ISSN: 0976-3031

Available Online at http://www.recentscientific.com

CODEN: IJRSFP (USA)

International Journal of Recent Scientific Research
Vol. 8, Issue, 8, pp. 18963-18966, August, 2017

International Journal of Recent Scientific Research

DOI: 10.24327/IJRSR

Research Article

COMPARATIVE STUDY OF EFFECTIVENESS OF LOW DOSE-VAGINAL MISOPROSTOL AND INTRACERVICAL DINOPROSTONE FOR CERVICAL RIPENING AND INDUCTION OF LABOUR IN TERM PREGNANCY IN KASHMIRI POPULATION

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DOI: http://dx.doi.org/10.24327/ijrsr.2017.0808.0602

ARTICLE INFO

Article History:

Received 05th May, 2017
Received in revised form 21st June, 2017
Accepted 06th July, 2017
Published online 28th August, 2017

Key Words:

Cervical ripening, Dinoprostone, Labour induction, Low- dose misoprostol

ABSTRACT

Background: Induction of labour is one of the most common obstetric interventions worldwide. The study was conducted to compare the efficacy and safety of 25µg (low dose) vaginal Misoprostol with intracervical Dinoprostone for cervical ripening and induction of labour in term pregnancy.
Methods: The study was conducted on 200 eligible term gravidas admitted for the purpose of labour induction. Subjects were randomly allotted to two groups. Group A (100 patients) received intracervical Dinoprostone 6 hourly for a maximum of 3 doses each, for cervical ripening and induction of labour. While Group B (100 patients) received 25µg vaginal Misoprostol 6 hourly The main outcomes analyzed were the induction-to-vaginal delivery interval, number of vaginal deliveries within 24 hours, dose of prostaglandin required, need for oxytocin augmentation and incidence of operative or caesarean delivery and rates of hyper stimulation, maternal complications and neonatal outcome. Results: The mean induction to delivery interval was more in Group "A" patients as compared to Group "B". It was 1034+363 minutes (17.2+6.0 Hours) in Group A and 832+293 minutes / 13.9+4.9 hours in Group "B. The mean change in Bishop's score was greater with Misoprostol, although the difference was not statistically significant. The rates of operative and caesarean deliveries, and indications for caesarean were similar in both groups. The rates of uterine hyper stimulation, maternal and neonatal outcomes were similar.
Conclusions: Vaginal Misoprostol is more efficacious than intracervical Dinoprostone for induction of labour in term gravidas.

INTRODUCTION

Induction of labour is defined as artificial beginning of cervical ripening and uterine contractions before its spontaneous onset directed to determine the progressive dilatation and effacement of cervix in order to promote vaginal delivery (1) Oxytocin and prostaglandins are the main stay for labour induction. Cervical favorability is the prime determinant of success of labour induction and vaginal delivery. Oxytocin does not promote cervical ripening. Prostaglandins, on the other hand, stimulate myometrial contractions as well as facilitate cervical ripening. (2) Two prostaglandin analogues are available commercially. Dinoprostone (PGE2) gel is a licensed, time tested preparation and is recommended widely as the preferred agent for labour induction. Misoprostol is a PGE1analogue used through oral or vaginal route. As compared to Dinoprostone, Misoprostol has certain decided advantages. It is stable at room temperature, does not require special storage, is inexpensive, less invasive to use, has no broncho constriction action and can be administered through several routes. There has been concern about uterine hyper stimulation with the use of higher doses of Misoprostol. Recent published studies have, however, established that lower dosages of Misoprostol give similar or better results than PGE2, but with similar safetyprofile. (3-5) The 25 µg dose is as effective as the 50 µg dose and with reduced risk of hyper stimulation.(6).This study aims to compare the efficacy and safety of low dose (25µg) vaginal Misoprostol with intracervical. Dinoprostone for cervical ripening and induction of labour in term pregnancies.

