ISSN: 2581 – 3633
PubMed - National Library of Medicine - ID: 101745081

International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at:www.ijmacr.com

Volume – 6, Issue – 2, April - 2023, Page No. : 525 - 531

Prospective study of maternal outcome in induction of labour with dinoprostone gel.

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How to citation this article: Dr. Prachi Korwar, Dr. Meenakshi S Devarmani, Dr. Neeta Harwal, "Prospective study of maternal outcome in induction of labour with dinoprostone gel", IJMACR- April - 2023, Volume – 6, Issue - 2, P. No. 525 – 531.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Induction of labour is defined as the initiation and perpetuation of uterine contractions with the goal of producing progressive cervical effacement and dilatation. Prostaglandin E2 gel is a useful agent for ripening and dilating the cervix. It can be administered intracervical or intravaginal.

Aim: Study aimed to evaluate the efficacy of intra cervical Prostaglandin E2 gel as a cervical ripening agent in unfavorable cervix for induction of labour and maternal outcome.

Methodology: This is a prospective study comprised of 56 women attended Obstetrics & Gynaecology department of Mahadev Appa Rampure Medical College & Hospital Kalaburagi who required labour induction with singleton pregnancy > 37 weeks gestational age. Dinoprostone 0.5 mg was instilled intracervical Ly, maximum up to 3 doses.

Results: The most common indication for induction was postdates followed by gestational hypertension and then pre-labour rupture of membranes. In our study, we have observed 66.07% of normal delivery and 33.9% of caesarean section. The rate of caesarean section was more in primigravida whereas in 2nd & 3rd gravid normal delivery was 76.6%. Maternal side effects were minimal and neonatal outcome was good.

Conclusion: The study showed that intracervical application of PGE2 is effective, safe and acceptable method for labour induction in women with unfavorable cervix.

All these effects were achieved without increasing maternal and neonatal morbidity

Keywords: induction of labour, dinoprostone gel, unfavorable cervix

Introduction

Labour is the initiation and perpetuation of uterine contractions with the goal of producing progressive cervical effacement and dilatation. Induction of labour is common in obstetric practice. Over recent decades, more pregnant women around the world have undergone labour induction to deliver their babies. In developing countries up to 25% of all deliveries at term now involve induction of labour, but in some developing countries the rate are generally lower.[1]

Induction of labour means deliberate termination of pregnancy beyond 28 weeks by any method which aims at the initiation of labour and delivery.[2]

The goal of modern obstetrics is to improve the safety of the mother and the foetus during the antenatal period as well as parturition.[3,4]

According to the most current studies, the induction rate varies from 9.5 to 33.7 percent of all pregnancies annually. The outcome of induced labour is highly depen dent on the cervical ripening.[3]

Pharmacologic agents available for cervical ripening and labour induction include prostaglandins, misoprostol, mifepristone, and relaxing. Studies in vitro have revealed that prostaglandin E2 (PGE2) reduces cervical stiffness. Prostaglandin E2 placed intracervical Ly is effective in improving unfavorable Bishop Scores. Tightly woven bundles of collagen fibres in the human cervix are thought to split, separate and dissolve into more abundant ground substance after prostaglandin therapy and an early uterine activity may start as well. [4]

Prostaglandins play a critical role in cervical ripening by increasing inflammatory mediators in the cervix and inducing cervical remodelling. Prostaglandin E1 (PGE1) and prostaglandin E2 (PGE2) exert different effects on these processes and on myometrial contractility. These differences may affect outcomes in women treated with dinoprostone, a formulation identical to endogenous PGE2, compared with misoprostol, a PGE1 analogue.

Dinoprostone is a Prostaglandin (PGE 2) which acts on the collagen structural network of the cervix and makes it favorable thus increasing the chances of a successful of a vaginal delivery.[2]

Local use of prostaglandin E2 (PGE2) by extra amniotic, intravaginal and intracervical route has been found to be effective in priming the cervix and inducing labour in patients at term with poor Bishop score. The re commended routes of application of Prostaglandins (PGE2) are intracervical and intravaginal as these have been reported to be most advantageous in terms of increased efficacy and diminished side effects. [5,6]

A single dose PGE2 of 0.5 mg has been found to be superior to placebo in ripening the cervix. However if the ripening effect is insufficient, failure of induction and caesarean rate are nearly as high as when the cervix has been ripened with placebo. 7 The present study aimed to observe the administration of PGE2 gel, and the benefits and hazards of such therapy. Study aimed to evaluate the efficacy of intracervical Prostaglandin E2 gel as a cervical ripening agent in unfavorable cervix for induction of labour.

