Print ISSN: 2321-6379
Online ISSN: 2321-595X

Original Article

Comparative Study on Transcervical Foley's Catheter and Intracervical PGE_2 Gel for Cervica Ripening for Induction of Labor

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Abstract

Introduction: Induction of labor (IOL) is a common obstetric intervention. It involves the use of mechanical or pharmacological methods to achieve cervical ripening, regular contractions, cervical dilatation, and subsequent delivery. Therefore, we decided to compare the efficacy of transcervical Foley's catheter and intracervical PGE_2 gel in cervical ripening for IOL.

Aims and Objectives: Aim of our study was to compare the efficacy of transcervical Foley's catheter and intracervical PGE_2 gel (0.5 mg) in cervical ripening for successful IOL.

Materials and Methods: This was a prospective case control study comprising 200 antenatal cases (ANC) admitted to labor ward for IOL. The ANC were divided into two groups, with one group of 100 pregnant women (cases) subjected to IOL by transcervical insertion of Foley's catheter while the second group of 100 pregnant women (controls) received intracervical PGE_2 for IOL. It was conducted in Department of Obstetrics and Gynaecology, M.K.C.G Medical College and Hospital, Berhampur, Odisha from October 2015 to September 2017. The following outcomes were studied: Maternal outcomes including maternal side effects, Labor Complications, Mode of delivery whether vaginal or cesarean section, need for augmentation, induction to delivery interval and neonatal outcomes including still or live birth, APGAR score at 5 min and neonatal intensive care unit admission and cost of the procedure.

Results: There was no statistically significant difference in terms of majority of maternal outcomes between cases and controls except for induction to delivery interval which was significantly shorter in PGE_2 gel. There was also no statistical significance between two groups in terms of neonatal outcomes. Foley's catheter was cost effective when compared to PGE_2 gel.

Conclusion: Both Foley's catheter and PGE_2 gel proved to be equally effective methods for pre-induction ripening for unfavorable cervix with comparable results.

Key words: Cervical ripening and induction of labor, Intracervical PGE_2 gel, Transcervical Foley's catheter

INTRODUCTION

Over the past several decades, obstetricians are fascinated with the process of parturition. Over the years, various professional societies have recommended the use of induction of labor (IOL) in circumstances in which the risks of waiting for the onset of spontaneous labor were judged to be greater than the risks associated with shortening the duration of pregnancy by induction. Although current guidelines do not recommend this, IOL is being used more and more at the request of pregnant women to shorten the duration of pregnancy or to time the birth of the baby according to the convenience of the mother and/or healthcare workers.[1,2]

In the course of a normal pregnancy, softening and dilatation of the cervix are the result of complex of biochemical reactions including decreased collagen and glycosaminoglycan concentrations as well as increased water content. This, in turn, results in a cervix favorable for normal or induced labor. In a normal pregnancy, these changes accelerate toward the end of the pregnancy and pave way for spontaneous labor. When this process fails at term, cervix must be ripened through artificial means.[3]

Access this article online

www.ijss-sn.com

Month of Submission : 05-2022
Month of Peer Review : 06-2022
Month of Acceptance : 06-2022
Month of Publishing : 07-2022

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The role of cervical ripening in success of IOL is well established, an unripe cervix is associated with high risk of induction failure, failure to progress in labor, cesarean section, infections, fetal distress, and postpartum hemorrhage.[4-6] When the cervix is ripe, induction of labor is done by artificial rupture of membrane (ARM) and intravenous Oxytocin. Numerous techniques have been used to ripen the unfavorable cervix to achieve the changes necessary for labor. At present, pharmacological and mechanical agents are used to modify the cervical status. Non-pharmacologic approaches for cervical ripening and labor induction have included herbal compounds, castor oil, hot baths, enemas, sexual intercourse, breast stimulation, acupuncture, acupressure, transcutaneous nerve stimulation, mechanical, and surgical modalities.