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METHODS

This was a retrospective study conducted in skims medical college Bemina Srinagar on 200 term gravida after approval from the Hospital Ethics Committee, informed consents were obtained from each participant. Allocation to the two study groups, All term gravidas >18 years old, with accurately dated single viable cephalic gestation, a Bishop's score of <5 and a reactive non stress test prior to induction were included in the study. Grand multiparas, women with history of prior uterine surgery, any suspicious vaginal bleeding, multiple pregnancies, suspected cephalopelvic disproportion, non-vertex presentation, abnormal placentation and history to cardiac disease, glaucoma, asthma, or drug allergy were excluded from the study. A detailed history was taken and a comprehensive general physical, systemic and obstetric examination was carried out. After the assessment of the cervical Bishop's score following a reactive NST, patients were allocated to two groups. Patients in group A were administered 0.5 mg Dinoprostone gel intracervical and those in group B were administered 25µg Misoprostol tablet pervaginum. In both groups, the blood pressure, pulse rate, uterine activity and foetal heart rate were monitored and notedevery 15 minutes for the first hour and half hourly thereafter. The onset of uterine contractions, duration, frequency and intensity of contractions were noted and patient were monitored for uterine tach systole, hypertonus, hyper stimulation or non-reassuring foetal heart rate patterns. If and when the patient went into active labour, liquor was meconium stained or the FHR was not reassuring, the patient was transferred to the labour room and further prostaglandin doses were withheld. After the administration of the first dose, the patient vitals, fetal heart rate and onset of uterine contractions were monitored. If at 6 hrs, good uterine contractions (2 ormore lasting 25-30 seconds each in a 10 minute period) were established and Bishop's Score >5, further doses were withheld and, augmentation, if and when required was carried out with oxytocin infusion and amniotomy. If there were no adequate pains or for Bishop's Score <5, doses were repeated at 6, 12 and 18 hrs. Successful induction was defined as the occurrence of vaginal delivery within 24 hrs. In the event of uterine hyper stimulation, the patient was put in left lateral position, intranasal oxygen inhalation was given and intravenous Dextrose Normal Saline drip was started. Tocolytics were administered for reversal of hyper stimulation. The trial was interrupted and decision for operative intervention taken, if the aforementioned measures failed. Caesarean section was performed for failure to progress and fetal distress. For the purpose of the trial, foetal distress was defined as persistent or recurring episodes of severe variable or late decelerations, late decelerations, or prolonged foetal bradycardia, or a combination of decreased beat-to-beat variability and a decelarative pattern with or without the presence of meconium stained liquor. Non progress of labour was defined as no change in cervical dilatation during the active phase of labour for two consecutive hours or no progress in the descent of the foetus through the birth canal in the second stage of labour for 1 hour in the presence of adequate uterine contractions. The primary outcome measures studied were the number of vaginal deliveries occurring within 24 hours and the induction- to- vaginal delivery interval. The secondary outcome measures were the number of prostaglandin doses required, need for oxytocin augmentation, duration of labour, maternal hyper stimulation and foetal outcome as described by need for resuscitation in the labour room, APGAR scores at 1 and 5 minutes and admission to the NICU.

RESULTS

The patients in both groups were similar with respect to age, gestational age, parity, pre induction cervical score and indication for induction. No patients were excluded from analysis. No patients were lost to follow up.

Demographic Feature of Study Groups in **Table No 1**

S No		Group A(Dinioprostone)	Group B(Misioprostone)
1	Age	26.2 ±3.3	26.1± 3.2
2	Gestional Age	39.2 ± 0.9	39.4 ± 1
3	Mean Bishop Score (pre induction)	3.2± .5	3.1 ± 0.6
4	Oxytocin needed	67 %	49 %
5	Induction to Delivery interval	17.2± 6.0	13.9±4.9

Mean patient age of group A (in years) 26.2±3.3, while of group B 26.1±3.2. There was no significant difference of age between two groups. Mean gestational age (in weeks) group A 39.2±0.9, group B 39.4±1.0, there was no statistically significant difference in gestational age between two groups.

Table No 2 parity distribution of studied patients

Parity	Group A (Percentage)	Group B (Percentage)	P Value
Primigravida	69	63	0.375
Multigravida	31	37	0.375
Total	100	100	

In group A out of 100, 69 patients were primigravida and 31 were multigravida as showed in table. In group B 63 were primigravida and 37 were multigravida. Mean pre induction Bishops score was 3.2±0.5 in group A and 3.1±0.6 in groupB. Therefore preinduction score was comparable between two groups. The mean induction to delivery time interval was 17.2±6.0 in group A and 13.9±4.9 in group B. The difference between two groups was statistically significant. The percentage of vaginal deliveries was 67 percent in group A and 72 percent in group B which is statistically significant. Mean change in Bishops score six hours after induction was 6.2±2.0 in group A and 6.2±2.2 in group B. The difference was not found to be significant. Oxytocinaugmentation was done in 67 women in group A and 49 women in group B. The difference was statistically significant. Foetal distress 22 in group A and 23 in group B.

