Original Article

Effectiveness of oral PGE1 Versus Intracervical PGE2 in induction of labor

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Abstract

Objective: To determine the effectiveness of oral PGE1 versus intracervical PGE2 in terms of induction of labor, mode of delivery and feto-maternal outcomes.

Methodology: A comparative study was carried out at department of gynecology and obstetrics of THQ Hospital Liaquatpur from April 2022 to September 2022. Pregnant women at term, with a singleton alive pregnancy, clinically favorable cervix, determined by Bishop score of 6 or less, who are not currently in active labor, and have not received any other cervical ripening or induction agents in the 24 hours prior to study enrollment were included. Cases were divided into two groups: one group receiving oral PGE1 and the other group receiving intracervical PGE2. Outcomes was evaluated in terms of time to onset of active labor, duration of labor, mode of delivery and feto-maternal complications. All the information was collected via study proforma and SPSS version 26 was used for the data analysis.

Results: A total of 80 women were comparatively studied; their overall mean age was 27.37±3.02 years and overall mean gestational age was 38.0±1.10 weeks. Time of onset of active labor and duration of labor showed slightly decreased in Oral PGE1 group, while difference was statistically insignificant. C-section rates was12.8% in Oral PGE1 and 9.1% in Intracervical PGE2, with insignificant difference (p=0.609). Maternal complications including hyperstimulation of the uterus, fever, bleeding, and nausea/vomiting were statistically insignificant across the groups, though only bleeding showed a significant difference (p=0.012). Fetal outcomes, such as Apgar scores at 1 and 5 minutes, showed a significant difference at 1 minute (p=0.036) but not at 5 minutes. NICU admissions and mortality rates were also statistically insignificant between the groups (p->0.05).

Conclusion: Both oral PGE1 and intracervical PGE2 observed to be effective in inducing labor, with almost similar success rates and similar maternal and fetal outcomes. However, oral PGE1 appears to have a higher rate of bleeding compared to intracervical PGE2.

Keywords**:** Induction of labour, prostaglandin, cervical ripening, complications

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Introduction

Labour induction at term with the aim of achieving vaginal delivery is a widespread and endorsed obstetric intervention when prolonging the pregnancy poses risks to the mother, fetus, or both.[1] It involves the artificial stimulation of uterine contractions before natural labor begins, typically after the fetus reaches viability. The practice of induction of labor (IOL) has seen an increase in the past few decades, exhibiting significant differences both within nations and between various health facilities.[2] In terms of the indications, women are frequently induced for post-term pregnancies to minimize the risk of stillbirth.[2,3] Induction is also frequently used to reduce the risk of maternal sepsis and newborn infection due to chorioamnionitis in women with preterm rupture of the membranes.[2] In order to lower the risk of stillbirth and adverse maternal complications like kidney failure, hepatic failure, coagulation disorders, pulmonary edema, and eclamptic convulsions, women with preeclampsia may also get induction. Moreover, the

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goal of induction for diabetic women is to reduce the stillbirth risk and birth problems related to macrosomia.[2,4]

Over the years, several distinct mechanical and pharmacological inducing agents have been applied, including the administration of medications such as prostaglandin E_2, misoprostol, or isosorbide mononitrate, as well as artificial rupture of membranes.[5] Induction procedures are typically conducted within a hospital setting, although certain approaches may be appropriate for outpatient settings, enabling women to return home while awaiting the advancement of labor.[5]

