www.jmscr.igmpublication.org
Impact Factor (SJIF): 6.379
Index Copernicus Value: 71.58
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v6i2.78

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

Intravaginal PGE1 versus Intracervical PGE2 for induction of labor: A Comparative Analytical Study

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Abstract

Introduction: *Though induction of labor is being practiced since 16th century it has become a relatively common procedure in modern day obstetric practice. Earlier it was being practiced mostly or predominantly for delivery of a dead fetus but in today's modern obstetric practice indications include diverse maternal and fetal conditions where risks of continuation of pregnancy far outweighs the effects of an early delivery. Common situations where induction of labor is required include preeclampsia, intrauterine fetal death, intrauterine growth retardation, fetal distress, severe oligohydramnios and compromised maternofetal or placentofetal circulation as indicated by abnormal Doppler studies. Before the era of oxytocin induction of labour was mostly done by unreliable methods like stimulation of nipples, laxatives, purgatives and herbal tea etc but with the advent of oxytocin and newer techniques induction of labor is being done now in an effective and predictable manner. The important components of any regimen used for induction of labor include cervical ripening and augmentation of labour. The approaches for cervical ripening may include pharmacological and surgical methods. Intracervical PGE2 and Intravaginal PGE1 can be used for cervical ripening and these agents have become immensely popular because of their effectiveness in induction of labor. Though these agents have been subject of immense curiosity and research there has been a lack of evidence regarding the most appropriate route of administration and dose of PGE1 and whether it has any advantage over use of PGE2 which is most commonly used prostaglandin for the purpose of induction of labor. With this background in mind we conducted this comparative study to know the efficacy and safety of intracervical PGE2 and intravaginal PGE1 for cervical ripening and induction of labor in women who have completed 37 weeks of gestation.*

Aims and Objectives

(1) To study the safety and efficacy of PGE2 gel 0.5 mg Vs low dose 25 microgram PGE1 by intravaginal route for cervical ripening and induction of labour.

(2) To assess the induction- delivery interval, maternal and fetal outcome in both the groups.

Materials and Methods: *This was an analytical observational study carried out in the department of obstetrics and Gynaecology at a tertiary care centre situated in an urban area. The study was approved by*

institutional ethical committee. 200 pregnant patients who have completed 37 weeks of gestation and in whom induction of labor was done with either intracervical PGE2 or Intravaginal PGE1 for any indications were included in the study after considering inclusion as well as exclusion criteria. The patients were divided into 2 groups (100 patients each) on the basis of whether they received intravaginal PGE1 or intracervical PGE2. A detailed history was taken in all the patients and all of them underwent thorough general, systemic and obstetrics examination. In addition to clinical examination ultrasonography, non-stress test, pre-induction bishop's score and cervical assessment was done in all the cases. The safety and efficacy of PGE2 gel 0.5 mg Vs low dose 25 microgram PGE1 by intravaginal route for cervical ripening and induction of labour were studied and an assessment with regards to induction- delivery interval, maternal and fetal outcome was done in both the groups.

Results: *This study comprised of 200 women who had completed 37 weeks of gestation and in whom induction of labor was done with either intracervical PGE2 or Intravaginal PGE1. In PGE1 group 42% and 58% patients were multi and primigravida. While this percentage was 48% and 52% respectively in PGE2 group. The most common age group in PGE1 group was found to be 21-25 years (40%) and 26-30 years (40%) while in PGE2 the most common age group was 26-30 years (38%). Majority of the patients in both the groups belonged to gestational age of 37-38 weeks. The most common indications for induction of labor in PGE1 and PGE2 group was found to be premature rupture of membranes (29% vs 23) and postdatism (28% vs 32%). Mean Bishop score in PGE1 and PGE2 was 4.41 and 4.29 at the induction of labour. In PGE2 group 72% cases showed Bishop score of more than 6 at the end of 4 hrs while this percentage was 70 % at the end of 6 hours in PGE1 group. The mean interval time from induction to onset of labor was found to be 3.51 hrs and 5 hrs in PGE1 and PGE2 group and the difference was found to be statistically significant. Oxytocin was required in less number of patients (25%) in PGE1 group than in PGE2 group (41%) and the difference was statistically significant. Only 1 dose of PGE1 or PGE2 was required in 70% of the patients in both the groups. Mean induction to delivery time was 11.61 and 8.39 hours in PGE2 and PGE1 group respectively. The difference was statistically significant. 87% patients in PGE1 and 66% patients in PGE2 group delivered within 12 hours after induction and the difference was found to be statistically significant. Patients in PGE1 and PGE2 group required LSCS In 26% and 16 % cases respectively and normal vaginal delivery occurred in 69% and 77%. The outcome of pregnancy in primigravida and multigravida patients didn't show any statistically significant difference. Failure of induction and non progression of labor was more common in PGE2 group than PGE1 group while fetal distress was more common in PGE1 group though the difference was not found to be statistically significant. Analysis of maternal complications like hyper-stimulation, diarrhea, vomiting and fever showed that there was no statistically significant differences in these 2 groups as far as maternal complications were concerned. The parameters like number of patients with hyper stimulation, use of tocolytics and non-stress tests were not comparable in both the groups. Though statistically not significant adverse neonatal outcome and need for NICU admissions were more common in PGE1 than in PGE2 group. Mean APGAR scores and mean baby weights were comparable in both the groups. Lastly the analysis of cost effectiveness showed that the PGE1 was more cost effective (Rs 11.07) than PGE2 (Rs 336.7) for induction of labor and the difference in costs was found to be statistically significant.*

