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Comparison of Efficacy of Trans-Cervical Foleys Catheter and PGE2 Gel for Induction of Labour

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Abstract

Background: Induction of labour is initiation of uterine contractions before the onset in order to vaginally deliver the fetoplacental unit. Common reasons for induction of labour (IOL) are post-term and hypertensive disorders of pregnancy. Many women who undergo induction do not have a favourable cervix, so some methods of cervical ripening either pharmaceutical or mechanical are used.

Aim & Objective: To compare the effectiveness of the transcervical Foley catheter and the prostaglandin E2 (PGE2) gel for the induction of labour.

Methodology: The clinical trial was conducted for a period of two years OBGY department of Bharati Vidyapeeth University, Pune. 196 pregnant women which included and randomly via block randomization divided into two groups. Group A had 98 women in whom the transcervical Foley catheter was inserted and Group B included 98 women in whom the PGE2 gel was inserted vaginally for IOL. Bishop's score and duration from induction to onset of labour was calculated. Data analysis was done and appropriate statistical tests were used.

Results: In Group A (37.8%) as well as in Group B (41.8%) most of the pregnancies were primigravida. The most common indication for induction in both groups was postdatism. The adjuvant therapy was required in 66.3% and 54.1% of women in Group A & B respectively. Significant higher median values were observed in Bishop's score at 12 hours as compared to 0 hour in both the groups. No significant association was observed between mode of induction and need of adjuvant therapy and induction to onset hours in both groups.

Conclusion: The study shows that both Foley's catheter and PGE2 gel are equally effective in pre induction cervical ripening.

Keywords: Labour Induction, Foley's catheter, Prostaglandins, Bishop's score, cervical ripening

Introduction

Labour is from the onset of regular painful contractions in uterus which leads to cervical effacement and also its dilation thereby causing the fetus to deliver along with placenta. Over the recent years, 20% of deliveries are due to induction of labour. The induction of labour (IOL) is common in the obstetric practice and it is aimed at, to deliver

a healthy baby and to maintain the health of the mother. The major indications for IOL for the past 60 years being post date pregnancy and hypertensive disorders, before this it was intrauterine fetal demise.[1] The incidence of IOL is 15-20% in UK, 30-38% in USA, and is 10% in India.[2]

In IOL there is artificial initiation of uterine contractions in acquiescent uterus, for the purpose of vaginal delivery by any method like medical, surgical, or combined prior to their spontaneous onset beyond the period of fetal viability. It is offered to pregnant women when it is thought the outcome will be better for the mother and/or baby if the baby is born than if the pregnancy continues.[3]

The state of cervix before induction is measured by Bishop's Score and it is an important determinant of success or failure for induction.[4] It is generally predicted that a patient with a poor Bishop's score of less than 3 have a higher rate of failure of induction, and is associated with higher rates of C-Section, maternal fever and fetal asphyxia.[5]

For ripening of unfavorable cervix various techniques are used including pharmacological and non-pharmacological (mechanical) methods. The pharmacological methods include prostaglandins (PGE1, PGE2), oxytocin, estrogens, mifepristone, etc. The non-pharmacological methods include a transcervical Foley catheter, bougies, hygroscopic laminaria tents and fore water amniotomy. Intra-cervical application of PGE2 gel is an effective method of cervical ripening[6] as it causes connective tissue softening, cervical effacement and uterine activity. It can be used in cases of heart disease, PIH and eclampsia.[7,8]

Nowadays currently accepted mechanical method is insertion of Foley catheter extraamniotically.[9] WHO has also recommended it as an acceptable method of IOL.[10] There was no evidence of increased infection for either mother or baby with catheter use.[11,12] The chances of infection in catheter is no different from the usual hospital rates of infection if strict aseptic precautions are taken[13] Also the low cost makes it particularly useful in limited resource settings like developing countries. Evidences have shown that use of catheter is associated with reduction in the induction and the delivery interval, decreased rate of C-Sections and increased rates of spontaneous deliveries.[14] As a result, this study was planned to compare mechanical method and pharmacological method for IOL.