IOL has previously been considered to increase the rate of caesarean section, but more recent research demonstrates that IOL is in fact associated with a decrease in caesarean section rates compared to expectant management at or beyond term.[7-11]

As per NICE clinical guideline 70 (2008), the most common method of pre-induction cervical ripening is pharmacological, with the administration of prostaglandin E_2 (PGE_2) intravaginaly or intracervically. Rath *et al.* (1993) revealed that PGE_2 work through increasing collagenase and proteinase activity within the cervix with a resultant fall in collagen concentration, allowing dilatation. Clinically, when compared to placebo or no treatment, IOL with PGE_2 pre-ripening is more likely to result in cervical change and achievement of vaginal delivery within 24 h. Prostaglandin preparations used for cervical ripening are expensive and unstable, requiring refrigerated storage. Feasibility to use prostaglandins was found to be limited largely due to its higher cost and inadequate infrastructure to maintain the narrow temperature range to keep its potency.[12-14]

Mechanical method in IOL is most commonly the insertion of extra-amniotic transcervical Foley's catheter. Lin *et al.* (2007) revealed that this method generated a change in cervical condition through both a direct mechanical dilatation and stretch induced release of endogenous prostaglandins.

Recent Cochrane review has concluded that IOL using mechanical methods such as Foley's catheter results in similar caesarean section rates to prostaglandins and yields a lower risk of hyper stimulation with or without fetal heart rate changes compared to prostaglandins. When compared with oxytocin, mechanical methods reduce the risk of caesarean section. Mechanical methods are as effective in achieving delivery within 24 h of intervention as any prostaglandins. According to the limited data available, there is no evidence of an increased risk of infectious morbidity with mechanical methods. Foley's catheter for cervical ripening is a far cheaper option than prostaglandin in terms of medication or device cost. The latter method also incurs significant additional cost in monitoring the maternal and fetal well-being during the process. Therefore, Foley's catheter is a logical option to consider in limited resource settings with a relative lack of monitoring facilities.[15,16]

Aims and Objectives

The aim of our study was to compare the efficacy of transcervical Foley's catheter and intracervical PGE_2 gel (0.5 mg) in cervical ripening for successful IOL.

MATERIALS AND METHODS

This was a prospective case control study comprising 200 antenatal cases (ANC) admitted to labor ward for IOL. The study was conducted in the Department of Obstetrics and Gynaecology, M.K.C.G Medical College and Hospital, Berhampur, Odisha from October 2015 to September 2017 after obtaining approval from Institute Ethics Committee and informed written consent from the subjects. The following outcomes were studied: Maternal outcomes including maternal side effects, labor complications, mode of delivery whether vaginal or caesarean section, need for augmentation, induction to delivery interval and neonatal outcomes including still or live birth, APGAR at 5 min, and neonatal intensive care unit (NICU) admission and cost of the procedure.

Inclusion Criteria

Subjects who fulfilled the following criteria were included in the study:

i. Pregnant women with gestational age between 37 and 42 weeks
ii. Singleton pregnancy
iii. Primigravida or multigravida
iv. Vertex presentation
v. Age above 18 years
vi. Modified bishop's score <6.

Exclusion Criteria

Subjects who fulfilled the following criteria were excluded from the study:

i. Pregnant women with gestational age <37 weeks and more than 42 weeks
ii. Multiple pregnancy
iii. Non vertex presentation
iv. Antepartum hemorrhage
v. Premature rupture of membranes
vi. Modified bishop's score >6.

The ANC were divided into two groups, with one group of 100 pregnant women (cases) subjected to cervical ripening and IOL by transcervical insertion of Foley's catheter while the second group of 100 pregnant women (controls) received intracervical PGE_2 (0.5 mg) gel for IOL.

Cases

Patient was placed in dorsal position. Under aseptic precautions, sim's speculum was placed in posterior vaginal wall and retracted. Anterior lip of cervix was held with sponge holder. Foley's catheter of No.18 was inserted directly into endocervical canal beyond internal os extra amniotically and inflated with 30 ml distilled water. Catheter was taped on medial aspect of thigh by traction.