Various authors have reported success rates ranging from 83% to 90%. [8]

The patients where attempts at cervical ripening failed after maximum doses of instillation that is 3 doses were considered failed induction. Multiple instillations (3

doses) of Prostaglandin gel in patients have shown to increase the rates of vaginal delivery and decrease the Caesarean section rate.

Aims and objectives.

Study aimed to evaluate the efficacy of intracervical Prostaglandin E2 gel as a cervical ripening agent in unfavorable cervix for induction of labour and maternal outcome.

Materials and methods

Inclusion criteria

• Singleton pregnancy

• Cephalic presentation

• Gestational age >37 weeks up to 42 weeks Bishops score =/<6

Exclusion criteria

• Gestational age<37 Weeks

• Multiple pregnancy

• Previous uterine surgery

• Non-cephalic presentation

A study was done at our institute in 56 patients to assess the efficacy and safety of intracervical PGE2 gel in induction of labour.

In this study the PGE2 gel commercially available Cervi prime containing 0.5 mg of PGE2 or dinoprostone was used for ripening of cervix.

The patients who fulfilled the inclusion criteria were admitted and evaluated for maternal and fetal wellbeing. Obstetric ultrasound and non-stress test were carried out. The patients with reactive non-stress test were taken for the study. Written informed consent taken.

Cervi prime gel was introduced intracervical with strict aseptic precautions up to maximum 3 doses and was cervical status was assessed 6th hourly.

Results

In our study, 26 patients were primigravida and 30 patients were multigravida.

Table 1: Distribution of patients according to parity

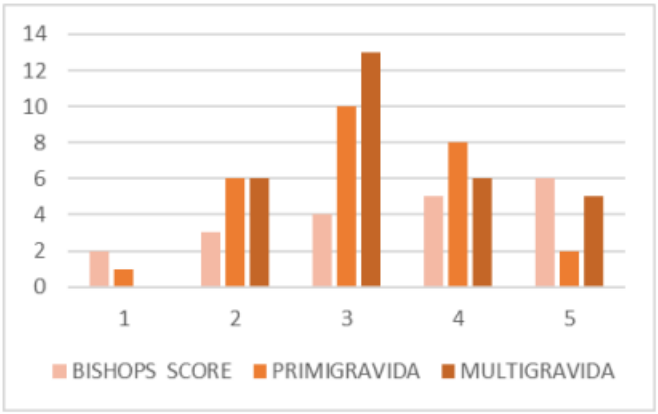
PARITY	NUMBER OF CASES
PRIMIGRAVIDA	26
MULTIGRAVIDA	30

In our study majority of patients had bishops score of 4 in primigravida and multigravida both. And bishops score of 6 was seen in 02 patients of primigravida and 05 patients of multigravida and majority of patients had bishops score of > 6 at the 6 hours assessment and mean bishop score increased from 2 to 6.

Table 2: Distribution of patients according to bishops' score.

bishops score	primigravida	multigravida
2	01	00
3	06	06
4	10	13
5	08	06
6	02	05

Graph 1: Bar diagram: According to bishops score.



In our study majority required 1 dose of dinoprostone gel and 08 patients required 2 doses and 04 required 3 doses of dinoprostone gel in primigravida

Table 3: Distribution of patients according to doses of dinoprostone gel.

number of doses	Primigravida	Multigravida
01	14	23
02	08	04
03	04	03

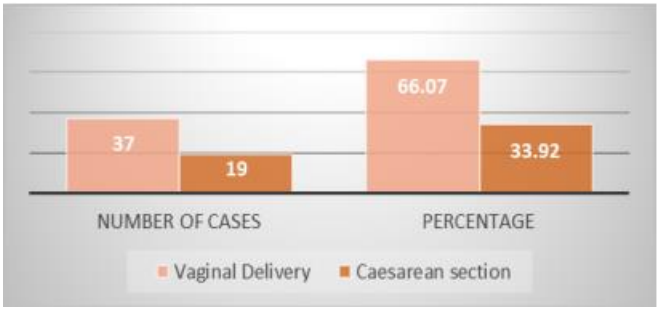
Graph 2: Bar diagram: According to number of doses.

