmed the safety and efficacy of misoprostol as an inducing agent. Misoprostol tablet has to be quartered and a quarter administered intravaginally which is less invasive and relatively easy. It does not require refrigeration for storage. Last but not the least, it is quite cheap compared to the inducing agents currently available. The purpose of our study was to determine whether the evidence from large number of clinical trials that supports the use of misoprostol as an effective and safe ripening and inducing agent would be applicable to our population. [2]

Material and Methods

All eligible women admitted during the study period from June 2019 to May 2020 were enrolled into the study at Obstetrics and Gynaecology Department of Sri Krishna Medical College & Hospital, Muzaffarpur, Bihar. Based on the sequential analysis design further recruitment of patients was stopped after 6 months when the study was greater than 80%. The inclusion criteria were singleton gestation, gestational age between 37 to 42 weeks, live intrauterine fetus, intact membranes, cephalic presentation, and Bishop's score of five or less. Those with multiple pregnancy, malpresentation, abnormal fetal heart rate pattern, cephalopelvic disproportion, ruptured membranes, previous cesarean section, a scar on the uterus, parity more than five, and a history of hypersensitivity to prostaglandin were excluded from the study. After taking informed consent, the women enrolled into the study were randomized to two groups, study group and control group, based on the code S or C enclosed in sealed envelopes. Women allocated to the study group, received 25 µg i.e. is one quarter of 100 µg scored tablet of misoprostol.

This was inserted into the posterior fornix of vagina digitally every 4 hours upto a maximum of 8 doses or a cumulative dose of 200 µg of misoprostol. Women allocated to the control group, received 0.5 µg of dinoprostone gel (PGE_2 gel) in the cervical canal. If the cervix was still unfavorable after 6 hours another dose of 0.5 mg PGE_2 gel was repeated upto a maximum of 1.5 mg PGE_2 or 3 doses to achieve optimal cervical ripening. If cervix was favorable, oxytocin infusion was started 6 hours after the last dose. From past experience it was found that irrespective of gravity and parity, delivery within 14 hours of starting induction reduced morbidity and mortality in both the mother and the neonate. Hence the primary outcome measure was interval between beginning of induction and vaginal delivery. Secondary outcome measures included mode of delivery (vaginal or cesarean) and indication for cesarean section (failure to progress or fetal distress). The total number of doses of the drug required for induction in each group and the average cost of therapy encountered in treating a woman of each group were calculated and compared. The induction to vaginal delivery interval in the two groups was compared using unpaired t test. Qualitative data like mode of delivery was assessed using Z test for difference between proportions and indication for cesarean section was compared using chi square test. The difference in the mean cost of therapy per patient between the two groups was compared using Z test for difference between means.

Results

The baseline data such as age, gravidity, parity and gestational age of the women were comparable in the two groups (Table 1). Indication for induction was similar in the two groups (Table 2). In the study group, 78.37% of women delivered vaginally including one forceps delivery for maternal exhaustion and 21.62% needed cesarean section. (Table 3). In the control group, 62.85% delivered vaginally including one forceps delivery and one vacuum delivery, both for maternal exhaustion, and 37.14% needed cesarean section. The percentage of women who had vaginal delivery was higher in the study group as compared to that in the control group and the percentage of women who underwent cesarean section was lower in the study group as compared to that in the control group. But these differences were not statistically significant ($P>0.05$).

The percentage of women who underwent cesarean section for failure to progress was higher in the control group as compared to that in the study group (69.23% vs 50%) and the percentage of women who underwent cesarean section for fetal distress was higher in the study group as compared to that in the control group (50% vs 30.76%). But these differences were not significant ($P>0.05$), (Table 4). After excluding the women who had cesarean section, induction to vaginal delivery interval in the two groups was compared (Table 5). The induction to vaginal delivery interval in the study group was 10.20 ± 3.50 hours and that in the control group was 14.27 ± 5.51 hours. The mean interval in the study group was at least 4 hours shorter than that in the control group and this difference was statistically highly significant ($P <0.001$; Table 5).

Table 1: Baseline data

	Study group (n=50) Mean±SD	Control group (n=50) Mean±SD
Age (years)	24.36±2.99	24.14±3.19
Gravity	1.45±0.72	1.37±0.86
Parity	0.40±0.59	0.25±0.49
Gestational age (weeks)	39.48±1.53	39.47±1.57

Table 2: Indication for induction

Indication	Study group (n=37)		Control group (n=35)	
Pregnancy induced hypertension	9	24	15	42
Postdated pregnancy	23	62.16	18	51.42
Oligohydramnios	2	5.40	-	-
Rh isoimmunization	-	-	1	2.8
Intrauterine growth restriction	3	8.10	1	2.8

Table 3: Mode of delivery

Mode of delivery	Study group (n=37)	Control group (n=35)
Vaginal delivery :		
• Spontaneous	28	20
• Instrumental	1	2
Total	29(78.37%)	22(62.85%)
Cesarean section	8(21.62%)	13(37.14%)*