Conclusion: *Both PGE1 and PGE2 are safe for induction of labor however that intravaginal PGE1 is more efficacious and cost-effective in comparison to intracervical PGE2.*

Keywords: *PGE1, PGE2, Induction of labor, Maternal and Neonatal Outcome.*

Introduction

Induction of labour is a relatively common procedure nowadays. It has been practiced since 16th century. In the past, induction of labour was performed for delivery of a dead fetus. With time indications for induction of labour have changed. Presently it is being used for benefits of the mother or the fetus. The World Health Organization defines 'induction of labour' as stimulation of contractions before the spontaneous onset of labour to achieve vaginal delivery[1]. Induction is indicated when the benefits to the mother or the fetus outweigh that of continuing the pregnancy. The most common indication for induction worldwide is post datism, others are premature rupture of membranes, preeclampsia,

intrauterine fetal death, intrauterine growth restriction, fetal congenital anomaly, gestational diabetes mellitus, potential fetal compromise [2,3].

Methods of induction of labour that can ripen the cervix in a short period of time play a very important role. Worldwide the most common method for induction of labour is the pharmacological method using prostaglandin E2 gel. The focus for induction of labour has shifted from the earlier oxytocin drips to prostaglandin E2 gel. Prostaglandin E2 gel is most commonly used for cervical ripening and induction of labour. However, it is expensive and requires stringent maintenance criteria like cold storage between 2-8 degree Celsius. Prostaglandin E2 has a very short half life even when maintained at the temperatures required. PGE2 has to be administered by the intracervical route. As the rate of absorption and its efficacy is dependent on many confounding factors, the results vary from failure of action to hypertonic uterine contractions and erratic response to the drug.

Recently it was found that, in patients who were administered with prostaglandin E1 (PGE1) analogue for its protective property against peptic ulcer, showed a dramatic increase in the rate of abortions and premature deliveries. This has lead to the exploration of a possibility of using PGE1 analogues for cervical ripening and induction of labour. As a result of the ongoing research and because of proven safety and efficacy[4], Indian FDA and American College of Obstetricians and Gynaecology (2013b) have given the approval for the use of this drug as cervical ripening and induction agent. Prostaglandin E1 analogue is cheap and does not have strict maintenance criteria. It can be stored at room temperature and has a long shelf life. Various routes are available for its administration –oral, intravaginal, sublingual, buccal. The above factors, seems to make PGE1 analogue an ideal pharmacological inducing agent. A meta-analysis, have found that PGE1 analogue can safely and effectively ripens the cervix and induces labour in patients with unfavourable cervices [5].

However, reliable evidence is lacking regarding the most appropriate route of administration and the dose of PGE1 and also whether it has any advantages over PGE2, which is the most commonly used prostaglandin for induction. Hence, the comparison between the efficacy and safety of intracervical PGE2 and intravaginal PGE1 for cervical ripening and induction of full term labour is the subject of this study.

Materials and Methods

This was an analytical observational study which was carried out in the Department of Obstetrics and Gynaecology, at a tertiary reference centre after due approval from the Institutional Ethics Committee. Patients who were induced with intra cervical PGE2 or intra vaginal PGE1 for various indications and fulfilled the inclusion and exclusion criteria were included. All admitted patients undergoing induction of labour underwent ultrasonography, non stress test was performed to assess fetal well being and Pre induction Bishops score and cervical assessment. The Study consisted of 200 patients who were divided into 2 groups (100 each) and each 100 patients were given prostaglandin E1 analogue (PGE1) and100 patients in prostaglandin E2 analogue (PGE2) respectively.

Group A- In the prostaglandin E1 analogue (PGE1), one dose of intravaginal PGE1 followed by a second dose after 4 hours. Each woman was administered 25 µg tablet of prostaglandin E1 analogue (PGE1), in the posterior fornix of the vagina under aseptic condition. After every dose, 4 hourly Bishop Score was re-evaluated and if score remained <6, reinstallation (25 µg) was done depending upon on the response, the patients received up to maximum 3 doses.

Group B- The first dose of Prostaglandin E2 analogue (PGE2) which is 0.5 mg was given intracervical (gel). After 6 hours Bishop's score was reassessed. If the Bishop's score remained < 6, Second dose was given. Maximum of two doses were given. Using sterile technique, the tip of a prefilled syringe containing 0.5 mg of PGE2

analogue was instilled intracervically, the gel was deposited just below the internal cervical os, and the women were kept in a recumbent position for at least 30 minutes.

A record of the number of PGE1 analogues tablets required or number of times reinstallation of PGE2 required were noted. Fetal monitoring by cardiotocography, bishops score and onset of labour pains, etc were observed routinely and recorded. After induction, progress of labour was observed carefully. The following women in which onset of labour (cervical dilation ≥ 3 cm) had started after application of either PGE1 or PGE2 and had regular uterine activity, amniotomy and/or oxytocin augmentation if performed, was noted. Further doses of PGE1 or PGE2 were withheld. FHR was monitored hourly by Doppler .Progression of labour was monitored by Partograph. Uterine activity was observed to assess the frequency and duration as well as abnormal uterine activity if any, such as tachysystole, hypertonus and hyperstimulation syndrome were noted. Use of any rescue tocolytics if used was also recorded.

