



COMPARISON OF DINOPROSTONE VAGINAL INSERT WITH VAGINAL MISOPROSTOL IN LABOR INDUCTION

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ABSTRACT **INTRODUCTION:** Induction of labor is the intentional initiation of labor which involves artificial initiation of uterine contractions before spontaneous onset of labor in order to generate progressive cervical dilatation effacement and descent of the presenting part of fetus, culminating in safe vaginal delivery of the baby.

AIMS AND OBJECTIVES: To compare effectiveness and safety of dinoprostone vaginal insert and vaginal misoprostol for induction of labor.

MATERIAL AND METHODS: The study was carried out in 70 pregnant women admitted in SRN Hospital Department of OBG Prayagraj over a period of 1 year from September 2018 to 2019 .

RESULTS: Majority of the patients in the study (67.14%) were induced for indication of prolonged pregnancy. Maternal complications was more in patients of Group B (25.95%) as compared to Group A (8.55%) with one patient from Group B had uterine rupture .Fetal complications were significantly higher in patients of Group B as compared to Group A.

CONCLUSION: Dinoprostone vaginal insert is a safer method of labor induction compared to misoprostol tablet.

KEYWORDS :

INTRODUCTION

Induction of labor is the intentional initiation of labor which involves artificial initiation of regular uterine contractions before spontaneous onset of labour in order to generate progressive cervical dilatation, effacement and descent of the presenting part of fetus, culminating in safe vaginal delivery of the baby after 28 week of gestation [1]. Induction of labor is indicated when benefit of delivery to the mother or fetus outweighs the potential risks of continuing the pregnancy [2]. The common indications of induction are prolonged pregnancy ,IUD, congenital malformation of the fetus, severe oligohydramnios , polyhydramnios , preeclampsia, eclampsia and PROM [3].

Bishop score <6 is defined as unripe cervix and cervical ripening agent is recommended before labor induction [4]. Multiple modalities for labor induction includes : laminaria tents, prostaglandins, oxytocin and artificial rupture of membrane [5].

Among all, prostaglandins have been described as the most effective method of induction. Various preparations of prostaglandin E1 and E2 are commercially available. [6,7].

Dinoprostone i.e. Prostaglandin E2 is available in three forms gel, vaginal suppository and intravaginal insert [8] which is commercially available prostaglandin E2 preparation that is approved by FDA in 1995 for labor induction.

Dinoprostone vaginal insert is locally applied formulation which comprises a thin, oblong, semi opaque hydrogel delivering device and a withdrawal tape. The hydrogel consist of polymeric matrix with 10 mg of dinoprostone evenly distributed throughout the matrix with advantage of single application, slow release of drug over 24 hour and removal allowing greater dose control [9]. To maintain the efficacy of dinoprostone preparations maintenance of cold chain is very important.

Misoprostol is a Prostaglandin E1 analogue which binds to myometrial cells to cause myometrial contractions and is used as an alternative agent for labor induction . It can be administrated through oral, vaginal route. Advantage over other agent is low price, stability at room temperature and availability in secured tablet form [10].

AIMS AND OBJECTIVE

- To evaluate effectiveness and safety of dinoprostone vaginal insert for cervical ripening and induction of labor

- To evaluate effectiveness and safety of vaginal misoprostol for cervical ripening and induction of labor
- To compare the safety and efficacy of dinoprostone vaginal insert with vaginal misoprostol in induction of labor.
- To assess the neonatal outcome in both the study groups .

MATERIAL AND METHODS

The study was carried out in 70 pregnant women admitted in SRN hospital Prayagraj over a period of 12 months from September 2018 to 2019 .

INCLUSION CRITERIA :

- Singleton pregnancy
- Cephalic presentation
- Live fetus

EXCLUSION CRITERIA –

- Malpresentation
- CPD
- History of previous caesarean section or scar on the uterus
- Allergy to prostaglandins

Prior to induction written informed consent was taken and NST was performed.

TOTAL NUMBER OF 70 PATIENTS IN THE STUDY WERE DIVIDED IN 2 STUDY GROUPS:

Group A : Included patients induced with 10 mg dinoprostone vaginal insert which was left for 24 hours.

Group B : Included patients induced with 25 µg misoprostol vaginal tablet , dose was repeated 4 hourly to a maximum of 5 dose in 24 hours.

STATISTICAL ANALYSIS

The data collected from the study was analysed in terms of t test and calculation of p value. . All statistical p value < 0.05 was considered significant.

OBSERVATION

Total number of 70 patients in the study were divided in 2 study groups:

TABLE 1 : INDICATION OF INDUCTION OF LABOUR

INDICATION OF INDUCTION	GROUP A	GROUP B	P Value
	No. (%)	No. (%)	
Prolonged pregnancy	26 (74.28)	21 (60)	P = 0.490
PROM	0 (0)	6 (17.14)	P = 0.740
Preeclampsia	2 (5.7)	4 (11.42)	P = 0.912
IHCP	6 (17.14)	4 (11.42)	P = 0.898
GDM	1 (2.85)	0 (0)	P = 0.962
TOTAL	35 (100)	35(100)	P = 0.399

Prolonged pregnancy was the most common indication of induction in both the study groups.

P value = 0.399 statistically not significant.

