

A Comparative Study on the Efficacy of Dinoprostone Sustained Release Vaginal Insert Versus Intracervical Gel in Induction of Labour.

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INTRODUCTION

Induction of labor is the process of treatment that stimulates childbirth and delivery. Inducing labor can be accomplished with pharmaceutical or non-pharmaceutical methods. Inductions most often performed either with prostaglandin drug treatment alone or with a combination of prostaglandin and intravenous oxytocin treatment. Commonly accepted medical reasons for induction of labor includes prolonged pregnancy, premature rupture of membranes, maternal conditions like preeclampsia, twin pregnancy, high BMI, and fetal conditions like intrauterine growth restriction, premature termination of pregnancy like abortions, intrauterine death or previous high risk pregnancy.

METHODS OF INDUCTION- Pharmaceutical methods include dinoprostone, misoprostol and intravenous oxytocin.

Non pharmaceutical methods include artificial rupture of membranes, stripping of membranes and some mechanical methods like balloon catheters, laminaria tents, synthetic osmotic dilators.

PROSTAGLANDINS- Prostaglandins play a critical role in cervical ripening by increasing inflammatory mediators in the cervix.

There are many forms of prostaglandins available for inducing the labor.

- 1) Vaginal PGE2 insert is a FDA approved controlled released vaginal pessary, which releases low dose of dinoprostone at a rate of 0.3mg per hour in 24hrs. vaginal PGE2 formulation added with polyethylene oxide which absorbs water and releases prostaglandins at a controlled rate. It can be easily removed at the end of 24hours, or onset of active phase of labor or in case of hyperstimulation and can be extracted rapidly.
- 2) DINOPROSTONE INTRACERVICAL GEL is a form of prostaglandin 0.5mg available in a 2.5ml disposable syringe with a catheter for endocervical application. Doses may be repeated every 6hours up to 3doses in a 24hour period.
- 3) MISOPROSTOL is a type of prostaglandin which is more effective cervical ripening agent and its usage reduces the need of oxytocin. However the relative risk for uterine

hyperstimulation, meconium stained liquor, fever, vomiting's, uterine rupture in scarred uterus made it matter of concern.

This study was performed to compare the efficacy between various types of prostaglandins that is vaginal PGE2 insert and dinoprostone intracervical gel for induction of labor, progression of labour, need for augmentation, induction to delivery interval and fetomaternal outcome.

AIMS AND OBJECTIVES

- To compare the clinical efficacy between vaginal PGE2 and dinoprostone intracervical gel
- To compare the induction to delivery interval and mode of delivery between the vaginal PGE2 and dinoprostone gel
- To compare the neonatal outcome between both types of prostaglandins for induction of labor.

MATERIALS AND METHODS

This study was performed in the department of gynecology in a tertiary care centre. In which 100 pregnant women taken as samples. 50 pregnant women who were induced with dinoprostone vaginal insert and 50 pregnant women who were induced with dinoprostone intracervical gel. Progression of labour was observed and results were analyzed.

INCLUSION CRITERIA-

- Vertex presentation
- Bishops score less than or equal to 6
- Unruptured membranes

EXCLUSION CRITERIA-

- Previous cesarean section
- Hypersensitivity to prostaglandins
- Bishops score more than 5
- Malpresentations
- Non reassuring NST
- Prolonged PROM

OBSERVATION AND RESULTS

MATERNAL OUTCOME

Successful maternal outcomes were considered only if in women who achieved cervical ripening with dinoprostone vaginal insert or intracervical gel. In dinoprostone vaginal insert group 36 out of 50 delivered vaginally which includes 2 instrumental deliveries and remaining 14 delivered by cesarean section and in intracervical dinoprostone gel group 32 delivered by vaginal route including 2 instrumental deliveries and 18 delivered by cesarean section (Tables 1, 2 & 3).

NEONATAL OUTCOME-

Among dinoprostone vaginal insert group, 42 babies were healthy and 8 babies were admitted in NICU in view of respiratory distress and low birth weight. In prostaglandin intracervical gel group 36 babies were healthy and 12 babies were admitted in NICU.

2 intrauterine death cases were induced with intracervical gel, delivered vaginally (Table 4).

NUMBER OF DOSES OF INTRACERVICAL GEL- Most (21) of the pregnant women delivered with 2 doses of intracervical gel. 11 were delivered with 1 dose and 18 were delivered with 3 doses .

INDUCTION TO DELIVERY INTERVAL- Divided in 4 intervals [less than 10hrs, 10 to 20hrs, 20 to 30hrs, 30 to 40 hrs] (Table 5).

In dinoprostone vaginal insert group 23 women delivered in 10 to 20 hrs, 13 were delivered 20 to 30hrs, 8 were delivered within 10hrs, and 6 were delivered in 30 to 40hrs.

In intracervical gel group 19 were delivered within 10hrs, 17 were delivered 10 to 12hrs, 10 were delivered in 20 to 30hrs, 4 were delivered 30 to 40hrs.

PARITY- Among 34 vaginal deliveries vaginal insert group 15 women were primi gravida and 19 were multigravida. In intracervical group 13 were primi gravida and 17 were multigravida.

DISCUSSION

The success of induction is based on condition of cervix. Unfavourable cervix may leads to failure of induction and increases chances of delivery by Caesarean section. In the present study , the effectiveness of dinoprostone intracervical gel and vaginal insert are compared. Most of the previous studies indicate that dinoprostone intracervical gel was more effective compared to vaginal insert.

In the present study vaginal insert is more effective compared to intracervical gel.

