



INDUCTION OF LABOR; EFFICACY AND SAFETY OF INTRAVAGINAL PROSTAGLANDIN E2 PESSARY

Dr. Raheela Baloch¹, Dr. Nigar Jabeen², Dr. Sana Zahiruddin³, Ms. Kiran Mawani⁴

1. M.S
Instructor
Aga Khan University Hospital
Hyderabad, Sindh Pakistan
2. F.C.P.S, M.C.P.S
Senior Instructor
Aga Khan University Hospital
Hyderabad, Sindh Pakistan
3. F.C.P.S, M.S
Senior Instructor
Aga Khan University Hospital
Hyderabad, Sindh Pakistan
4. F.C.P.S
Senior Instructor
Aga Khan University Hospital
Hyderabad, Sindh Pakistan
5. B.com, M.A (economics)
Aga Khan University Hospital
Hyderabad, Sindh Pakistan

Correspondence Address:

Dr. Raheela Baloch
House no B/53, Ghulam
Shah Kalhora Colony
Hyderabad, Sindh Pakistan
Raheela1981@live.com

Article received on:

23/09/2016

Accepted for publication:

20/12/2016

Received after proof reading:

14/02/2017

ABSTRACT: Efficacy and safety of intra-vaginal prostaglandin E2 pessary for induction of Labor. **Objectives:** To evaluate the efficacy and safety of intra-vaginal prostaglandin E2 pessary for induction of Labor. **Study Design:** Case control study. **Setting:** Gynecological and obstetric ward of Liaquat University of Medical and Health Sciences Hospital, Hyderabad. **Period:** 14 Feb 2012 to 13 Feb 2013. **Study Population:** All the Pregnant women at term or post term admitted in gynae ward from 14th February 2012 to 13th February 2013. **Results:** 100 women recruited in the study, study carried out at Gynecological ward of Liaquat University of Medical and Health Sciences Hospital Hyderabad. Analysis of booking status listed in Table-I revealed that 68% (n = 68) were un-booked having no antenatal care and 32.0% (n = 32) were booked. There were no protocol violation, relation to the parity listed in Table-II showed maximum number of patients (n = 62) 62.0% Primigravida and (n = 38) 38.0% multigravidas were include. Age distribution is listed in Table-III maximum patients (n = 49) 49.0% at age between 26 - 35 years, 35 (35.0%) were between 20 - 25 years, 10 (10.0%) were >35 years and 06 (6.0%) patients were belong to less than 20 years. Regarding the gestational age 57 (57.0%) patients in our study presented between 37 - 39 weeks of gestation. However, 47 (47.0%) patients were at 40 - >40 weeks of gestation showed in the (Table-IV). Indication for cervical ripening and induction of labor is listed on Table-V commonest indication was pregnancy induced hypertension followed by prolonged pregnancy, and IUGR etc. Table-VI shows the Bishop score 30 (30.0%) had Bishop Score 2 - 3, while 70(70.00%) had a bishop score 4-5. Table-VII shows induction-delivery interval, Greater number of women (66/100) delivered within 24 hours of start of induction. Table-VIII showed mode of delivery, majority of the women had normal vaginal deliveries 64.00 while 16 deliveries by assisted vaginal deliveries while in remaining 20 cases caesarean section done. Table-IX shows four babies had an Apgar score 4/10 at end of 1 min and 7/10 at end of 5 min, whereas 96 babies had an Apgar score of 9/10 in 1 min. The indications for caesarean section are shown in Table-X. There were 09(9%) cases of failed induction, 11 cases of a fetal distress (Meconium stained liquor). There was no increased incidence of neonatal sepsis or Chorioamnionitis or puerperal sepsis in any of our patients. No perinatal morbidity or mortality or any severe maternal complications were noted while mild side effects were noted which is mentioned in (Table-XI). **Conclusion:** In developed countries prostaglandin E2 are widely used for ripening of unfavorable cervix in induction of labor but patient response vomiting, diarrhea, tachycardia, and fever are commonly observed minor side effects. Induction with Prostaglandin reduced the rate of pregnancies progressing beyond 41 weeks and related fetomaternal morbidity and mortality. After excluding contra indication all women should be offered induction at 41 completed weeks. Induction with prostaglandin with medical disorder like preeclampsia is safe and better fetomaternal outcome.