In our study we observed 66.07% of normal delivery and 33.9% of caesarean section

Table 4: Distribution of patients according to mode of delivery

Mode of Delivery	Number of cases	Percentage
Vaginal Delivery	37	66.07
Caesarean section	19	33.92

Graph 3: Bar diagram: according to mode of delivery

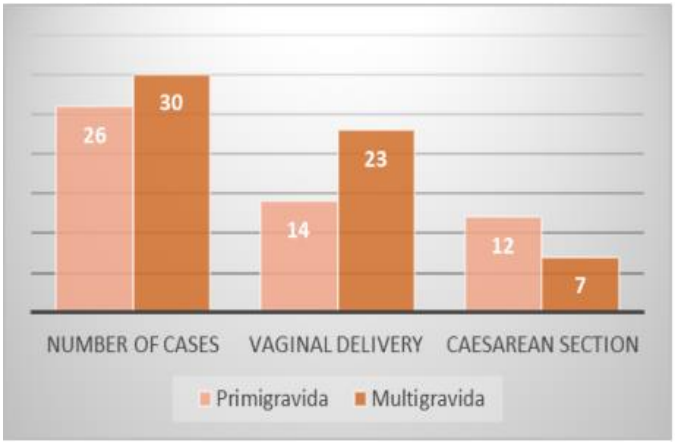


In our study 12 patients underwent caesarean section in primigravida and 14 had vaginal delivery. In multi gravida 23 patients had vaginal delivery and 07 patients underwent caesarean section.

Table 5: Distribution of patients according to mode of delivery with respect to parity.

	Number of cases	Vaginal delivery	Caesarean section
Primigravida	26	14	12
Multigravida	30	23	07

Graph 4: Bar diagram: according to mode of delivery with respect to parity.

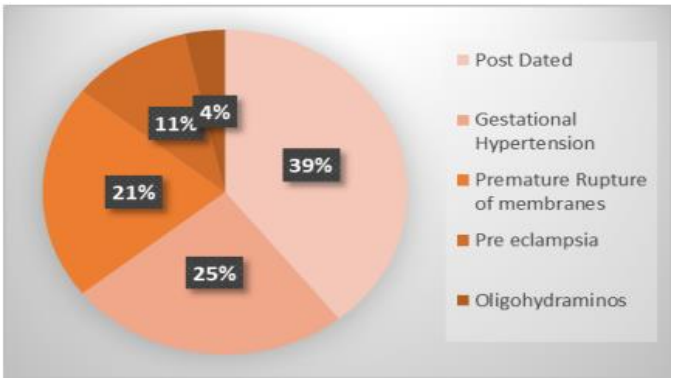


In our study the indication of induction was postdates with 39.2 % followed by gestational hypertension with 25% then premature rupture of membranes with 21.4% and preeclampsia with 10% and oligohydramnios in 3.5%.

Table 6: Distribution of patients according to indication of induction of labour.

INDICATION FOR INDUCTION	NUMBER OF CASES	PERCENTAGE
Post Dated	22	39.2%
Gestational Hypertension	14	25%
Premature Rupture of membranes	12	21.4%
Pre eclampsia	06	10%
Oligohydraminos	02	3.5%

Graph 5: Pie diagram: according to indication of induction of labour.



In our study 10 patients had fetal distress as indication of caesarean section and 3 had failure of induction.

Table 7: Distribution of patient according to indication of caesarean section.