Westgate j et al¹ and Trofater KF² et al had outcomes in which dinoprostone intracervical gel was more effective than vaginal insert , whereas Fachinetti et al³ , Marconi et al⁴ , compared the cervical ripening efficacy of both dinoprostone intracervical gel and vaginal pessary and concluded that intracervical gel was more effective than vaginal insert in achieving cervical ripening. Mostly the above studies taken primi and multigravidae and used the dinoprostone vaginal insert for only 12hours. Whereas the current study used vaginal insert for 24 hours in both primi and multigravidas.

In vaginal insert group 16% of neonates required NICU admission for more than 24 hours in this study , whereas in intracervical gel group 24% required NICU admission for more than 24 hours.

In a study conducted by rugarn o et al⁵ had only 3.7% of neonates had NICU admission with vaginal insert. Stroblrt et al⁶ found more incidence of meconium stained liquor in dinoprostone vaginal insert group than in intracervical gel group (9.1% versus 7.5%). present study revealed 18% meconium stained liquor in dinoprostone intracervical gel group whereas 16% in PGE2 vaginal pessary group. In this study 3rd trimester IUD cases were induced with intracervical gel who delivered vaginally.

In the present study the neonates born with APGAR more than 7 at 5 minutes in both the groups and this was consistent with the findings of Strobl et al⁶, Volibregt et al⁷, and El-Shawarby et al⁸.

In the present study, dinoprostone vaginal insert group 16% delivered within <10 hours of induction compared to 38% in the intracervical group.

Induction delivery interval was shorter in intracervical gel group, however more number women in vaginal insert group delivered vaginally. In a study conducted by Ottoinger et al⁹ observed shorter mean induction delivery interval in vaginal insert group. Witter et al¹⁰ conducted randomised control trials of dinoprostone vaginal pessary and observed average induction delivery interval of 27 hours. In Hennessey et al¹¹ study, intracervical gel was found to be more effective in shortening the induction delivery time interval than the use of controlled release of vaginal insert. Miller et al¹² observed 30% of pregnant women delivered within 12 hours after induction. Whereas study by Stewart et al¹³ observed 19.5% of pregnant women delivered within 12 hours. These studies included both nulliparous and multiparous women.

In the present study the incidence of c-section was more in intracervical gel group (36%) than vaginal insert group (28%).

Mazouni et al¹⁴ using dinoprostone vaginal pessary found that pregnant women had 3.5 folds higher risk of Caesarean section. Similarly higher incidence of caesarean delivery in vaginal insert group as compared to intracervical gel were noted by Ottoinger et al⁹ (28.9% versus 24.4%), Stewart et al¹³ (23.3% versus 22.1%) and Triglia et al¹⁵ (31% versus 28%).

Various indications for caesarean delivery in both groups (dinoprostone vaginal insert and intracervical gel group) as noted in the present study are fetal distress due to meconium stained liquor or hyper stimulation and other causes like secondary arrest of descent or dilatation, deep transverse arrest or failed induction.

CONCLUSION

Using dinoprostone vaginal insert for a period of 24 hours improves effective progression of labour and delivery by vaginal route unlike dinoprostone intracervical gel. In case of hyperstimulation vaginal insert can be removed thereby decreasing the incidence of fetal distress and improving the neonatal outcome. However higher cost, need for cold storage, drop out rate of pessary were drawbacks of the prostaglandin vaginal insert.

In cases like postdated pregnancy and trial of labour after caesarean section, dinoprostone intracervical gel is preferred compared with dinoprostone vaginal insert for early detection and better fetomaternal outcome.

Sustained release vaginal insert appears to be a more attractive option than intracervical gel in induction of labor in view of it being a single application drug thereby preventing the risk of infections by repeated per vaginal examination and interventions.

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Mode of delivery	Intracervical Gel(n=50)	Vaginal Insert(n=50)
Vaginal delivery	30(60%)	34(68%)
Outlet forceps delivery	2(4%)	2(4%)
EMLSCS	18(36%)	14(28%)

Table 1: Comparison of Mode of delivery (p-value: 0.687).

	Intracervical Gel(n=50)	Vaginal Insert(n=50)
HYPERSTIMULATION	3(6%)	6(12%)
MECONIUM STAINED LIQUOR	9(18%)	6(12%)
SECONDARY ARREST OF DESCENT/DILATATION	2(4%)	1(2%)

DEEP TRANSVERSE ARREST	2(4%)	1(2%)
FAILED INDUCTION	2(4%)	0

Table 2: Comparison of incidence of complications in study

Augmentation required		Intraacervical Gel	Vaginal Insert	Total
None	Count	25	31	56
	%	50	62	56
Oxytocin	Count	18	16	34
	%	36	32	34
Misoprostol	Count	4	3	7
	%	8	6	7
Artificial Rupture of Membranes	Count	3	0	3
	%	6	0	3
Total	Count	50	50	100
	%	100	100	100

Table 3: Comparison of Augmentation requirement (p-value: 0.272).

Neonatal Outcome	Vaginal insert (n=50)	Intracervical gel(n=50)
Healthy	42(84%)	38(76%)
IUD	0	0
NICU stay	8(16%)	12(24%)

Table 4: Comparison of Neonatal outcome (p-value: 0.196).

Induction to delivery interval	Intracervical Gel(n=50)	Vaginal Insert(n=50)
Less than 10 hrs	19(38%)	8(16%)
10-20 hrs	17(34%)	23(46.93%)
20-30 hrs	10(20%)	13(26%)
30-40 hrs	4(8%)	6(12%)

Table 5: Comparison of Induction to delivery interval (p-value: 0.181).