A prospective study of induction of labor with prostaglandin vaginal gel: ambulatory versus in-patient administration

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Summary

Background: Elective induction of labour is a common obstetrical practice. Dinoprostone (prostaglandin E2 in triacetin base gel) has been shown to be an effective and fairly safe agent for this purpose in inpatient settings. Currently published work does not assess the effectiveness and safety of dinoprostone in an ambulatory setting.

Objective: To assess the difference between inpatient and outpatient use of dinoprostone for elective induction of labour with regard to effectiveness, safety, length of hospital stay, and patient satisfaction.

Methods: A prospective non-randomized study, in which two groups of low risk obstetrical patients who were undergoing elective induction of labour were studied. The outpatient group was drawn from Regina Health District while the inpatient (control group) was drawn from Saskatoon. The maternal and fetal morbidity was compared in both groups as well as the efficacy, length of hospital stay and degree of patient satisfaction.

Results: There were statistically significant reductions in the length of hospital stay and greater patient satisfaction in the outpatient group. No difference was found in efficacy and safety of prostaglandin use.

Conclusions: The findings suggest that ambulatory use of prostaglandin gel for induction of labour reduces the length of hospital stay, and leads to greater patient satisfaction. Further randomized studies with a larger number of patients are needed to evaluate the safety of this agent in an ambulatory setting.

Key words: Prostaglandin induction of labor; Inpatients; Ambulatory method.

Introduction

Elective induction of labour has increased in frequency over the last three decades. Several studies have investigated different agents to identify the most effective and safe method of induction, and prostaglandin E2 in triacetin base gel has shown the greatest efficacy [1-5]. In prospective randomized studies, the use of prostaglandin E2 vaginal gel (2 mg given in a 12-hour period for a maximum of three doses) proved to be effective and safe used in a hospital setting [6, 7]. Current trends are directed at identifying outpatient management that is safe, cost-effective, and more acceptable to patients.

Our study sought to investigate whether outpatient induction of labour with vaginal prostaglandin E2 gel was as effective and safe as the hospital method. We also assessed the degree of patient satisfaction.

Objectives

The objective of this study was to look for differences in maternal and fetal safety, efficacy, length of hospital stay and patient satisfaction in patients undergoing induction of labor by vaginal prostaglandin E2 gel administered either as inpatients or outpatients.

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Materials and Methods

The study was carried out at the Royal University Hospital, Saskatoon and Regina General Hospital, Regina. It was prospective but non-randomized and based on the practice patterns at the two locations. The outpatients were located in Regina, while the inpatient group was drawn from Saskatoon during the study period (January to April 1997). Patients were simultaneously recruited by the house staff in Regina and by one of the investigators in Saskatoon.

Women included in this study were medically fit and parous with singleton pregnancies presenting cephalically. Other inclusion criteria were Bishop score less than eight and a normal non stress test before induction of labour. Patients were excluded if they had bronchial asthma or allergy to prostaglandin or if there was intrauterine fetal growth restriction, post-date pregnancy (>42 weeks), hypertensive disorders of pregnancy, premature rupture of membranes, surgically scarred uterus, abnormal placentation, polyhydramonios, oligohydramnios, congenital anomalies, or intrauterine fetal death.

All the patients undergoing elective induction of labour were seen at the fetal assessment unit where they had initial non-stress test monitoring for half an hour. The participants gave informed consent. Fifty patients were enrolled in each group.

Treatment

Patients in both groups received an initial dose of 2 mg of prostaglandin E2 in triacetin gel intravaginally in the posterior fornix and were subjected to continuous monitoring for one to two hour(s), after gel insertion. All patients were assessed for abnormal fetal heart pattern, uterine hyperstimulation, abruptio placenta, nausea, vomiting, or diarrhea.

Patients in the outpatient study group were discharged home, and were instructed to return to the labour room 12 hours after the first dose for reassessment and possible insertion of a second dose. They were also asked to report to the fetal assessment unit if they experienced distressful and repetitive regular contractions, spontaneous rupture of membranes, vaginal bleeding, or reduced fetal movements (less than 10 movements in 12 hours). They were instructed about uterine hyperstimulation (any series of single uterine contractions lasting 2 minutes or more, or frequency of uterine contractions of 5 or more in 10 minutes), and advised to report for evaluation and possible admission to the hospital. These patients were admitted if they were in active labour (most common), in presence of abnormal fetal non-stress test prior to gel reinsertion, or failed induction.