TABLE 2:MODE OF DELIVERY :

Mode Of Delivery	Primigravida		Multigravida		Total
	Group A (n1=25)	Group B (n2=20)	Group A (n3=10)	Group B (n4=15)	
	No. (%)	No. (%)	No. (%)	No. (%)	
Vaginal delivery	11(44)	9(45)	7(70)	9(60)	36(51.42)
LSCS	14(56)	11(55)	3(30)	5(33.33)	33(47.14)
Laparotomy	0(0)	0(0)	0(0)	1(6.66)	1(1.42)
P Value	0.498	0.497			

P value > 0.05 statistically not significant.

TABLE 3: MATERNAL COMPLICATIONS:

MATERNAL COMPLICATION	Group A	Group B	P value
	No. (%)	No. (%)	
Fever	2 (5.7)	6 (17.14)	0.092
Tachysystole	1 (2.85)	2 (5.7)	
Uterine rupture	0 (0)	1 (2.85)	
TOTAL	3 (8.55)	9 (25.95)	

Maternal complications related to induction of labor was more in patients of Group B (25.95%) as compared to group A (8.55%).

P value = 0.092 statistically not significant.

TABLE 4: FETAL AND NEONATAL COMPLICATIONS

FETAL AND NEONATAL COMPLICATION	Group A	Group B	P Value
	No. (%)	No. (%)	
APGAR score < 7	3 (8.57)	7 (20)	0.047
NICU Admission	2 (5.7)	6 (17.14)	
IUD	0 (0)	1 (2.85)	

In Group B there was more fetal and neonatal complication(20%) compared to Group A (8.57%).

P value = 0.04 statistically significant which shows that Dinoprostone vaginal insert is a better inducing agent with less fetal and neonatal complications.

DISCUSSION

INDICATION OF INDUCTION (TABLE 1)

Prolonged pregnancy was the most common indication of labor induction in both Group A and Group B (74.28% in Group A and 60% in Group B). This is because labor induction before 39 completed weeks have significant and appreciable adverse neonatal morbidity. Apart from prolonged pregnancy, intrahepatic cholestasis of pregnancy was the second major indication of labor induction in both groups. In a patient with IHCP, pregnancy is terminated preferably at 36 completed weeks because raised bile acids can lead to suppression of SA node of fetal heart that can lead to sudden IUD .

Other indication of labor in Group B is PROM because in PROM there are chances of fetal distress due to drainage of liquor and maternal complication if the patient do not deliver in time but no patient in Group A was induced with this indication as in Group A dinoprostone vaginal insert releases dinoprostone 0.3 mg /hr but in patient with PROM the rate of release and absorption is increased which may lead to tachysystole and fetal distress .

MODE OF DELIVERY (TABLE 2)

Mode of delivery in both Group A and Group B was compared on the basis of their parity as there is more chance of vaginal delivery in a previously vaginally delivered patient as compared to a primigravida patient as multigravida patient have wider birth canal and the rate of cervical changes is better in them.

In the study we found that in both the Group A and B in primigravida patient, the rate of vaginal delivery and LSCS are comparable (p = 0.498) but the rate of LSCS for failed induction was more in Group A whereas LSCS for fetal distress was more in Group B.

In multigravida patient we found that number of vaginal delivery and LSCS was similar in both the study groups (p = 0.498) but the rate of vaginal delivery was more than LSCS in both the Group A and Group B.

MATERNAL COMPLICATION (TABLE 3)

In the study it was seen that patients from Group B had more maternal complications (25.95%) as compared to patients from Group A (8.55%) .The most common complication was fever in both the study groups.

The most life threatening complication of Group B was uterine rupture due to tachysystole after which patient became hemodynamically unstable and emergency laparotomy with uterine rupture repair was done .One patient in Group A also had tachysystole but dinoprostone vaginal insert used in Group A had a withdrawal tape so it was removed immediately and the contraction subsided in few minutes. There is no such facility in patients induced with Misoprostol so it is to be used cautiously .

FETAL AND NEONATAL COMPLICATION (TABLE 4)

Fetal and neonatal complications were also significantly greater in patients of Group B as compared to Group A . In Group B 20% neonates had APGAR score < 7 at birth out of which 17.14% neonates required NICU admission .On the other hand in Group A only 8.57% of neonates had APGAR score less than 5 and required NICU admission . One fetus in Group B died due to uterine rupture as a complication of induction with misoprostol tablet .

CONCLUSION

From the study we concluded that amongst the pharmacological inducing agent prostaglandins has always been preferable and amongst the prostaglandins PGE2 preparations has been preferable.

Misoprostol do have a satisfactory response in labor induction but its hypertonic response leading to fetal distress and uterine rupture is highly unpredictable that makes it risky drug for induction of labor.

PGE2 gel is a time tested drug for induction of labor but its administration requires a little expertise along with the need for instruments for intracervical administration , so the development of PGE2 vaginal insert overcomes the cumbersomeness of insertion . The other drawback of gel is that once induced it cannot be removed which is overcome by the vaginal insert form which has a retrieval system for easy removal of the insert in cases of fetal distress and uterine tachysystole.

Thus we can conclude that Dinoprostone vaginal insert is a safer method of labor induction compared to misoprostol tablet.

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