Vaginal Prostaglandin E_2 Pessary Versus Gel in induction of Labour at Term

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Objective: To compare the prostaglandin E_2 Vaginal pessary and gel with respect to cervical ripening, labour out come, side effects and cost effectiveness in induction of labour at term. **Design:** Experimental study. **Place and duration of study:** Lady Willingdon Hospital, Lahore February to July, 2005. **Subjects and Methods:** The trial was conducted on two group of patient for labour induction such that one group (n=30) received PGE_2 vaginal pessary 6 hourly to maximum of 3 doses. Other group (n=30) received PGE_2 gel at 6 hourly interval upto 2 doses. Labour induction, number of doses applied, need of augmentation, side effects, induction to delivery interval, mode of delivery, neonatal outcome and cost effectiveness were the main outcome measures. **Results:** Our results depicted that PGE_2 gel produced favourable bishop score more rapidly and initiating uterine contraction simultaneously than PGE_2 pessary. Few patients required oxytocin augmentation in gel group ($P<0.05$). There was no statistically significant difference in number of patients delivering vaginally with in 24 hours, the neonatal outcome and cost effectiveness in two groups ($P>0.05$). However, more side effects such as uterine contractions, abnormalities, and fetal distress observed in gel group ($P<0.05$). **Conclusion:** The PGE_2 pessary was safe and easily applied, but PGE_2 intracervical gel was more effective as it achieved greater changes in mean bishop score. However, more side effects encountered with gel category.
Key words: Induction of labour, prostaglandin E_2 pessary, prostaglandin E_2 gel.

The use of vaginal prostaglandin (PG) for labour induction in the presence of unripe cervix results in a short induction to delivery interval and lower operative delivery rate[1]. PG reduces the rate of failed induction [2]. In the west more than 13% of women are induced [3]. Among the different preparation available PGE_2 is more important in cervical ripening. It is available in many forms but the more readily available preparation are vaginal pessary and gel.

The recent evidence based clinical guidelines from the Royal College of Obstetrician and Gynaecologists concluded that the gel and pessary appeared more effective than other formulation (RCOG 2001)[4]. Each method has some benefits over the other but the optimal way to use these agents and best preparation to use still remains unclear [5,6].

The objectives of this study was to compare the PGE_2 vaginal pessary and gel with respect to cervical ripening, labour outcome, side effects and cost effectiveness in induction of labour at term.

Material and methods:
This was an expefrimental study carried out on 60 patients in Lady Willingdon Hospital from February to July, 2005. Convenience sampling method was used.

Inclusion Criteria: Pregnant patient at term with medical and fetal indication induced. There was single fetus with longitudinal lie, cephalic presentation and intact membrane and the Bishop score of less than or equal to four.

Exclusion Criteria: Patient with known hypersensitivity to PG, previous uterine surgery, cephalopelvic disproportion, grandmultiparity, antepartum haemorrhage, in labour, fetal distress, malpresentation such as transverse lie excluded from study.

Methodology: Patients fulfilling the inclusion criteria selected for induction. Patients were counselled about the procedure in detail before initiating the research and consent for emergency LSCS was also taken. A baseline CTG performed and bishop score done. The PGE_2 vaginal pessary (3mg) was placed in posterior fornix. While the PGE_2 gel was placed intra-cervically.

After first application, the FHR monitored and the patient evaluated for the initiation of uterine contraction, and side effects such as uterine contraction abnormalities, gastero-intestinal upset and fetal distress. Six hours after the initial dose, if Labour had not started another cervical evaluation performed. If the bishop score was less than or equal to 4 second application of the respective drugs done after the reassuring CTG tracing was obtained. The bishop score was again checked after 6 hour and third application used if it was equal to or less than 4. Oxytocin was used according to normal labour ward protocol. Uterine hyperstimulation was defined as hypertonic contraction (each lasting at least two minutes) or tachysystole (six or more contraction in 10 min, for at least two 10 minute interval) resulting in a pathological CTG training that necessitated intervention[7]. Failed induction was categorized as cervix unfavourable for an ARM following the recommended dose of either PGE_2 gel or pessary and requiring abdominal delivery[7]. Data was analysed on SPSS. Tests of significance applied.

Results:
The baseline maternal characteristics of the women in pessary and gel group were almost similar. The main indication for induction was post date in both groups (Table 1).

Table 1:Maternal characteristic in two groups mean (SD), (number %) (n=60)

Parameters	PGE_2 pessary group	PGE_2 gel group
Age (in years)	29.1	28
Gestational age (days)	282.6	281
Parity		
Primigravida	19 (63.3%)	17 (56.6%)
Multigravida	11(36.7%)	13 (43.3%)
Indication for labour induction		
Borderline B.P.P	7 (23.3%)	5(16.6%)
P.I.H	10 (33.3%)	7 (23.3%)
Post date pregnancy	13 (43.3%	18 (60%)

The labour and delivery out come is shown in table II & III for successful inductions. 25 patients (83.3%) in pessary group and 22(73.3%) patient in gel group were successfully induced (table II). In pessary group one dose was used by 13 patients (52%), two by 11 (44%) and 3 doses by one patients (4%). In the gel group one application was required by 16(72.7%) and two by 6 patients (27.3%). However, non required three doses. It is clear from table II that the mean changes in cervical score in two groups at six hours were not different significantly. On the other hand the mean bishop score of gel at 12 hour was significantly higher than pessary at 12 hour. Few patients required oxytocin augmentation in gel group as compared to the pessary group (6 vs 12) (P<0.05).

It was observed that some side effects were more in gel group as compared to pessary group including uterine contraction abnormality, GI upset and fetal distress. (Table-2).