Key words: Induction, Prostaglandin E2, pre-eclampsia

Article Citation: Baloch R, Jabeen N, Zahiruddin S, Mawani K. Induction of labor; efficacy and safety of intravaginal prostaglandin E2 pessary. Professional Med J 2017;24(2):288-292. DOI: 10.17957/TPMJ/17.3644

INTRODUCTION

Induction of labor is frequent method in the obstetrical practice.² Labor induction is a procedure in which onset of a labor starts artificially before its spontaneous onset and

aim to accomplishing of safe delivery of fetoplacenta.⁶ Labor induction is defined as by using different methods such as mechanical or the pharmacological methods for cervical ripening and stimulation of regular uterine contractions

to generate progressive cervical dilation and subsequent delivery.¹

20 to 30 % of the deliveries are induced worldwide.⁷ Unpublished data from WHO global survey on maternal and perinatal health, which included 373 health care facilities in 24 countries and nearly 3, 00000 deliveries, showed that 9.6% of the deliveries involved labor induction. over all, the survey showed that use of labor induction is higher in Asian and Latin American countries (highest rate: 33.5% in Srilanka) compared with African country in which rate of labor induction is (lowest : 1.4% in Nigeria).^{3,4}

If bishop score is less than 6 then cervix is considered unfavorable and its ripening is indicated prior to oxytocin infusion and artificial ruptured of a membranes to decrease failure rate of induction and risk of caesarean section.⁵ Need of cervical ripening and induction should be considered when it is felt that the benefits of vaginal delivery out weight the potential fetal and maternal risk of induction. These issues should be discussed with the women in detail before initiation of induction.

Post term pregnancy is one of the most common indications for induction to reduce the risk perinatal death.¹⁰ Other indications such as premature rupture of membrane⁸, intrauterine growth restriction, non-reassuring fetal surveillance, maternal medical conditions (such as hypertension, diabetes mellitus, renal disease), Chronioamnionitis suspected or proven, antiphospholipid syndrome, placental abruption, and intrauterine fetal death. This list is not meant to be all inclusive.

Number of different techniques has been used for cervical ripening.⁹ Now a days different pharmacological and mechanical agents are used for cervical ripening, prostaglandin E2 is considered as agent of a choice for labor induction¹¹ but are expensive.

A variety of mechanical methods used for labor induction such as intra cervical folly's catheter,

bogies and hygroscopic laminaria tents. In 1967 Emberey and Mollison first time describe intracervical folley's catheter as a mechanical agent for labor induction¹² Worldwide survey showed that pharmacological methods for pre induction cervical ripening are more successful, safe than the mechanical methods.

Our study aimed to evaluate the efficacy and safety of intravaginal E2 pessary in women with unfavorable cerviced (modified Bishop Score < 6)

MATERIAL AND METHODS

During the study period, 100 patients were selected for cervical ripening; 3 mg of dinoprostone OR Prostaglandin E2 (PGE2) pessary kept vaginally after counseling and consent. Pre-induction cervical scoring was noted. After 6 hours change in bishop's score was noted. The cervical dilatation and improvement in bishop's cervical score and outcome of induction of labor were noted.

The protocol followed was as follows:

- 1) Time for score greater than 6 was noted and if the score still was less than 6, then reinstallation done after a period of 6 hours.
- 2) If score was more than 6 were subjected to artificial ruptured of the membranes, followed by titrated oxytocin drip at rate of 1 mu/min and then increased by algebraic progression.

Indications for cervical ripening and induction of labor were:

- Post-term pregnancy.
- Pregnancy induced hypertension/Toxaemia of pregnancy.
- Oligohydramnios
- Intrauterine growth retardation.
- Suspected placental insufficiency.
- Bad obstetrical history.
- Diabetes mellitus.

Total 100 patients studied. These patients were admitted for induction of labor due to various indications described above. Under aseptic conditions 3 mg dinoprostone PGE 2 pessary was inserted in the posterior fornix of vagina,

patient lied recumbent for 60 minutes, repeat per vaginal examination was done later after 6 hours, improvement in Bishop's score more than 6 was noted. Fetal heart rate and uterine activity was monitor strictly and half hourly intrapartum monitoring of fetal heart rate on CTG machine and progress of labour on partograph recorded in all cases.

RESULTS

During the study duration from 14 Feb 2012 to 13 Feb 2013 of the 100 women recruited in the study, study carried out at Gynecological ward of Liaquat University of Medical and Health Sciences Hospital Hyderabad.

Analysis of booking status listed in Table-I revealed that 68% (n = 68) were un-booked having no antenatal care and 32.0% (n = 32) were booked.

Distribution of cases	Number	Percentage
Un-booked	68	68.0%
Booked	32	32.0%
Total	100	100

Table-I. Booking Status

There were no protocol violation, relation to the parity listed in Table-II showed maximum number of patients (n = 62) 62.0% Primigravida and (n = 38) 38.0% multigravidas were include.

Parity	Total No.
Primigravida	62
Multigravidas	38
Total	100

Table-II. Parity of Patients

Age distribution is listed in Table-III maximum patients (n = 49) 49.0% at age between 26 - 35 years, 35 (35.0%) were between 20 - 25 years, 10 (10.0%) were >35 years and 06 (6.0%) patients were belong to less than 20 years.