Because prostaglandins possess the dual function of ripening the cervical mucosa and generating uterine contractions, they have become the most widely used and well-liked pharmacologic treatment for IOL and registered in numerous countries.[6] Cerviprime gel, also known as prostaglandin E2, serves as an expensive inducing drug that requires refrigeration since it is temperature-sensitive and it is inserted either deeply in the vaginal posterior fornix or intra-cervically, and if necessary, it might require to be reinserted after six hours.[6] Conversely misoprostol, an analog of prostaglandin E1, is a low-cost synthetic prostaglandin. According to studies, vaginal prostaglandin E1 analog is a useful tool for cervical ripening and inducing labor,[7,8] especially in women who have a low Bishops score (a score below 6).[7] Misoprostol also has several other benefits, including reduced gastrointestinal discomfort, affordable at lower dosages, convenience of administration, and most importantly, no need for cold chain keeping.[7,9] According to the literature there are inconsistent treatment results from earlier research have been found. Such as, Mendez-Figueroa et al[10] found that the use of prostaglandin E1, as opposed to E2, was linked to higher rates of adverse maternal and neonatal effects. Conversely, few other studies observed that misoprostol, an analog of PGE1, is both more effective and cost-efficient than dinoprostone (PGE2) for labor induction.[7,8] However Raval BM et al have suggested that both misoprostol and dinoprostone gel are safe and effective for cervical ripening and labor induction, with misoprostol being more cost-effective and stable at room temperature.[11] Considering above conflicting findings and the lack of sufficient local data, we believe that further investigation at the local level is necessary to ascertain the optimal approach for labor induction, whether it involves PGE1 or PGE2, as this could offer insightful information that could guide clinical practice.

Methodology

A comparative study was carried out at department of gynecology and obstetrics of THQ Hospital Liaquatpur from April 2022 to September 2022. All the pregnant women at or beyond 37 weeks of gestation, with a singleton pregnancy and a live fetus, clinically favorable cervix, determined by Bishop score of 6 or less, who are not currently in active labor, and have not received any other cervical ripening or induction agents in the 24 hours prior to study enrollment and who are able to attend the hospital for follow-up and monitoring during the induction process were included. All the patients with multiple gestations, fetal anomalies incompatible with life, history of uterine surgery or cesarean section scar, patients with hypersensitivity to prostaglandins and patients with active labor or rupture of the membrane were exclude. All participants provided written informed consent after discussing the study's purpose and the confidentiality of their personal information. All the study subjects as per the randomization were divided into two groups: one group receiving oral PGE1 and the other group receiving intracervical PGE2. Administration of the allocated induction agent according to a pre-determined protocol, as 25-mcg oral misoprostol every 4-hourly interval or 3 applications of intracervical PGE2 at a 6-hour interval for effective cervical ripening. Oxytocin augmentation was used once the cervical ripening was successful. Outcomes was evaluated in terms of time to onset of active labor, duration of labor, mode of delivery and feto-maternal complications. All the information was collected via study proforma and SPSS version 26 was used for the data analysis.

Results

The study groups were divided into two categories: Oral PGE1 (n=47) and Intracervical PGE2 (n=33). Overall mean age of the women was 27.37$\pm$3.02 years and overall mean gestational age was 38.0$\pm$1.10 weeks. Furthermore, the clinical and outcome variables of 80 patients categorized based on their administration of oral PGE1 and intracervical PGE2 for labor induction. This comparative analysis, reveals significant differences in certain parameters. Such, cervical dilatation was notably different between the two groups (2.23±0.63 cm in Oral PGE1 group vs. 2.86±1.01 cm in Intracervical PGE2, p=0.001), while other factors such as time of onset of active labor and duration of labor showed slightly decreased in Oral PGE1 group, while difference was statistically insignificant. Modes of delivery varied with C-section rates at 10.8% for Oral PGE1 and 12.1% for

Table I: Clinical and outcome variable of patients' basis on oral PGE1 and intracervical PGE2 in induction of labor. (n=80)

Variables		STUDY GROUPS		p-value
		Oral PGE1 (n=47)	Intracervical PGE2 (n=33)	
Cervical dilatation		2.23±0.63 CM	2.86±1.01 CM	0.001
Time of onset of active labour		3.90+1.10 hours	4.12±1.80 hours	0.537
Duration of labour		8.90+2.14 hours	9.10+2.40 hours	0.707
Umbilical cord PH		7.18+0.24	7.09+0.10	0.070
Mode of delivery	C-section	5(10.6%)	4(12.1%)	0.836
	SVD	42(89.4%)	29(87.9%)	
Maternal complications	Hyperstimulation of uterus	8(17.0%)	6(18.2%)	0.893
	Fever	3(6.4%)	3(9.1%)	0.651
	Bleeding	6(12.8%)	00	0.012
	Nausea and vomiting	15(31.9%)	9(27.3%)	0.656
Fetal outcome	At 1 minutes	8.16±1.45	7.88±1.33	0.036
	At 5 minutes	9.16±0.62	9.11±0.32	0.670
	NICU admission	1(2.1%)	00	0.399
	Mortality	2(6.1%)	2(4.3%)	0.120