Patients in the inpatient group were admitted to the hospital after the insertion of prostin gel, and kept for monitoring and for further gel insertion if necessary in a 12-hour period.

Active labour was defined as at least two painful contractions every 15 minutes with the finding of a fully effaced cervix, cervical dilation of 3 cm, or two painful contractions every 15 minutes with spontaneous rupture of membranes after vaginal gel insertion irrespective of cervical dilation or effacement [8]. Induction of labour was considered to have failed if the patient was not in active labour within 12 hours after the administration of the third dose of prostin gel. Uterine hyperstimulation was defined as either a series of single uterine contractions lasting two minutes or longer, or frequency of uterine contraction of five or more in 10 minutes [9]. Maternal systemic side-effects, fetal heart rate abnormalities, and adverse neonatal outcomes were recorded. All the treatment and the assessment of patient satisfaction was done by physicians for both groups.

Outcome Measures

The primary outcomes were neonatal intensive care unit (NICU) admissions, and the frequency of uterine hyperstimulation, placental abruption, and systemic side-effects. The secondary outcomes were efficacy, assessed as induction-to-active-labour intervals, and induction-to-delivery intervals. The duration of hospitalization from induction of labour to discharge from hospital was also noted. We also evaluated the number of doses of vaginal prostaglandin gel used, the need for augmentation with oxytocin, the caesarean section rate, and newborn Apgar scores. The degree of patient satisfaction with the method of induction was assessed by telephone calls to the patient after discharge from the hospital.

Statistical Analysis

Categorical data were summarized by proportions. Statistical significance of differences in proportions was determined using the Chi square test. Statistical significance of differences in arithmetic means between two treatment groups were assessed by the two tailed t-test. All p values of less than 0.05 were considered to indicate statistical significance.

Results

Table 1 shows the baseline characteristics of the subjects enrolled. Both groups were similar in age, duration of pregnancy, and parity. There was a significant difference in the Bishop scores, with the inpatient group having a lower mean Bishop score (3.3±1.6) than the outpatient group (4.2±1.2; p<0.001).

Forty-three (86%) of the inpatient group were induced because of postdates, while only 34 (68%) outpatients were induced for that indication (p=0.01). In six percent of the inpatient group and 12 percent of outpatients the reason for induction was a suspicion of fetal macrosomia (p=0.2). Social reasons were noted in 10 percent of outpatients, and in none of the inpatients (p=0.02). Among the study population, eight percent of the inpatients and 19 percent of the outpatients were induced for other indications.

There was no significant difference in number of doses of gel required by patients in the two groups to achieve active labor. Thirty-one patients (62%) of the outpatients required only a single dose, while 33 (66%) of the inpatients had only one dose (p=0.6) (Table 2). In each group, 30 percent needed two doses, while six percent of the outpatients and four percent of the inpatients needed three doses of prostin gel (p=0.6).

None of the inpatients had more than three doses of gel, while one outpatient needed four doses. There was no statistically significant difference between the two groups in the time needed to establish active labour (Table 2).

The mean induction to active labour interval time for the inpatients was 11.7 hours (±7.4), and 12.0 hours (±12.2) for the outpatients (p=0.9). The mean induction to delivery interval was similar for both inpatients (19 hours ±8.9) and outpatients (18.9 hours ±15.2; p=0.9).

Table 1. — *Characteristics of patients undergoing induction of labour.*

	Inpatient group (n=50)	Outpatient group (n=50)	p value
Age	27.1±[4.14]	25.42±[4.4]	0.06
Gestational age (wks.)	40.9±[0.9]	40.6±[1]	0.96
Primigravidity	31 (62%)	23 (46%)	0.11
Multiparous	19 (38%)	27 (54%)	0.11
Bishop score	3.26±[1.59]	4.22±[1.21]	0.001

Values are mean ± [SD] or (%).