Age (years)	No. of Cases (100)	Percentage
< 20	06	6.0%
20 - 25	35	35.0%
26 - 35	49	49.0%
> 35	10	10.0%

Table-III. Age Distribution

Regarding the gestational age 57 (57.0%) patients in our study presented between 37 - 39 weeks of gestation. However, 47 (47.0%) patients were at 40 - >40 weeks of gestation showed in the (Table-IV).

Gestational Age (W)	Number	Percentage
37 - 39weeks	57	57.0%
40 - > 40 weeks	43	43.0%
Total	100	

Table-IV. Duration of Gestation

Indication for cervical ripening and induction of labor is listed on Table-V commonest indication was pregnancy induced hypertension followed by prolonged pregnancy, and IUGR etc.

Indication	Number	Percentage
PIH /HT in pregnancy	58	58.0%
Postdates	40	40.0%
Other (IUGR) etc.	02	2.0%

Table-V. Indication for Induction of Labor

Table-VI shows the Bishop score 30 (30.0%) had Bishop Score 2 - 3, while 70(70.00%) had a bishop score 4-5.

Bishop's Score	Numbers= 100	Percentage
2 - 3	30	30%
4 - 5	70	70%

Table-VI. Bishop Score before induction

Table-VII shows induction-delivery interval, Greater number of women (66/100) delivered within 24 hours of start of induction.

No of patients delivered within 24 hours	66	66.0%
No of patients delivered between 24- 36hrs	34	34.0%

Table-VII. Outcome of labor induction (induction -delivery interval)

Table-VIII showed mode of delivery, majority of the women had normal vaginal deliveries 64.00 while 16 deliveries by assisted vaginal deliveries while in remaining 20 cases caesarean section done. Table-IX shows four babies had an Apgar score 4/10 at end of 1 min and 7/10 at end of 5 min, whereas 96 babies had an Apgar score of 9/10 in 1 min.

Mode of Delivery	Number	Percentage
Normal Vaginal Delivery	64	64.0%
Forceps Delivery	06	6.0%
Vacuum Delivery	10	10.0%
LSCS	20	20.0%

Table-VIII. Mode of Delivery

	Score	
APGAR at 1 min	4 – 6	04
	7 – 8	Nil
	9 – 10	96
APGAR at 5 min	4 – 6	Nil
	7 – 8	04
	9 – 10	96

Table-IX. Apgar score

The indications for caesarean section are shown in Table-X. There were 09(9%) cases of failed induction, 11 cases of a fetal distress (Meconium stained liquor). There was no increased incidence of neonatal sepsis or chorioamnionitis or puerperal sepsis in any of our patients. No perinatal morbidity or mortality or any severe maternal complications were noted while mild side effects were noted which is mentioned in (Table-XI).

Indication	Number	Percentage
Meconium stained liquor	05	5.0%
Fetal Distress (non-reactive CTG)	11	11.0%
Failed induction	04	4.0%
Uterine hyper stimulation	Nil	Nil

Table-X. Indication of Labor

Side Effects	Number
Nausea	23
Vomiting	11
Diarrhea	02
Fever	02
Accidental rupture of membrane	Nil
Chorioamnionitis	Nil
Infection	Nil
Uterine Hyper stimulation	Nil

Table-XI. Side Effects

DISCUSSION

Need of a pre induction cervical ripening has become a reality in our life as an obstetrician. Survey of the national center for health statistics in United States show that approximately 10% of all inductions required cervical ripening.¹³ In our study, unbooked patients were 68 (68.0%), it indicates that maternal and fetal morbidity and mortality due to lack of antenatal care.

A study done in Karachi reveals that awareness regarding health and nutrition is more among women who receives antenatal care.¹⁴

In our study most of the patients were primigravida 62(62.0%) and multigravidas were 38 (38%). Gestational age in our study were between 37- 42, while the study done F.Dewan shows minimum age 28 weeks and maximum 42 weeks that is similar with our study.¹⁵

Hypertension during pregnancy was the common indication in our study; it was matched with the study done in Punjab, while study did in Dhaka show lower number of patients having hypertension in pregnancy for induction of labor.¹⁶ Postdate pregnancy was the second most common indication for induction of labor n=40 (40.0%). it was closure with other studies.^{15,16} Number of patient with indication of IUGR was 2 (2%), while it was lower in study done in Punjab.¹⁶ The patient with bishop score 2-3 were 30%, with score 4-5 were 70%. The Study had done in Dhaka show the similar rate.¹⁶

In our study 66% of patients were delivered within 24 hours and 34% of patients were delivered between 24 -36hrs. The study done in Punjab show similar results¹⁶ while the study done by F.Dewan show contradict results with our study.¹⁵

In our study 20% of patients were delivered by caesarean sections and most of the indications were meconium stained liquor and failed induction. The study done in nether land show same report.