The Inclusion criteria were

- Patients consenting for Observational study
- ANC Registered and Booked patient
- Singleton pregnancy
- Gestational age >37 weeks
- Adequate liquor on USG Longitudinal lie with cephalic presentation
- Normal fetal heart rate (FHR) (110 – 160 beats per minute)
- Reactive NST
- Bishop's score <6
- Adequate Pelvis

The Exclusion criteria were:

- Unregistered Patient
- Women with multiple pregnancy ,
- Estimated fetal weight >4000 gm or <2000 gm.
- Prior uterine scar [previous lower segment or classical caesarean scar or myomectomy].
- Abnormal fetal heart rate tracking on NST.
- Any obstetric indication for elective caesarean section (Placenta previa, cephalopelvic disproportion, and fetal malpresentations like transverse lie or footling presentation, cord presentation.)
- Known Hypersensitivity to prostaglandin
- Known case of severe bronchial asthma, renal, hepatic, or cardiovascular disease.

Results

According to this data, out of 100 cases 58 were primigravida and 42 were multigravida in PGE1 group and out of 100 cases in PGE2 group, 52 were primigravida and 48 were multigravida but the difference was not significant.

Table 1: Profile of Gravida Status between two groups

Gravida	PGE1 (N= 100)		PGE2(N= 100)	
	No.	%	No.	%
Multigravida	42	42.0	48	**48.0**
Primigravida	58	58.0	52	**52.0**
By chi square test	**P = 0.394,**		**Not Significant**	

9 out of 100 women in PGE1 group and 11 out of 100 women in PGE2 were 18-20 years, 40 out 100 women in PGE1 and 35 out of 100 women in PGE2 group were 21-25 years, 40 out of 100 women in PGE1 group and 38 out of 100 women were 26-30 years and 11 out of 100 women in PGE1 group and 16 out of 100 women in PGE2 group were 31-36, the difference was not significant.

Table 2: Comparison of Maternal Age between two Groups

Maternal Age (year)	N	PGE1				N	PGE2			
		Primi		Multi			Primi		Multi	
		No.	%	No.	%		No.	%	No.	%
18-20	09	07	77.8	02	22.2	11	10	90.9	01	09.1
21-25	40	22	55.0	18	45.0	35	17	48.6	18	51.4
26-30	40	19	47.5	21	52.5	38	17	44.7	21	55.3
31-36	11	03	27.3	08	72.7	16	07	43.8	09	56.3
By Chi – Square Test					**P = 0.413, Not Significant**					

The analysis of the gestational age in both the groups showed that there was no statistically significant difference in the gestational ages of the 2 groups. The analysis of the data for reason of induction showed that in 28.0% of cases indication of induction was post date pregnancy among PGE1 group which was comparable with 32.0% of cases among PGE2 group and difference was statistically not significant. 29.0% of cases showed indication of induction as PROM among PGE1 group which was more as compared to 23.0% of cases among PGE2 group but difference was statistically not significant.

Table 3: Indications of Induction in the two group

Indication Of Induction	PGE1 (N= 100)		PGE2 (N= 100)	
	No.	%	No.	%
Congenital Anomaly	03	03.0	**02**	**02.0**
Eclampsia	05	05.0	**02**	**02.0**
IUFD	04	04.0	**04**	**04.0**
IUGR	07	07.0	**06**	**06.0**
Oligohydramnios	15	15.0	**16**	**16.0**
Post Date Pregnancy	28	28.0	**32**	**32.0**
Preeclampsia	17	17.0	**18**	**18.0**
PROM	29	29.0	**23**	**23.0**
GDM	04	04.0	**04**	**04.0**
Severe Preeclampsia	09	09.0	**10**	**10.0**
By chi square test		**P = 0.537, Not Significant**		

At induction, mean Bishop Score was 4.41 among PGE1 group which was comparable to 4.29 among PGE2 group and the difference was not significant. At the end of 1st dose in PGE1 group, mean Bishop's score was 7.66 which was comparable to 7.87 in PGE2 group. Amongst PGE1 group at the end of 4 hrs, Bishop's score of 16.0% of cases was between 0 – 4, for 12% of cases was between >4 to <6 and for 72% of cases was ≥6. At the end of 8 hrs, Bishop's score of 5 out of 30 cases was 0-4, for 7 out of 30 cases was >4 to <6 and for 18 out of 30 cases was ≥6. None of the cases showed bishop score between 0 – 4 at end of 12 hrs among PGE1 group. 72.0% of cases showed bishop score ≥ 6 at end of 4 hrs which was more as compared to 60.0% and 50.0% of cases at end of 8 hrs and12 hrs among PGE1 group.

Table 4: Induction to Cervical Ripening Interval in PGE1 Group

Bishop Score	At End Of 4 hrs (N = 100)		8 Hrs (N = 30)		12 hrs (N = 12)	
	No	%	No	%	No	%
0 – 4	16	16.0	05	16.7	-	-
> 4 to < 6	12	12.0	07	23.3	06	**50.0**
≥ 6	**72**	**72.0**	**18**	**60.0**	**06**	**50.0**

In PGE2 group Bishop's score at the end of 6 hrs for 9 out of 100 cases was between 0-4, for 21 cases was >4 to <6 and for 70 cases was ≥6 but the difference was statistically not significant. At the end of 6 hrs, 70% cases shows Bishop's score ≥6.

Table 5 : Induction To Cervical Ripening Interval In PGE2 Group

Bishop Score	At End Of 6 hrs (N = 100)		12 Hrs (N = 30)	
	No	%	No	%
0 – 4	09	09.0	-	-
> 4 to < 6	*21	21.0	13	**43.3**
≥ 6	**70**	**70.0**	**17**	**56.7**

Mean duration of Interval time of induction to onset of labour pains and uterine activity was 3.51 hrs in PGE1 group which was significantly less as compared to 5.00 hrs among PGE2 group.