Table 2. — *Induction-labour data.*

	Inpatient group (n=50)	Outpatient group (n=50)	p values
Number of doses of prostin gel required			
One	33 (66)	31 (62)	0.68
Two	15 (30)	15 (30)	1
Three	2 (4)	3 (6)	0.65
Induction-active labour interval (hrs)	11.7±[7.4]	11.9±[12.1]	0.9
Induction-delivery interval (hrs)	19±[8.9]	18.8±[15.2]	0.93
Syntocinon augmentation	17 (34)	27 (54)	0.043
Failed induction	1 (2)	3 (6)	0.31
Spontaneous vaginal delivery	34 (68)	40 (80)	0.17
Operative vaginal delivery	11 (22)	7 (14)	0.3
Caesarean section	5 (10)	2 (4)	0.4

Values are mean ± [SD] or (%).

Thirty-four inpatients (68%) and 41 outpatients (82%) had spontaneous vaginal delivery (p=0.1). Operative vaginal delivery was done in 11 patients (22%) in the inpatient group and in seven (14%) of the outpatients (p=0.3). Five patients from the inpatient group delivered by cesarean section as compared to only two from the outpatient group (p=0.4). Syntocinon augmentation of labor was used in 27 patients (54%) from the outpatient group, and in 17 patients (34%) from the inpatient group (p=0.04). Failed induction occurred in three outpatients and in one inpatient (p=0.3).

In both study groups, no patient experienced placental abruption, uterine hyperstimulation, or systemic side-effects. In comparing the neonatal outcome in both groups, five cases were admitted to the NICU from the inpatients and nine cases from the outpatients (p=0.2). The median five-minute Apgar score was the same for both groups and no newborn had an Apgar score less than seven at five minutes.

We found a significant difference in the length of hospital stays between the two groups. The mean duration of hospital stay was (3.4±1.2 days) for inpatients, versus (2.8±0.9 days) for the outpatients (p=0.004). There was greater patient satisfaction with the outpatient management; 96 percent of the outpatients were satisfied compared to 56 percent of the inpatients (p<0.0001).

Discussion

Prostaglandin E2 (PGE2) has shown to be effective in cervical ripening using various clinical protocols [10]. We have used PGE2 gel in an inpatient setting, and found it to be effective and safe. Although it has been used as an outpatient method in some centres, good evidence to justify its use in that fashion is not available.

The two groups in this study had similar baseline parameters, including maternal age, gestational age, indications for induction, and parity. The outpatient group's mean Bishop score was significantly higher than the inpatients' mean score (p<0.01). This might be due to more primigravid patients being included in the inpatient group. The number of doses of PGE2 gel required by patients in both groups was comparable. Both groups showed similar mean induction-to-active labour interval, and induction-to-delivery interval. This may be interpreted to suggest that induction of labour in the two groups was equally successful. The higher frequency of syntocinon augmentation of labour in the outpatient group could be attributed to the differences in the intrapartum philosophy of active management of labour by the attending physicians at both centres.

Our findings suggest that outpatient induction of labour has a higher trend toward spontaneous vaginal delivery (82% of the outpatients compared to 68% of inpatients), and a lower trend toward caesarean delivery. These results confirm earlier research and clinical impressions showing an association between obstetric intervention with early hospitalization in parturients [11, 12]. One patient in the outpatient group failed to deliver after the fourth dose of gel and had another trial after one week. This was considered to be a failed induction. None occurred in the inpatient group. There was a similar margin of feto-maternal safety during induction of labour using vaginal prostaglandin either as an outpatient or inpatient [11-13]. For both groups, we found no cases of uterine hyperstimulation, abruptio placenta, or systemic side-effects. Overall the mean Apgar scores and frequency of NICU admissions were comparable in patients undergoing induction of labour, either as inpatients or outpatients. The results of our study are similar to that of a previous study using a similar protocol for inpatient induction of labour [6].

The most striking result was that outpatient induction of labour was associated with significantly shorter hospital stays. This was mainly due to a shorter hospital stay in the prelabour period in the outpatient group. The finding that patients who had outpatient induction had much higher levels of satisfaction than those who had inpatient induction may be related to the shorter hospital stay. It would appear that a shorter hospital stay would be more convenient for most patients. This shorter duration of hospitalization would also be more cost-effective.

We conclude that outpatient induction could be a useful alternative to inpatient induction, but a much larger prospective randomized trial will be required to validate our findings.

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