Aim & Objective

1. To compare the efficacy of PGE2 with trans cervical Foley's catheter for induction of labour with respect to Bishop's score.
2. To study the duration from induction to onset of labour.
3. To study the need of adjuvant method for induction.

Methodology

Study setting and design

A randomized controlled trial was conducted in the Obstetrics and Gynaecology Department (OBGY) in a tertiary care hospital, Bharati Hospital at Bharati Vidyapeeth University, Pune for a period of two years in antenatal females coming to OBGY Department for delivery.

Inclusion criteria

1. Those who were willing to participate in the study and gave consent.
2. Those who were fit for vaginal delivery with cephalic presentation.
3. Those with Bishop's score less than or equal to 3.

Exclusion criteria

1. Those who did not give consent to participate in the study.
2. Those with history of multiple pregnancies.
3. Those with Malpresentation
4. Those with Ante partum haemorrhage

Sample size and sampling

A total of 196 study participants were included in the study and after matching the inclusión and exclusion criteria the cases were admitted for induction in the department of OBGY.

Method

After explaining the purpose of study written informed consent was taken from the study participants. Detailed history was taken and thorough examination was done. After this the participants were selected for induction by using block randomization technique and divided into two blocks. Participants underwent vaginal examination to determine Bishop score. The participants were randomly allocated in two groups Group A & B with equal number (i.e 98 participants) in both groups.

In Group A study participants size 14 single balloon Foley's catheter was used for IOL. The catheter was introduced under sterile conditions into the transcervicalcanal past the internal os of the cervix and the bulb was inflated with 50ml. of distilled water. The end of the Foley's catheter was closed with linnen No 4-0. Foley's was fixed to the inner thigh with a sticking. The Foley's was kept for 12 hours and the assessment of the Bishop's score was done.

In Group B study participants 3ml (0.5mg) PGE 2 gel was introduced in the cervical canal and patient was asked to lie down in the same position for 30 minutes for absorption of drug. After 6 hours, assessment was done for Bishop's score. If there was no improvement in the Bishop's score, reinstallation was done again after 6 hours.

After 12 hours assessment was done to know the efficacy of both the methods of induction. Patients were monitored for painful uterine contractions with respect to the number, duration and frequency and foetal heart rate every half hourly. At the end of 12 hours improvement in Bishop's score was noted down. Induction to onset of labour time was calculated.

Data Collection

Data was collected by face-to-face interview method with the study participants. A pretested, predesigned, semi structured questionnaire was used to collect data regarding menstrual cycles, gestational age of the participants which was ascertained and correlated clinically. Also, Obstetric history, past medical and surgical history and demographic profile of the participants were noted.

Data analysis

The collected data was coded and entered in Microsoft Excel sheet. The data was analysed using SPSS version 20.0 software.

Ethical consideration

Protocol was submitted in Institutional Ethical Committee. Informed written consent from the participants were obtained after informing that the participation will be voluntary and there will be no harm to the participants in the study. Confidentiality of the information obtained from the patient was maintained and the identity of the patient was not revealed.

Result

Table 1 depicts mean maternal age of study participants is 26.14 (+-3.75) and 25.71 (+-4.16) and mean gestational ageis 38.66 (+-2.88) and 38.57 (+-2.84) in Group A and Group B respectively. When frequency distribution of parity in PGE2gel and Foley's catheter groups seen then in Foley's catheter group maximum (84.6 %) were para 1 and in PGE2gel group also maximum (82.9%) were para 1. Maximum frequency distribution of gravidity in Foley's catheter group (37.8%) were G1 and in PGE2gel group (41.8 %) were also G1.