CONCLUSION

In developed countries prostaglandin E2 are widely used for ripening of unfavorable cervix in induction of labor but patient response vomiting, diarrhea, tachycardia, and fever are commonly observed minor side effects.

Induction with Prostaglandin reduced the rate of pregnancies progressing beyond 41 weeks and related feto-maternal morbidity and mortality. After excluding contra indication all women


should be offered induction at 41 completed weeks. Induction with prostaglandin with medical disorder like preeclampsia is safe and better fetal maternal outcome.

Copyright© 20 Dec, 2016.

REFERENCES

1. Wolf JP, Sinosich M, Anderson TL, Ulman A, Bauliac EE, Hodgen GD. **Progestroneautagonist (RU 486) for cervical dilation, labor induction, and delivery in monkeys: Effectiveness in combination with oxytocin.** Am.J. Obstet. Gynaecol. 160: 45-47. Jan 1989.
2. Kavita goel*, jaya k gedam†, DISHA A RAJPUT †, MINAL V BHALERAO* **Induction of Labor: A Review Indian Journal of Clinical Practice**, Vol. 24, No. 11, April 2014.
3. Delee JB. **Preparatory obstetric operations in: The Principles and Practice of Obstetrics.** 5th Edition Philadelphia: WB Saunders. 1992, P.966.
4. Bishop EH. **Pelvic scoring for elective induction obstetric Gynaecology** 1964; 24: 266-68.
5. Hannah ME, Ohlsson A, Farine D, Hewson SA, Hodnett ED, Myhr TL, et al. **Induction of Labour compared with expectant management for prelabour rupture of the membranes at term.** N Engl J Med 1996, 334: 1005-10.
6. Mackenzie IZ. **Labour induction including pregnancy termination for fetal anomaly, in: James DE, Steer PJ, Weiner CP, Gonik B, (eds). High risk pregnancy, management options.** London: WB Saunders 1994:104159.
7. Bouvain M, Stan C, Irion C, Irion O, **Membrane sweeping for induction of labour. Cochrane review.** The Cochrane Library 2008 (1) [update software].
8. Macdonald D. **Surgical induction of labour.** Am J Obstet. Gynaecol. 1970, 107: 98.
9. Asaf KH, Yusuf AW, Rauf S, Raza S. **Induction with prostaglandin E2 Vaginal Pessaries; a success Pak J Obstet. Gynaecol.** 1998; 11(1-3): 45-49.
10. Hannah ME, Hannah WJ, Hellmann J, Hewson S, Milner R, Willana, and the Canadian multicenter post term pregnancy trial group. **Induction of labour as compared with serial antenatal monitoring in post term pregnancy.** A randomized controlled trial N Engl J Med 1992; 326: 1587-92.
11. Mazhar SB, Alam K. **Induced Labour: Indication and Outcome, PIMS Experience.** J Surg 2001; 23-24: 31-33.
12. Gaucherand P, Delignette M, Gelas M, Rudigoz RC. **Declenchement de travail de accouchement par les prostaglandins.** Rev. for Gynaecol. Obstet. 1991, 86, 11, 647-652.
13. Rix P, Ladehoff p, Moller AM, TilmaKA, Zdravkovic M. **Cervical ripening and induction of delivery by local administration of prostaglandin E2 gel or vaginal tablets is equally effective.** ActaObstet Gynaecol Scand 1996; 75: 45-7.
14. Rouben D, Arias F. **A randomized trial of extra-amniotic saline infusion plus intracervical Foley catheter balloon versus prostaglandinE2vaginal gel for ripening the cervix and inducing labour in patients with unfavorable cervix.** Obstet Gynaecol 1993; 92: 290-4.
15. Dewan F, Begum R, Chowdhury SB. **Comparative study of induction of labour by Foley catheter with that of sweeping of the membrane in prolonged pregnancy.** Sir Salimullah Med Coll J 1995; 3: 22-7.
16. 36. Manabe Y, Manabe A, Takahashi A. **Prostaglandin levels in amniotic fluid during balloon – induced cervical softening and labor at term.** Prostaglandins 1982; 23:247-56.
17. Sandhu S.K., Arora S and A.S; J. **ObstetGynae, India** 1984; 34: 226.
18. American College of Obstetrician and Gynaecologists Committee Opinion. **Monitoring during induction of labor with dinoprostone.** 1998; 209: 135.

AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author-s Full Name	Contribution to the paper	Author=s Signature
1	Dr. Raheela Baloch	Literature Search, Performance, Data collection, Analysis	
2	Dr. Nigar Jabeen	Data collection, Literature Search	
3	Dr. Sana Zahiruddin	Study concept, Literature search	
4	Ms. Kiran Mawani	Data collection + Analysis	