Intracervical PGE2, but this difference was not statistically significant (p=0.836). Maternal complications including hyperstimulation of the uterus, fever, bleeding, and nausea/vomiting were documented with varying incidences across the two groups, though only bleeding showed a significant difference (p=0.012). Fetal outcomes, such as Apgar scores at 1 and 5 minutes, showed a significant difference at 1 minute (p=0.036) but not at 5 minutes. NICU admissions and mortality rates did not exhibit statistically significant differences between the groups as shown in Table I.

Discussion

Induction of labor is a common obstetric intervention used to initiate or augment labor in pregnant women for various indications. This study has been done to determine the comparative safety and effectiveness of oral PGE1 and intracervical PGE2 in terms of induction of labor, mode of delivery and feto-maternal outcomes. In the all the term women incorporated with an overall mean age of the women was 27.37±3.02 years and overall mean gestational age was 38.0±1.10 weeks. In aligns to this study Ilyas AY et al[12] reported that average age of patients in oral misoprostol group was 26.0 years with a standard deviation of 3.8 years, while in PGE2 gel group, it was 25.7 years with a standard deviation of 3.9 years. Furthermore, average gestational age, in oral misoprostol group was 38.8±1.1 weeks, while in PGE2 gel group it was 38.9±1.2 weeks. In the comparison of this study Nadar AN et al[13] found most common age group of women in both groups was 25-28years, with mean age 27.33 years in group A and 27.11 years in group, average gestational age in group A 270.94±7.05 days and in group B was 270.33±7.80 days according to their study. The mean age being predominantly above 37 weeks in the studies could stem from the inclusion criteria of the selected term women in the studies.

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In this study C-section rates at 12.8% for Oral PGE1 and 9.1% for Intracervical PGE2, but this difference was not statistically significant (p=0.609). Furthermore, the maternal complications including hyperstimulation of the uterus, fever, bleeding, and nausea/vomiting were

documented with varying incidences across the two groups, though only bleeding showed a significant difference (p=0.012). These findings were also supported by the Mukherjee S et al.[8] Study conducted by Ali S et al[17] also demonstrated that 18.5% women underwent emergency C-section in group A, which was lower compared to group B 27.1%. In the comparison of this study Qazi Q et al[16] found the higher cesarean section rate in Misoprostol 50 mcg tablet group at 24.1%, contrasting with the lower rate of 12.1% observed in Prostaglandin E2 gel group. According to a systemic review ana meta-analysis, administering misoprostol orally is more advantageous than via the vaginal route.[18] However, in that systematic review, only randomized controlled trials (RCTs) show that misoprostol and dinoprostone seem to share a comparable safety profile, without any discernible superiority of one medication over the other.[18] In accordance to fetal outcomes, such as Apgar scores at 1 and 5 minutes, showed a significant difference at 1 minute (p=0.036) but not at 5 minutes. NICU admissions and mortality rates did not exhibit statistically significant differences between the groups.

Consistently Swami RS et al[19] and Saritha C et al[20] reported that there was no statistically significant difference observed in APGAR scores between both groups. It is important to note that while our findings slightly favor the oral PGE1 group over the PGE2 group, this difference was not statistically significant. This contrasts with other studies that have reported highly significant differences between the groups, could be the differences in study sample size, patient demographics, and the infrastructure of health facilities across different studies. Current study also had a smaller sample size or different patient characteristics compared to those studies reporting significant differences, which could have influenced the conclusive findings. To provide more robust evidence, further large-scale comparative studies should be conducted, taking into account potential effect modifiers such as demographics characteristics of patients, gestational age, and comorbidities.

Conclusion

Both oral PGE1 and intracervical PGE2 found to be effective in inducing labor, with almost similar success rates and similar maternal and fetal outcomes. However, oral PGE1 appears to have a higher rate of bleeding compared to intracervical PGE2. However, due to several limitation of study, further large-scale comparative studies are recommended to validate the findings.

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