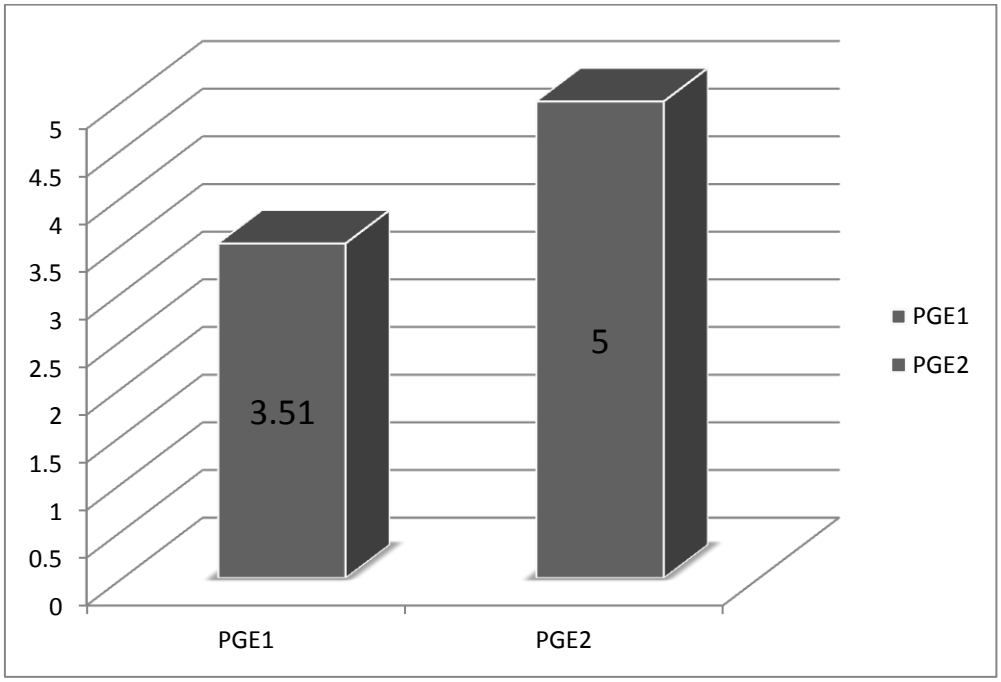

Figure 1: Comparison of Mean Interval Time of Insertion and Onset of Labour between two groups

According to this observation, 25.0% of the cases of PGE1 group required oxytocin for labour augmentation which was significantly less as compared to 41.0% of the cases among PGE2 group.

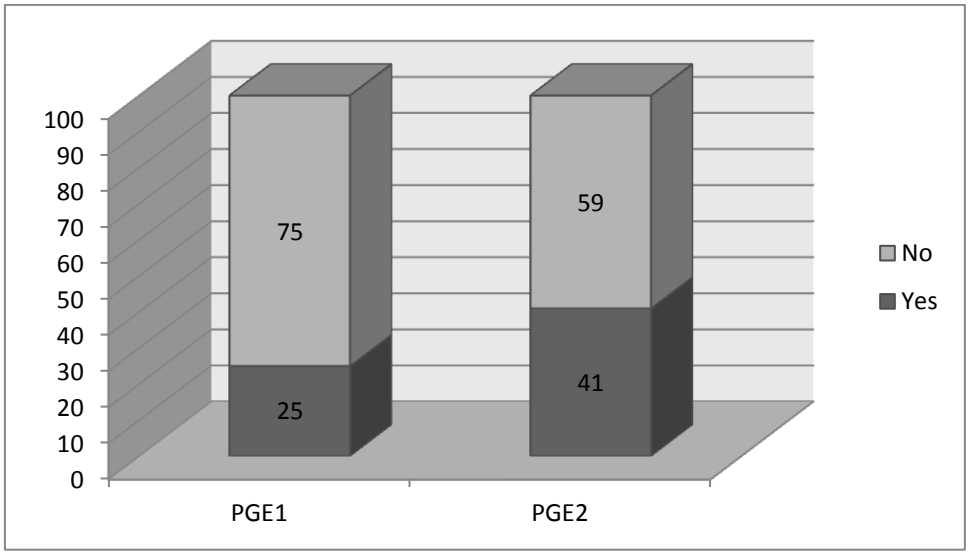

Figure 2: Profile Of Oxytocin Between Two Groups

According to this study, 1 dose required for cervical ripening in 70% of cases which was same among both the groups and difference was statistically not significant. 2 doses required for 18 cases in PGE1 group and 17 cases in PGE2 group. In PGE1 group 6 cases required 3 doses for cervical ripening.

Table 6: Comparison of Doses Required for Cervical Ripening between two groups

Dose	PGE1 (N = 100)		PGE2(N = 100)	
	No	%	No	**%**
1	70	70.0	70	**70.0**
2	18	18.0	17	**17.0**
3	06	06.0	-	-
Chi square test		**P = 1.000,**	**Not Significant**	

Comparison of mean induction to delivery interval between two groups showed that it was 8.39 hrs among PGE1 group which was significantly less as compared to 11.61 hrs among PGE2 group. 87.0% of cases of PGE1 group delivered within ≤ 12 hrs after induction which was significantly more as compared to 66.0% of cases among PGE2 group.