Figure 1 depicts shows the frequency distribution of indications for induction in Foley's catheter group. Maximum (50%) of cases were induced due

Table 1: Maternal Demographic profile

Parameters	Group –A (N =98) Foley catheter	Group – B (N=98) PGE2 Gel
Mean maternal age	26.14 (+-3.75)	25.71 (+-4.16)
Mean Gestation age	38.66 (+-2.88)	38.57 (+-2.84)
Parity		
P1	33 (84.6)	29 (82.9)
P2	6 (15.4)	4 (11.4)
P3	0 (0.0)	2 (5.7)
Gravida		
G1	37 (37.8)	41 (41.8)
G2	34 (34.7)	38 (38.8)
G3	21 (21.4)	16 (16.3)
G4	6 (6.1)	2 (2.0)
G6	0 (0.0)	1 (1.0)

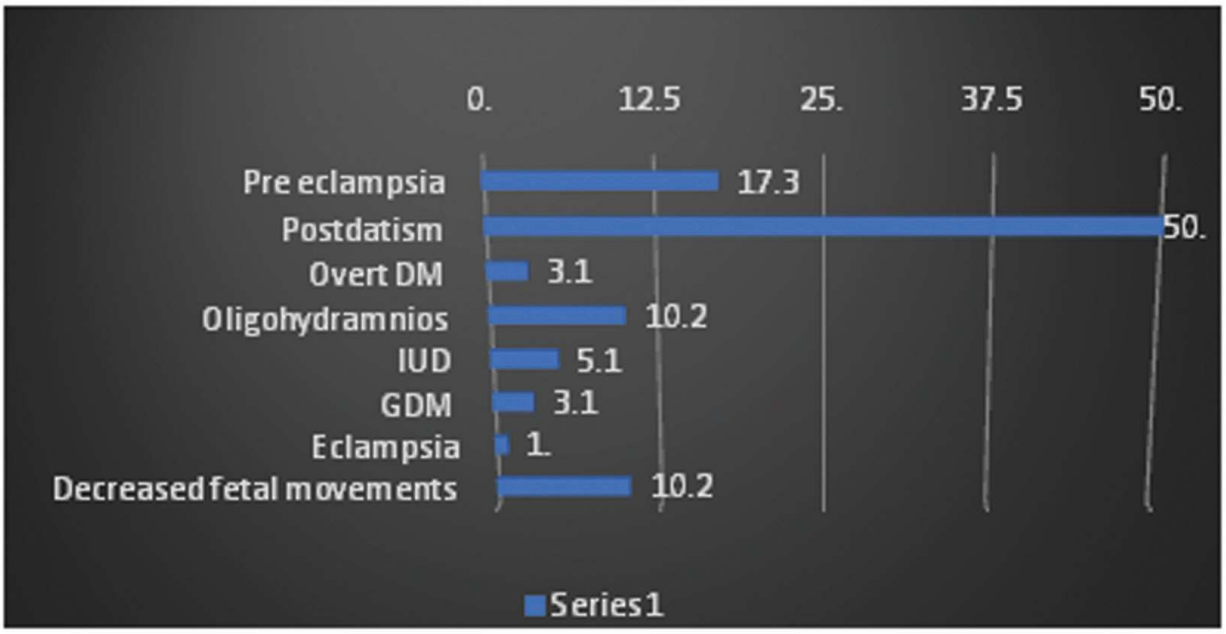

Fig 1: Indication for induction Foley'scatheter (n=98)