INDICATIONS OF CAESEREAN SECTION	NUMBER OF CASES
FETAL DISTRESS	10
NON PROGRESSION OF LABOUR	06
FAILURE OF INDUCTION	03

Discussion

Instillation of PGE2 gel has been accepted as a useful method of cervical ripening before induction of labour. The dose required is much less and the side effects are often acceptable. [5,6]

A single application of PGE2 gel has been reported to be successful in 83% to 96% of cases. Successful use includes both spontaneous onset of labour and improvement in Bishop score. [8]

However in about 5% to 25% of patients, a single application may not achieve spontaneous labour or cervical ripening. These patients may end as failed inductions if labour is induced with oxytocin as such. Several workers have attempted to use multiple instillations to overcome the problem of failure with single instillations. [9-11]

In our study, 26 patients were primigravida and 30 patients were multigravida and majority of patients had bishops score of 4 in primigravida and multigravida both. And bishops score of 6 was seen in 02 patients of primigravida and 05 patients of multigravida and the mean bishop score was 2 and improved to 6 in majority of the patients which was comparable to a study done by Shagun et al where 65 patients received one dose of Cervi prime gel forming Group 1and multiple doses in Group 2, bishops score mean was improved to 4.2 in Group 1 and 4.1 in Group 212 and to a study done by Calder et al, the cervical score had improved from a mean of 2.3 to 6.3 in 6 hours. 15 This shows that Cervi prime gel has a huge impact in improving bishop's score. This was comparable to studies done by Rao R et al where initial bishops score was 2.5 to 3 in all the groups and significantly improved with PGE2 gel. [16]

In our study majority required 1 dose of dinoprostone gel and 08(53.8%) patients required 2 doses and 04

required 3 doses of dinoprostone gel in primigravida and majority 76.66% in multigravida required single instillation which was comparable to a study done by Shagun Gupta et al, Out of 54 primigravida women, 77.7% required single instillation and 22.2% had multiple instillations.

Out of 36 multigravidas 23 patients (63.8%) required single instillation and 13 (36.1%) required multiple doses. 12 In our study we observed 66.07% of normal delivery and 33.9% of caesarean section that was comparable to Dr kannapa Durga et al study, where 64% of normal delivery and 36% of caesarean section was observed. In our study 12(46.1%) patients underwent caesarean section in primigravida and in multigravida 23(76.6%) patients had vaginal delivery and 07 patients underwent caesarean section that was comparable to Dr kannapa Durga et al study, where the rate of caesarean section was 61% in prim gravida, whereas in 2nd & 3rd gravid normal delivery was 62%. Further there was no maternal morbidity and mortality. [17]

In our study the indication of induction was postdates with 39.2 % followed by gestational hypertension with 25% then premature rupture of membranes with 21.4% and preeclampsia with 10% and oligohydramnios in 3.5% which was comparable to Shagun Gupta et al study where the most common indication for induction of labour in both the groups was post-dated pregnancy (35.38%) followed by pre labour rupture of mem branes12 and also comparable with a study done by Warke HS et al, where the most common indication was postdate (52%). [13]

In our study 10 patients had fetal distress that included meconium-stained liquor and non-reassuring fetal heart rate as indication of caesarean section and 3 had failure of induction and others included non-progression labour which was comparable to study done by Mainprize et al, and Bhatla et al, reported caesarean section for fetal distress in 33.3% of their patients. Other indications were non reassuring fetal heart rate, meconium-stained liquor and Non progress of labour, persistent poor bishops score. [13,14]

In the present findings, majority of the cases showed normal delivery after instillation of Cervi prime gel. By using this method we can also reduce the rate of caesarean sections. In all cases, administration of Cervi prime gel induced safe labor without any morbidity and mortality. Now a days Cervi prime instillation is safe induction and alternative method for labor.

In the non-pregnant state, the cervix consists of around 80% water and it increases to around 86% in late pregnancy. Glycosaminoglycans are highly hydrophilic and increase tissue hydration and destabilise the collagen fibrils and promote ripening. The most abundant glycosaminoglycans in the cervix are chondroitin sulphate and its epimer derma tin sulphate[18,19]

Conclusion

The study showed that intracervical application of pro stag Landin E2 is an effective, safe and acceptable method for induction of labor in women with unfavorable cervix and indications for induction.

Dinoprostone gel application facilitates the process of induction, increased number of successful inductions, shortened application delivery interval and decreased cesarean delivery rate. Hence PGE2 gel can be re commended as a useful and potent method of induction of labor with an unfavorable cervix.

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