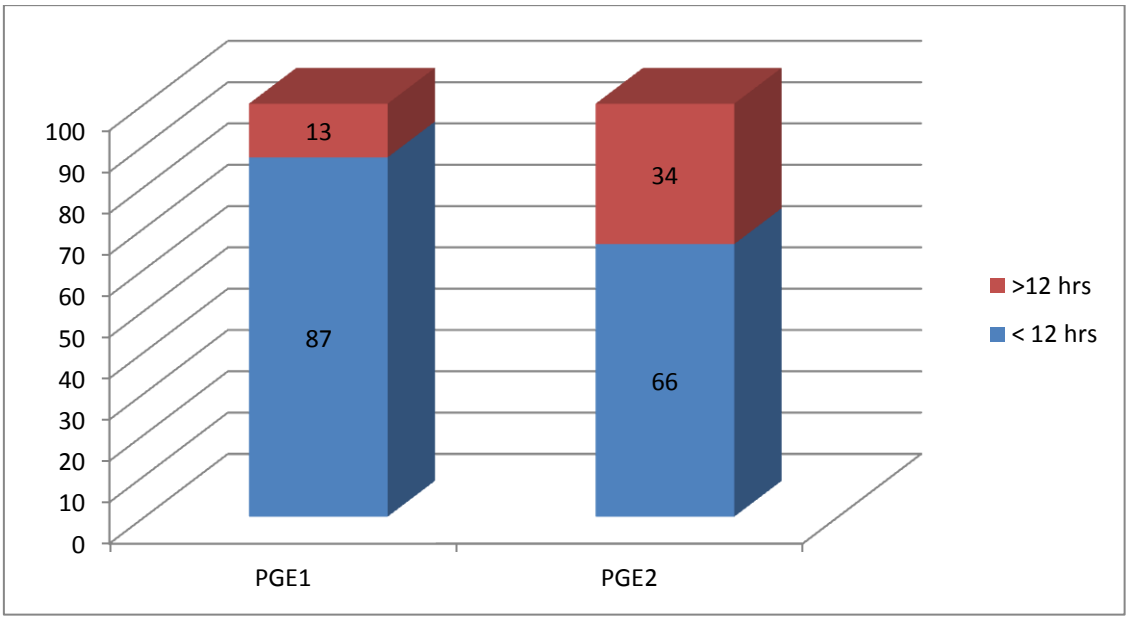

Figure 3: Profile Of Number Of Delivery After Induction Between Two Group

Amongst PGE1 group, 77.0% of the cases delivered by normal vaginal delivery which was more as compared to 69.0% of the cases among PGE2 group but difference was not significant.16.0% of the cases required LSCS among PGE1 group which was less as compared to 26.0% of the cases among PGE2 group but difference was not significant.7.0% of the cases delivered by instrumental delivery among PGE1 group which was comparable with 5.0% of the cases among PGE2 group and difference was statistically not significant.

Figure 7: Comparison of Outcome of Pregnancy in Primigravida in the Two Groups

Outcome of Pregnancy	**No of Cases Of Primigravida**			
	PGE1 (N = 58)		**PGE2 (N = 52)**	
	No	%	No	**%**
Normal Vaginal Delivery	41	70.7	35	**67.3**
Instrumental Delivery	06	10.3	03	**05.8**
LSCS	11	19.0	14	**26.9**
By chi square test P = 0.702 Not Significant				

Amongst PGE2 group, in multigravida, 36 cases (85.7%) delivered by normal vaginal delivery, 5 cases (11.9%) required LSCS and 1 case (2.4%) delivered by instrumental delivery in comparison to PGE2 group in which 34 cases(70.8%) delivered by normal vaginal delivery, 12 cases (25%) required LSCS and 2 (4.2%) cases delivered by instrumental delivery, difference was statistically not significant. Amongst PGE1 group 6.0% of the cases had indication as failure of induction which was less in comparison to 13% of cases of PGE2 group. 4% of cases of PGE1 had indication as fetal distress in comparison to 2% of cases of PGE2 group, 4% of cases of PGE1 had indication as fetal distress with MSAF in comparison to 4% cases of PGE2 group. 2% of cases of PGE1 group had indication as NPOL which was less in comparison to 7% of cases of PGE2 group but the difference was not significant.

Table 8: Comparison of Indications of LSCS between two groups

Indication of LSCS	**PGE1 (N= 16)**		**PGE2 (N= 26)**	
	No.	**%**	**No.**	**%**
Failure of induction	06	06.0	**13**	**13.0**
Fetal distress	04	04.0	**02**	**02.0**
Fetal distress with MSAF	04	04.0	**04**	**04.0**
NPOL	02	02.0	**07**	**07.0**
08 By chi square test		**P = 0.091,**	**Not Significant**	

Amongst PGE1 group 2% cases had fever in comparison to 1% of case of PGE2 group. 7.0% of the cases had Hyperstimulation among PGE1 group which was comparable with 3.0% of cases among PGE2 group but the difference was not significant. 6% cases of PGE1 group had vomiting in comparison to 4% cases of PGE2 group and 4% of cases of PGE1 group had diarrhea in comparison to 3% of cases of PGE2 group.