***Z=1.54, P>0.05, not significant.**

Table 4: Indication for cesarean section

Indication	Study group (n=8)	Control group (n=13)
Failure to progress	4 (50%)	9 (69.23%)
Fetal distress	4 (50%)	4 (30.76%)

***X^2=0.17, df=1, P>0.05, not significant.**

Table 5: Indication to vaginal delivery interval

Indication to vaginal delivery interval (hours)	Study group (n=29)	Control group (n=22)
5-9	11(37-93%)	5(22.72%)
10-14	14(48.27%)	6(27.27%)
15-19	3(10.34%)	8(36.36%)
20-24	1(3.44%)	1(4.54%)
25-29	-	2(9.09&)
Mean±SD	10.20±3.50*	14.27±5.51*

*** Unpaired t test, t value at df 49 = 3.0373. Highly significant, P<0.001.**

The average cost of therapy was Rs.9 per women in the study group compared to Rs. 406.57 in the control group. The average cost of therapy of the control group was significantly higher than that of the study group, (Z test, P<0.001). There was no difference between the mean apgar scores of babies of the two groups. In the study group one woman reported nausea, two women experienced uterine tachysystole (5.4%) and one woman had hyper stimulation syndrome. In the control group, one woman complained of local irritation, one had vomiting, one had diarrhea, one developed fever and one had uterine tachysystole (2.85%). The differences are not significant statistically.

Discussion

The two groups did not differ significantly with respect to baseline characteristics like age, parity, gravidity, gestational age (Table 1) and indication for induction of labor (Table 2). Hence the two groups were comparable. The mean induction delivery interval in the study group was at least 4 hours shorter than that in the control group and this difference was statistically highly significant (P<0.001). The findings of our study were consistent with the findings reported by Mundle and Young [5] and Bartha et al. [1]

The proportion of women who underwent cesarean section was higher in the control group but not significantly so (37.14% vs 21.62%; P>0.05. Table 3). Our findings were consistent with those reported by Mundle and Young5 and Wing et al. [9] However a metanalysis conducted by Sanchez-Ramos et al by pooling 44 studies involving 5735 women and comparing misoprostol with other regimens for labor induction noted a significant reduction in cesarean section rate in women receiving misoprostol compared to that in women belonging to other groups.

When the indications for cesarean section among the two groups were compared, it was found that the proportion of women who underwent cesarean section for failure to progress (dystocia) was higher in the control group as compared to that in the study group (69.23% vs 50%) and the proportion of women who underwent cesarean section for fetal distress was higher in the study group as compared to that in the control group (50% vs 30.76%) (Table 4). But these differences are not significant.

Our findings are consistent with the results of the metanalysis reported by Sanchez-Ramos et al. It was seen that the occurrence of tachysystole was not significantly different in the two groups (5.4% in the study group vs 2.85% in the control group). One woman in the study group and none in the control group experienced hyper stimulation syndrome. Our findings are similar to those of Danielian et al. [3] Thus misoprostol is more efficacious than combination of dinoprostone and oxytocin in decreasing the induction to vaginal delivery interval while the cesarean rate is comparable.

The mean cost of therapy in the study group compared to in the control group. This difference is highly significant (P<0.001). Most of the studies comparing misoprostol with other regimens for labor induction conducted both in India and abroad have confirmed the similar cost effectiveness of misoprostol.

Conclusion

Misoprostol for induction of labor is effective and cheap.

References

1. Bartha TL, Comino-Delgado R, Garcia-Benasach F et al. Oral misoprostol and intracervical dinoprostone for cervical ripening and labor induction: a randomized comparison. Obstet Gynecol. 2000; 96:465-9.
2. Chuck FJ, Huffaker BJ. Labor induction with intravaginal misoprostol versus intracervical prostaglandin E_2 gel (Prepidil gel): randomized comparison. Am J Obstet Gynecol. 1995; 173: 1137-42.
3. Danielian P, Porter B, Ferri N et al. Misoprostol for induction of labour at term: a more effective agent than dinoprostone vaginal gel. Br J ObstetGynaecol. 1999; 106:793-7.
4. Fernandes E, Vavilala S Misoprostol – A miracle drug? ObstetGynaecol Today. 2001; 6:530-4.
5. Mundle WR, Young DC. Vaginal misoprostol for induction of labor: a randomized controlled trial. Obstet Gynecol. 1996; 88:521-5.
6. Sanchez-Ramos L, Kaunitz AM, Wears RL et al. Misoprostol for cervical ripening and labor induction: a metaanalysis. Obstet Gynecol. 1997; 89:633-42.
7. Soni N, Rajput P. Comparative study between tablet misoprostol (PGE_1) and dinoprostone gel (PGE_2) for the induction of labor. J Obstet Gynecol India. 2004; 54:554-5.
8. Surbek DV, Boesiger H, Hoesli I et al. A double blind comparison of the safety and efficacy of intravaginal misoprostol and prostaglandin E_2 to induce labor. Am J Obstet Gynecol 1997; 177:1018-23.
9. Wing DA, Jones MM, Rahall A et al. A comparison of misoprostol and prostaglandin E_2 gel for preinduction cervical ripening and labor induction. Am J Obstet Gynecol. 1995; 172: 1804-10.