Table 3 Mode of Delivary and Reason Fot Lscs Amoung the Study Groups

Mode of Delivery		Group A	Group B	P Value
	Vaginal	67%	72%	0.603 (NS)
	LSCS	33%	28%	
Reason for LSCS	Acute Foetal Distress	66%	82.14%	
	Non Descent of Head	6.06%	7.14%	0.3260(NS)
	Failed Induction	15.15%	3.57%	
	Non Progression of Labour	12.12%	7.14%	

Failure to progress 4 in group A and 2 in group Failure of induction 5 in group A and 1 in group B. Non descent of head was seen in 2 patients in group A and 2 in group B. The need for augmentation with oxytocin was significantly greater in the Dinoprostone group as compared to the Misoprostol group (p <0.001). The mean Apgar score at 1 minute was 7.7±1.3 in group A and 7.9±1.3 in group B. The difference was not statistically significant. The mean Apgar score at 5 minute was 9.6-±1.0 in group A and 9.5±0.9in group... In all patients under study, the initial Bishop Score was unfavorable (< 5). There was marked improvement in Bishop Score 6 hours after induction and results were comparable in both the groups. In Group" lesser number of patients required oxytocinaugmentation. Only 49 (49%) of patients in Group "B required oxytocin augmentation compared to 67 (67.0 %) in case of Group "A". The mean induction to delivery interval was more in Group "A" patients as compared to Group "B". It was 1034+363 minutes (17.2+6.0 Hours) in Group A and 832+293 minutes / 13.9+4.9 hours in Group "B". There were 67 % vaginal deliveries in Group "A" and 72% in Group "B". Caesarean section rate was 33% in Group "A" and 28% in Group "B". The most common indication for caesarean section was Acute Foetal Distress in both groups. Perinatal outcome was comparable in both groups but patients with normal cardiotocography in both groups had good perinatal outcome as compared to patients with abnormal cardiotocography. The foetal distress was more in patients with abnormal cardiotocography in both groups as comparedto normal cardiotocography. Predictive ability of cardiotocography was evaluated to identify the fetuses at high risk for developing intrapartum distress. It was seen that cardiotocography had a sensitivity of 57.1 % in Group "A" and 69.7 % in Group "B", specificity90.3 % in Group "A" and 88.1 % in Group "B", positive predictive value of69.6 % in Group A 74.2 % in Group B and negative predictive value of84.4% in Group "A" and 85.5% in Group "B". It can be inferred that cardiotocography can be used as important noninvasive method to diagnose foetal compromise during labour and to prevent adverse perinatal outcome. The Apgar score of newborn babies at one minute and five minutes was comparable in both the groups.

The present study demonstrates that vaginally administered misoprostol seems to be an effective agent for cervical ripening and induction of labour. It shortens induction to delivery interval, however it is associated with higher prevalence of tachsystole and hypertonus than Dinoprostone. The application of this drug to induce labour requires special caution and care, as well as continuous cardiotocography monitor. The current study has used 25 microgram misoprostol6 hourly dose for induction with vaginal Misoprostol in keeping with thelatest WHO and ACOG recommendations.(7,8) The regimen used for Dinoprostone has also been recommended by the ACOG in its guidelines on labour induction.(8) The trial design and dosing regimens used have been in keeping with previous similar comparative studies by Blanchette *et al*, Shivarudraiah *et al* and SheelaCN *et al*.(9-11) This study demonstrate the superiority of low dose (25 µg) vaginal Misoprostol over the time tested and standardised regimen involving Dinoprostone for cervical ripening and labour induction in term pregnancies. The induction to vaginal delivery interval has been most frequently employed to determine the success of induction regimens. Our study shows the Misoprostol achieves a significantly shorter induction todelivery interval, with lesser need for oxytocin augmentation and similar maternal and neonatal outcome as compared to intracervical Dinoprostone. In our study no statistically significant difference was observed between two groups with respect to age, gestational age and parity. These observations were consistent with observations (RamseyPSetal, Wing DA *et al*, Gupta N *et al*, Tan TC *et al*) In the present study the mean pre induction Bishops score was comparable between two groups, same observation was made by (RamseyPS *et al*, Gupta N, Mishra *et al*). In present study the mean rise of Bishops Score after induction was comparable in two groups. These observations were similar to study made by (Gupta N, Mishra *et al*). In the present study women in misoprostol group less likely required oxytocin augmentation, the results were consistent with those observed by (Wing DA, Jones MM *et al*, LindsayKoiderup, McLean *et al*). The most common indication for Caesarean sections was acute fetal distress in both the groups. Perinatal outcome was comparable in both groups. The Apgar score of newborn babies at one minute and five minutes was comparable in both groups. The present study demonstrates that vaginally administered misoprostol seems to be an effective agent for cervical ripening and induction of labour. The application of this drug to induce labour requires special caution and care, as well as continuous cardiotocographic monitoring. Misoprostol against Dinoprostone gel and insert and concluded that Misoprostol was associated with a greater mean Bishops score change, shorter induction- to delivery interval and similar maternal and neonatal outcomes.(12)

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How to cite this article:

Aquisa Bashir *et al.*2017, Comparative Study of Effectiveness of Low Dose-Vaginal Misoprostol And Intracervical Dinoprostone For Cervical Ripening And Induction of Labour In Term Pregnancy In Kashmiri Population. *Int J Recent Sci Res.* 8(8), pp. 18963-18966. DOI: http://dx.doi.org/10.24327/ijrsr.2017.0808.0602

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