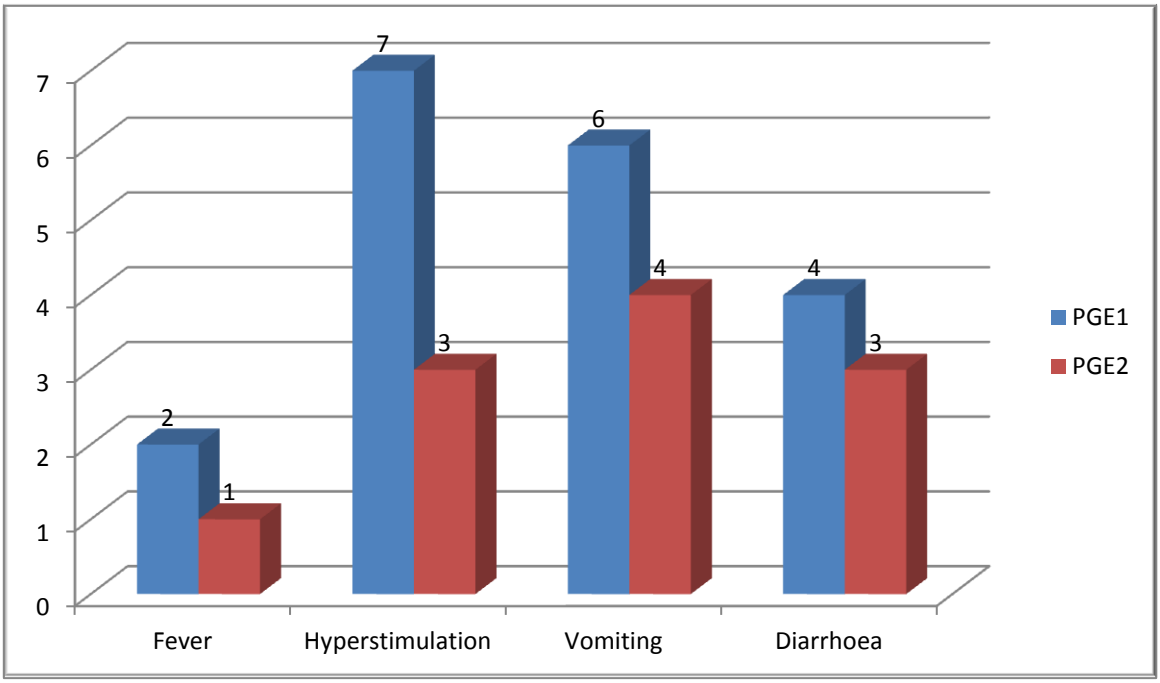

Figure 4 : Maternal Complications in the studied groups

10.3% of cases had hyperstimulation in primi which was more as compared to 2.4% of cases in multi among PGE1 group but difference was statistically not significant while 3.8% of cases had hyperstimulation in primi which was comparable with 2.1% of cases in multi among PGE2 group and difference was statistically not significant.

In this study 4.0% of cases used tocolytics among PGE1 group which was comparable with 2.0% of cases among PGE2 group and difference was statistically not significant.

While 75.0% of cases required LSCS who used tocolytics among PGE1 group which was more as compared to 50.0% of cases among PGE2 group but difference was statistically not significant.

Table 9: Comparison of Used of Tocolytics between two Groups

Groups	**No of Cases With Use of Tocolytics**		**Required LSCS**	
	No	%	No	**%**
PGE1	04	04.0	03	**75.0**
PGE2	02	2.0	01	**50.0**
By chi square test P = 0.407 Not Significant				

According to this study, 94.0% of cases after 1st dose were reactive among PGE1 group which was comparable with 97.0% of cases among PGE2 group and difference was statistically not significant.

Table 10: Profile of NST Between two Groups

NST	**PGE1**						**PGE2**			
	Dose 1 (N = 100)		Dose 2 (N = 30)		Dose 3 (N = 12)		Dose 1 (N = 100)		**Dose 2 (N = 28)**	
	No	%	No	%	No	%	No	%	No	**%**
Reactive	94	94.0	29	96.7	10	83.3	97	97.0	26	**92.9**
Non Reactive	06	06.0	01	03.3	02	16.7	03	03.0	2 02	**07.1**
By chi square test P = 0.306 Not Significant										

The neonatal outcome was also studied in these cases. 9.0% of babies had passed meconium among PGE1 group which was comparable to 5.0% of the cases among PGE2 group and the difference was not significant. Whereas Amongst PGE1 group 3% babies developed birth asphyxia in comparison to 3% cases of PGE2 group, 3% babies of PGE1 group developed meconium aspiration syndrome in comparison to 2% cases of PGE2 group. There was no case of IUD or HIE.