Table II: Comparison of labour outcome mean (SD), (number %)

Parameters	PGE_2 pessary group	PGE_2 gel group	Signifi-cance of Difference
	n = 30	n = 30	P value
Labour Outcome			
Successfully induced	25 (83.3%)	22(73.3%)	-
Failed induction	5(16.7%)	8 (26.7%)	-
No of doses in successfully induced patients			
1	13(52%)	16(72.7%)	(P>0.05)
2	11(44%)	6(27.3%)	
3	1(4%)		
Pre-induction Cervical score	3.1 (1.1)	2.3 (1.3)	P<0.05
6 hours Cervical score	5.6(1.9)	5.3(2.3)	P>0.05
12 hours Cervical score	6.6(1.5)	7.7(1.2)	P<0.05
Needs for augmentations			
Oxytocin infusion	12(40%)	6(20%)	P<0.05
Side effect encountered			
Uterine contraction abnormality	3 (10%)	10(33.3 %)	P<0.05
G.I upset	9 (30%)	12(40%)	P>0.05
Fetal distress	3 (10%)	8(27%)	P<0.05

There was no significant difference in the modes of delivery or in neonatal out come in both groups (Table III & IV). The most of patient delivered with in 24 hour except 4 patients (13.3%) in the pessary group who took more than 24 hours. There were more Caesarean section in gel group than pessary group. In the gel group the 8 Caesarean section were done for fetal distress and 5 babies were admitted in intensive nursery care. However, in pessary group 5 Caesarean section were done, for fetal distress (n=3), suspected abruption (n=1), worsening pre-eclampsia (n=1), and among them 3 babies were admitted. All babies were discharged within 24 hours.

Table III: Comparison of Delivery Outcome (n=60)

Parameter	PGE_2 pessary group	PGE_2 gel group
Induction to delivery interval		
< 12 h	6 (20%)	8 (26.6%)
12 – 24 h	15 (50.0%)	14 (46.6%)
> 24 h	4 (13.3%)	
Mode of delivery		
SVD	20(66.6%)	19(63.3%)
Instrumental delivery	5 (16.6%)	3 (10%)
C/S	5 (16.6%)	8(26.6%)
Indication for operative delivery		
Fetal distress	3(10%)	8(26.6%)
Suspected abruption	1(3.3%)	
Worsening PE	1(3.3%)	

Significance of differences: NS

Table IV: Neonatal outcome (n=60)

Parameter	PGE_2 pessary group	PGE_2 gel group
Mean apgar score at one min	6.35	6.23
Mean apgar score at five min	8.74	8.89
Mean birth weight	3.19	3.24
Admission to intensive nursery	3(10%)	5(16.6%)

Significance of differences: NS

The pessary and gel were available in the same price (Rs.355/-). 13 patients (52%) in pessary group and 16 patients (72.7%) in gel group used one application. However, 11 patients (44%) used 2 pessaries and 6 patients (27.3%) used 2 applications of gel. Cost ranged from (Rs.355-700). In one patient (04%) three pessaries were used at the cost of Rs. 1065/-.(Table-V)

Table V: Cost of PG in successfully induced patient.

Parameter	Pessary group (n=30)	Gel group (n=30)
Rs.355	13(52%)	16 (72.7%)
Rs.355–700	11 (44%)	6 (27.3%)
Rs.700-1065	1 (04%)	

Significance of differences: NS

Discussion:

The ideal agent to be used for the induction of labour should be effective, convenient, safe and inexpensive. The Royal College of Obstetrician and Gynaecologist recommends that prostaglandin should be used in

preference to oxytocin for induction of labour in women with intact membrane[4].

In this study two different preparation of the same prostaglandin that is E_2 were compared in hope to find out the ideal method for induction of Labour with poor bishop score.

In this study majority of the women induced for post-dated pregnancy. This is comparable to the study conducted in PIMs[8]. It was seen that average changes were more with application of intra-cervical gel as compared to vaginal pessary. Rath W showed that PGE_2 gel is more effective method for induction of Labour[9].

In this study 2mg gel was used intra-cervically in primigravida patient with cervical score of 4 or less. However, all parous patients had only 1mg of gel administered. The second dose of gel (1mg) was administered into cervix if the Labour had not started after a reassuring CTG was obtained [7]. On the other hand, with pessary in accord with RCOG guidelines the regime included 3mg PGE_2 inserted into the posterior fornix. The second dose repeated after 6hr if the labour had not started, however, the third dose decision was taken by the obstetrician[4].

In this trial, the pessary had greater role in the local cervical response but the gel had dual properties of producing local changes in cervix and initiating uterine contraction because the gel is more rapidly absorbed and achieves a higher plasma level more quickly as compared to pessary. The metaanalysis by Hughes EG et al reported comparable results [6].

Thiery M et al and Smith et al defined success rate as progression in bishop score of a least 3 points with in 12 hours to be higher in gel category as compared to pessary group (55% versus 37%) respectively[10,11].

In this study, the side effect such as fetal distress and uterine contraction abnormalities were higher in gel group as compared to pessary groups ($P<0.05$). The main cause for this is the extra amniotic spillage of gel which result in hyper stimulation. These results are comparable to trial by Crane M, Grey Bush M[12,13].

The pessary and gel are available at the same cost. It is clear from the study that total cost of pessary used in successfully induced patient was slightly more than gel used, however, not different significantly [14].

Although gel produces much significant average changes in cervix and cost effective, the side effects encountered with its use set back its advantages over the pessary. The risks can be overcome with proper patient selection and monitoring of patient.

Conclusion:

The PGE_2 pessary is easily and more conveniently applied and has lesser side-effects, the gel also has some advantages in the form of producing a favorable bishop score more rapidly and initiating uterine contraction simultaneously. However, its use is limited by its side effects in form of uterine contraction abnormalities and fetal distress.

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