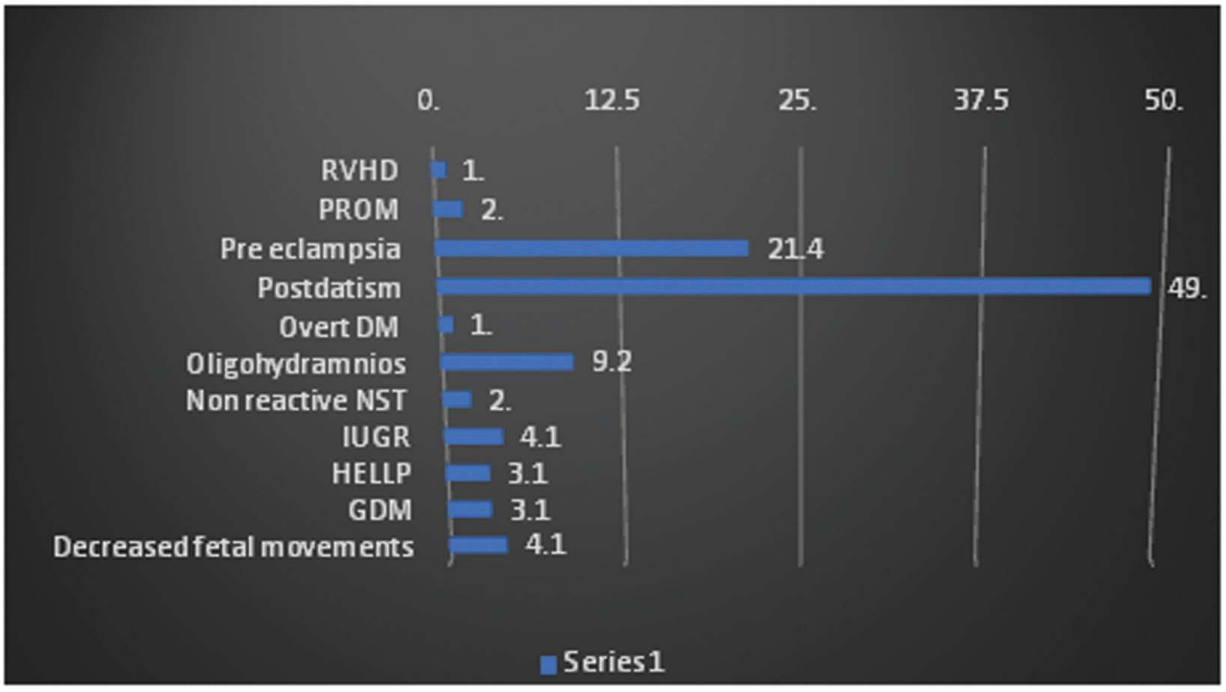

Fig 2: Indication for induction PGE 2 Gel (n=98)

to postdatism whereas only 1.0% were of eclampsia. Figure 2 also depicts that maximum indication for induction in PGE2gel group was due to postdatism (49%) and minimum (1%) was due to RVHD.

Table 2 shows that the percentage of the mode of delivery in both the groups of Foley's catheter (78.57%) and PGE2gel (69.39%) were full term vaginal deliveries. In Foley's catheter group 66.3% cases and in PGE2gel group 54.1 % cases required adjuvent therapy. In Foley's catheter 7.1% of cases and in PGE2 gel 13.3% of cases were reinstilled.

In table 3 statistically significant higher median value observed in Bishop's at 12 hours as compared to Bishop's at 0 hour in Foley's catheter (p-value<0.001) and PGE2 gel (p-value <0.001) respectively. But in table 4 there was no significant association observed between mode of induction and need of adjuvant therapy (p-value=0.08). Also,

Table 2: Mode of Delivery and other parameters in two Group

Parameters	Group –A (N =98) Foley catheter	Group – B (N=98) PGE 2 Gel
Mode of delivery		
Emergency LSCS	17 (17.35)	23 (23.47)
FTVD	77 (78.57)	68 (69.39)
PTVD	4 (4.08)	5 (5.10)
PTVDFSB	0 (0.0)	2 (2.04)
Need of adjuvant therapy		
Yes	65 (66.3)	53 (54.1)
No	33 (33.7)	45 (45.9)
Reinstillation		
Yes	7 (7.1)	13 (13.3)
No	91 (92.9)	85 (86.7)

Table 3: Effect of modesof inductionon Bishop's score

Mode of Induction	Bishop's Score	N	Median	p-values
Foley'scatheter	Bishop's at 0 hour	98	2	<0.001
	Bishop's at 12th hour	98	6	
PGE2 Gel	Bishop's at 0 hour	93	2	<0.001
	Bishop's at 12th hour	93	6	

Table 4: Need of adjuvant therapy

Mode of Induction	Need of adjuvant therapy		Total	Chi-SquareValue	p-value
	Yes	No			
Foley' scatheter	65	33	98		
PGE2gel	53	45	98	3.06	0.08
Total	118	78	196		

Table 5: Induction to on setintervalin hours

	Mode of Induction Cat	N	Median	Pvalue Mann-Whitney-U-Test
Induction to on setinter valin hours	Foley'scatheter	98	3.00	0.28
	PGE 2 Gel	98	3.00	

in table 5 no significant median value of induction to onset hours was observed between Foley's catheter and PGE2 gel groups (p- value = 0.28).