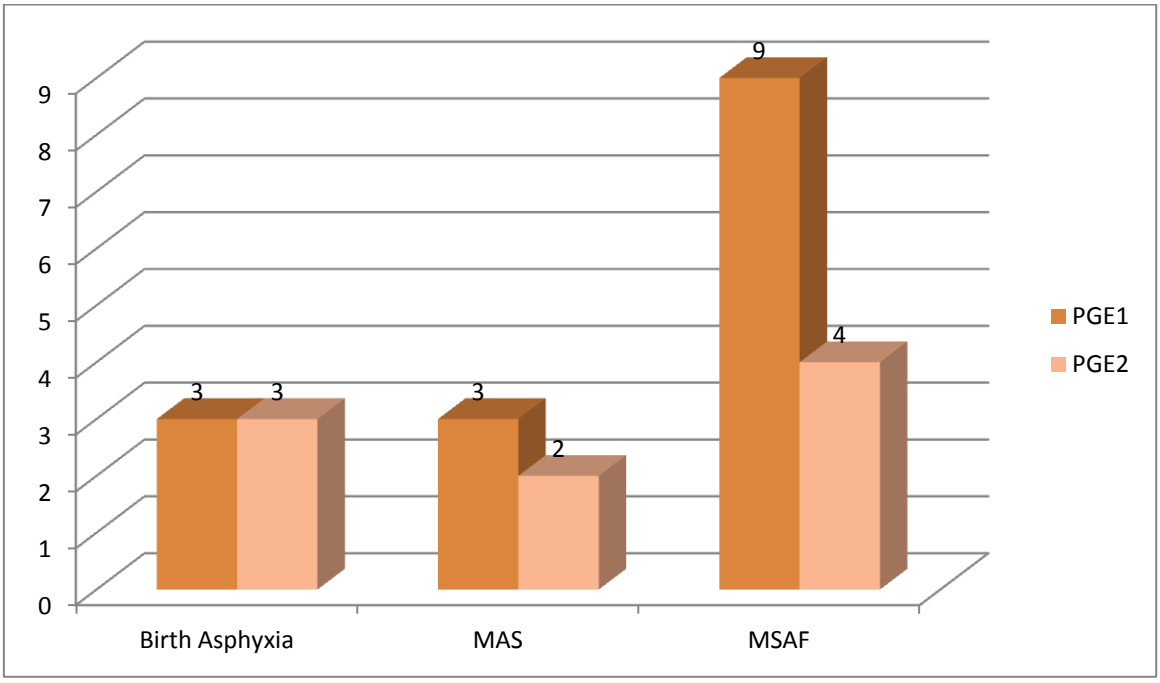

Figure 5 : Profile of Baby Record between two groups

14.0% babies of the cases of PGE1 group required NICU/TCU admission which was more as compared to 7.0% babies of the cases among PGE2 group but the difference was not significant

Table 11: Profile of Need of NICU between two groups

Need of NICU/TCU	PGE1 (N= 100)		PGE2 (N= 100)	
	No.	%	No.	%
Yes	14	14.0	07	**07.0**
No	86	86.0	93	**93.0**
By Chi Square Test P = 0.106, Not Significant				

At 1minute, mean APGAR score was 7.36 among PGE1 group which was comparable to 7.33 among PGE2 group and the difference was not significant. At the end of 5 minutes also mean APGAR score were comparable and difference was not significant. The analysis of mean body weights in both the groups showed that mean baby weight was 2628.80 gms among PGE1 group which was comparable with 2729.60 gms among PGE2 group and difference was statistically not significant. It was further found that, 91.4% of cases with dose 1 were reactive in primi which were less as compared to 97.6% of cases in multi among PGE1 group but difference was statistically not significant. 1.7% of cases with dose 3 were Non reactive in primi which were comparable with 2.4% of cases in multi among PGE1 group and difference was statistically not significant. Finally, 96.2% of cases with dose 1 were reactive in primi which were comparable with 97.9% of cases in multi among PGE2 group and difference was statistically not significant. None of cases with dose 2 were Non reactive in primi which were less as compared to 4.2% of cases in multi among PGE2 group but difference was statistically not significant. Whereas in

multigravida, 96.2% of cases with dose 1 were reactive in primi which were comparable with 97.9% of cases in multi among PGE2 group and difference was statistically not significant. None of cases with dose 2 were Non reactive in primi which were less as compared to 4.2% of cases in multi among PGE2 group but difference was statistically not significant.

Finally the analysis of cost effectiveness showed that mean cost was 11.07 Rs among PGE1 group which was significantly less as compared to 336.70 Rs among PGE2 group.

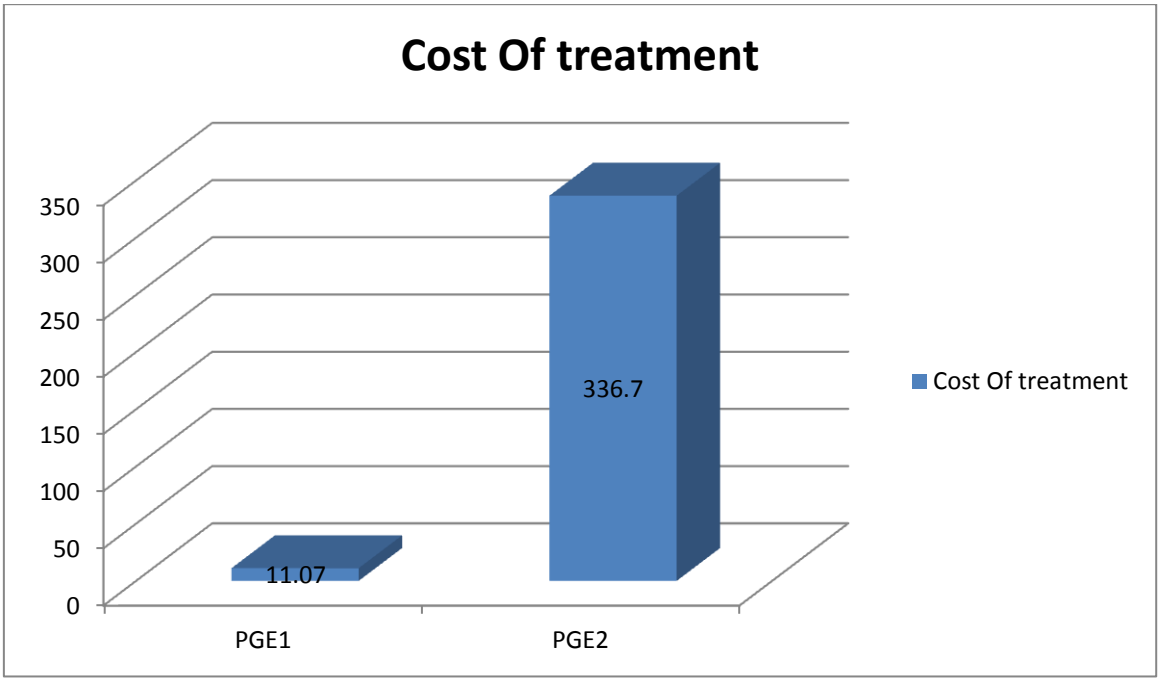

Table 12: Comparison of Mean Baby Weight between two groups

Discussion

The present study was carried out to compare efficacy and safety of low dose PGE1 Vs PGE2 for cervical ripening. This study was an analytical observational study conducted in tertiary care referral hospital in 200 patients over a period of 1 and half years, satisfying the inclusion criteria. During 1 and half years, the total confinement was 18,951 and 3790 cases required induction. In this study, 58% of cases among PGE1 group were primigravida and 42% of cases were multigravida. In PGE2 group 48% cases were primigravida and 52% cases were multigravida. The patients enrolled in each group were standardized carefully in order to minimize the implications of various risk factors affecting the results.

The physiological progress of labour is different in primigravida and multigravida women. Hence, prior to randomization women were divided in 2 subgroups, primigravida and multigravida to analyse the difference in the labour patterns between the sub populations.72% of all women in PGE1 group achieved cervical ripening with Bishop's score of >6 after 4 hrs as compared to 70% in PGE2 group and the percentage of women who achieved cervical ripening in PGE1 group further improved to 96% after 12 hrs of induction whereas it was only 87% in the PGE2 group.

The above observations show that PGE1 intravaginally in the dose of 25 microgram is a better cervical ripening agent when compared with intracervically PGE2 analogue. These results were similar to those observed by W.Nongkhlaw et al[6], CHIOSSI G[7] and a Meta analysis of Randomised Control Trials by Royal College of Obstetricians and Gynecologists[8]

In this study, 25% women induced with PGE1 group required oxytocin for labour augmentation compared to 41% women in PGE2 group. So in the present study, it was proved that PGE1 was

better as an inducing agent than PGE2; the percentage of oxytocin requirement of PGE1 was also less than PGE2. These results were similar to those observed by Murthy Bhaskar Krishnamurthy et al[9], Chowdhury SB et al[10] and Austin SC et al[11].

In the present study, cervical ripening was observed in 70 cases after 1 dose, in 18 cases after 2 doses and in 6 cases after 3 doses in PGE1 group. In PGE2 group cervical ripening was seen in 70 cases after 1 dose and in 17 cases after 2 doses.

In the present study, 84% of women induced with PGE1, out of these 79.3% women were primigravida and 85% multigravida delivered vaginally within 12 hrs of induction. As compared to 59% of women who were induced with PGE2, out of these 55.7% were primigravida and 62.5% multigravida had delivered vaginally within 12 hrs of induction. PGE1 group had more deliveries in less than 12 hours compared to PGE2 which had more deliveries in the time frame of 12-24 hrs. Similar results were observed in study conducted by Dara Aruna Kumari et al[12] . The Cochrane reviewers Hofmeyr and Gumezoglu[13] observed that use of PGE1 results in higher incidence of vaginal delivery within 24 hours of application and a reduced need for oxytocin augmentation.

In the present study, the caesarean section rate was more in women who were induced with PGE2. This result was similar to the study conducted by Kundodyiwa et al[14]. The caesarean section rate was observed high among primigravida in both the groups. 18.9% of primigravida women induced with PGE1 were delivered by caesarean section and 26.9% underwent caesarean in the PGE2 group. Among the multigravida, 11.9% women in the PGE1 group and 25% in the PGE2 group required caesarean section.

The proportion of women who underwent caesarean section for fetal distress was higher in the PGE1 group as compared to that in the PGE2 group. But these differences were not significant. These findings were similar with the results of the metaanalysis reported by Sanchez-Ramos et al[15].

In this study, 7% of cases of PGE1 group and 3% of cases of PGE2 group had developed uterine hyperstimulation. In such cases, tocolytics were used for 4% of cases in PGE1 group and 2% of cases in PGE2 group. Despite the treatment 3% of cases of PGE1 and 1% of cases of PGE2 group required LSCS in view of fetal distress. A retrospective study of case notes (n=3099) observed that after tocolytics treatment in the cases with uterine hyperstimulation, there was an improvement regardless of hyperstimulation patterns. Three cases required caesarean section and there were no postpartum complications[16.] .

Wing et al[17].while comparing 25 microgram vaginal PGE1 with intravaginal PGE2 gel observed that the neonatal outcome between the two groups was comparable and there were no significant differences in the birth weight, 1 or 5 min. APGAR scores, required for neonatal resuscitation or admission to neonatal intensive care unit.

Meconium passage occurred in 9% of babies born to women in PGE1 group as compared to 5% of babies in PGE2 group, although meconium aspiration syndrome occurred only in 4% of the babies, in the study. Thus PGE1 in the dose of 25 microgram is safe and there is no significant difference in the incidence of intrapartum fetal complications in the form of abnormal FHR patterns and meconium passage as compared to PGE2. Mozurkewich EL et al[18].found meconium stained liquor were more common with PGE1 than with PGE2.

In the present study, the average cost of therapy was Rs11.07/- per women in the PGE1 group compared to Rs 336.70/- in the PGE2 group. According to market values of both the prostaglandin analogues, the average cost of therapy of PGE2 group was significantly higher than that of the PGE1 group, so patients usually prefer PGE1 over PGE2. Similar results were observed by Van Barren et al[19] and Beckmann M et al[20]. In this study the cost of therapy was significantly less in the PGE1 group (Rs 9/- vs. Rs 406.57/- respectively) per woman.

Conclusion

Both PGE1 and PGE2 are safe for induction of labor. Though maternal and fetal outcomes were comparable in both the groups Induction to delivery time, need for LSCS and overall cost was found to be less in PGE1 group hence our study concludes that intravaginal PGE1 is more efficacious and cost-effective in comparison to intracervical PGE2.

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