Discussion

Over the past several decades, the incidence of IOL for shortening the duration of pregnancy has continued to rise. In developed countries, the proportion of infants delivered at term following IOL can be as high as one in four deliveries.[15] Several factors may influence the choice of method for induction of labour including cervical and membrane status, parity, and patient and provider preference.[16] We undertook this study to compare

the efficacy of the two methods viz. Trans cervical Foley's catheter and PGE2 gel for induction of labour to achieve cervical ripening. In the present study maternal age of study participants is 26.14 (+-3.75) and 25.71 (+-4.16) and mean gestational age is 38.66 (+-2.88) and 38.57 (+-2.84) in Group A and Group B respectively. Similar findings were recorded by Kanada A[17] et al, with respect to the maternal age, gestational age, indication for induction and pre-induction Bishop's score of both the study groups were comparable with no statistically significant difference. Majority of the patient were between the age of 21 - 25 years, with mean age of 22.59±3.38 and 22.32±3 years in Foley's catheter and PGE2 groups respectively. The mean gestational age was 38.48±1.35 weeks in Foley's catheter and 38.43±1.29 weeks in PGE2 group. Similar to present study, in a study by Ziyauddin F[18] et al there was no significant difference in the maternal age, the gestational age or the parity of the cases. In the present study the postdatism was the most prevalent indication for induction of labour in both the Foley's catheter and In PGE2gel groups. Similar findings were shown by Bembalgi S[19] et al. In the present study among Foley's catheter and PGE2gel groups the emergency LSCS was carried out in 17.35 % and 23.47% women respectively whereas Full term vaginal delivery was performed after IOL among 78.57% and 69.39% women respectively. Similar results were shown by Ziyauddin F[18] et al reported 71.43% & 60% vaginal delivery, and 28.57% & 40% deliveries by caesarean section, in the Foley's catheter and PGE2 groups respectively. In the present study the augmentation for induction of labor was required among 7 and 13 women in Foley's and PGE2 gel groups respectively. Similarly, Deshmukh VL[20] et al reported requirement of augmentation of labor in Foley's catheter and PGE2 gel groups by doing ARM, oxytocin infusion and both ARM + oxytocin with no significant difference in need for augmentation in both groups. In the present study the improvement in the Bishop's score was reported in both Foley's catheter and PGE2 groups, which was statistically significant. Bembalgi S[19] et al calculated pre-induction Bishop score which did not differed significantly between the study groups. A considerable improvement in the Bishop's score after 6 hours of induction was noted in Foley's as well as PGE 2 group, with greater progress in Foley'sgroup.In the present study there was no statistically significant difference in the median values of induction to onset hours observed between Foley's catheter and PGE2 gel groups. The induction to delivery interval has been compare dinvarious studies whereas in our study the comparison is made between induction to onset interval which has not been compared in many other studies.

Conclusion

The present study concluded both Foley's catheter and PGE2 gel have significant effect on improvement of the Bishop's score required for cervical ripening. However, no comparable results could be found justifying better efficacy of one method over the other. No significant difference was noted in the induction to onset interval among both the groups. Number of vaginal deliveries were noted to be more in Foley's catheter group. No significant difference was noted with respect to need of adjuvant therapy and reinstillation among both the groups.

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References

1. Hutchison J, Mahdy H, Hutchison J. Stages of Labor. [Updated 2021 Aug 25].In: StatPearls [Internet]. Treasure Island (FL): Stat Pearls Publishing; 2021Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK544290/
2. Sharma JB, Malhotra M, Arora R. Incidential Fitz-Hugh-Curtis syndrome atlaparos copy for benig ngynecologic conditions. International Journal of Gynecology & Obstetrics. 2002 Dec1;79(3):237-40.
3. Ezebialu IU, Eke AC, Eleje GU, Nwachukwu CE. Methods for assessing pre-inductioncervicalripening. Cochrane Database Syst Rev.2015 Jun 12;2015(6):CD010762.
4. Karjane NW, Brock EL, Walsh SW. Induction of labor using a foley balloon, with and without extraamniotic saline infusion. Obstet and Gynecol. 2006;107(2):234-9
5. Murmu S et al. Int J Reprod Contracept Obstet Gynecol. 2018 Aug;7(8):3122-3125.
6. Sherman DJ, Frenkel E, Toblin J, Arieli S, Caspi E, Bukovasky I. Ripening of the unfavourable cervix with extra-amniotic catheter balloon: clinical experience and review. Obst Gynecol Survey. 1996;51(10):621-7.

7. Arias F. Pharmacology of Oxytocin and Prostaglandins. Clinical Obst Gynecol. 2000;43(3):455-68.
8. Sandhu SK, Arora S. Preinduction cervical ripening with endocervical PGE2 gel and a placebo control study. J Obstetgynec India. 1994; 1:537-42.
9. Boulvain M, Kelly A, Lohse C, Stan C, Irion O. Mechanical methods for induction of labour. Cochrane database Syst Rev. 2001;(4):CD001233.
10. WHO Recommendations for Induction of Labour - PubMed - NCBI.
11. Dalui R, Suri V, Ray P, Gupta I. Comparison of extraamniotic Foley catheter and intracervical prostaglandin E2 gel for preinduction cervical ripening. Acta Obstet Gynecol Scand. 2005;84(4):362–7.
12. Hoffman M, Sciscione A, Bedder C, Shlossman P. The safety of the Foley catheter for preinduction cervical ripening in a low-risk population. Am J Obstet Gynecol. 2011;204(1): S121–2.
13. RevathiV,ArchanaI.Comparativestudyofefficacyoftranscervicalprostaglandin E2gel and transcervicalFoley'scatheterforpre-inductioncervical ripening. JDentalMedSci (IOSR-JDMS).2015;14(4):42-6.
14. Alam A et al. Int J Reprod Contracept Obstet Gynecol. 2016 Aug;5(8):2644-2647.
15. World health organization. WHO recommendations for Induction of labour. Available at http://apps.who.int/iris/bitstream/handle/10665/44531/9789241501156_eng.pdf;jsessionid=1BD89131A7ACA35B8C7EC28574A0A103?sequence=1
16. Mozurkewich, E.L., Chilimigras, J.L., Berman, D.R. et al. Methods of induction of labour: a systematic review. BMC Pregnancy Childbirth 11, 84 (2011). https://doi.org/10.1186/1471-2393-11-84
17. Kanada, Anjali & Jain, Mahima. (2019). A comparative study of intra-cervical Foley's catheter and PGE2 gel for induction of labour at term. International Journal of Reproduction, Contraception, Obstetrics and Gynecology. 8. 3689. 10.18203/2320-1770.ijrcog20193799.
18. Ziyauddin F, Hakim S, Beriwal S. The transcervical Foley's catheter versus the vaginal prostaglandin e2 gel in the induction of labour in a previous one caesarean section - a clinical study. J Clin Diagn Res. 2013 Jan;7(1):140-3.
19. Bembalgi, Shobha, Lavanya, & Vinutha M. B.. "Comparison of Foley's catheter with PGE2 gel and Foley's catheter with PGE2 gel with extra amniotic saline infusion for labour induction." International Journal of Reproduction, Contraception, Obstetrics and Gynecology [Online], 7.5 (2018): 1782-1785.
20. Deshmukh VL, Yelikar KA, Deshmukh AB. Comparative Study of Intra- cervical Foley's Catheter and PGE (2) Gel for Pre-induction Ripening (Cervical). J Obstet Gynaecol India. 2011;61(4):418-421. doi:10.1007/s13224- 011-0063-2