Fetal heart rate and uterine contraction were monitored, if no abnormalities were detected then patient was allowed to ambulate. Foley's catheter if spontaneously expelled, modified bishop's score was reassigned. Immediately following such expulsion or alternatively when the modified bishop's score attained a value of ≥6, for acceleration of labor the membranes were ruptured artificially or oxytocin was begun if necessary.

If not expelled in 12 h, catheter was adjusted to maintain continuous traction. Once again modified bishop's score was reassigned after 12 h. Cases were taken as failure if patient was not in active labor within 24 h.

Controls

After assigning modified bishop's score, sterile sim's speculum was introduced into vagina. Cervix and upper vagina were examined. Excess mucus was removed.

Anterior lip of cervix was held with sponge holder. About 0.5 mg of PGE_2 gel was administered intracervically. Patient was instructed to lie in left lateral position following gel administration for half an hour. Fetal heart sound and uterine contractions were monitored and then patient was made to ambulate. After 6 h, per vaginal examination was done and modified bishop score was reassigned.

If modified bishop's score was not favorable 12 h after the first dose, second dose of 0.5 mg PGE_2 gel was administered. Women received maximum of 2 doses only. When modified bishop's score attained a value of ≥6, for acceleration of labor the membranes was ruptured artificially or oxytocin was begun if necessary. Oxytocin was given 4 h after the last dose of PGE_2 gel. Controls were taken as failure if patient was not in active labor within 24 h.

For both groups, maternal pulse rate, blood pressure, temperature, and fetal heart rate were monitored. Frequency and duration of uterine contraction were assessed for regular uterine contraction and uterine tachysystole (>5 contractions per 10 min averaged over 30 min).

Any subjective adverse effects reported by patient sich as pain, nausea, and vomiting were also recorded. Inj. Tramadol (100 mg) or Inj. Pentazocine (30 mg) for pain relief was given on maternal request.

Need for augmentation of labor was done by methods such as ARMs, oxytocin drip, or both.

Statistical Analysis

Differences between the case and control groups were evaluated using student '*t*' test and Chi-square test. Statistical significance was deemed at a $P < 0.05$ with the confidence limit of 95%.

RESULTS

As shown in Table 1, there was no difference between cases and controls with respect to age group. The *P* value is not significant ($P = 0.569$). As shown in Table 2, there was no difference between cases and controls with respect to gravidity status. The *P* value is not significant ($P = 0.560$). As shown in Table 3, there was no difference between cases and controls when pre-induction modified bishop's score was compared between the two groups. The *P*-value

Table 1: Age matching

Age group (years)	Cases (induction by Foley's Catheter)	Controls (induction by PGE_2 gel)	*P*-value
18–21	17	23	0.569
>21–25	53	49	
>25–30	30	28	
Total	100	100	

Table 2: Gravidity status

Gravidity status	Cases (induction by Foley's Catheter)	Controls (induction by PGE_2 gel)	*P*-value
Primigravida	64	60	0.560
Multigravida	36	40	
Total	100	100	

Table 3: Pre-induction modified bishop's score.

Pre-Induction modified Bishop's Score	Cases (induction by Foley's Catheter)	Controls (induction by PGE_2 gel)	*P*-value
1	22	25	0.770
2	28	29	
3	24	20	
4	12	16	
5	14	10	
Total	100	100	

is not significant ($P = 0.770$) by Chi-square test. As shown in Table 4, there was no difference between cases and controls in terms of reason for induction. The *P* value is not significant ($P = 0.641$). Hence, the cases (subjects undergoing induction by transcervical Foley's catheter) and controls (subjects undergoing induction by intracervical PGE_2) in our study were comparable in terms of maternal age, gravidity status, pre-induction modified bishop's score, and reasons for IOL.

Maternal Outcomes

As given in Table 5, in terms of maternal side effects, 17% of cases and 26% of controls had side effects and 83% of cases and 74% of control group did not have maternal side effects. The difference between the cases and controls was not statistically significant ($P = 0.1214$). As given in Table 5, labor complications were present in only 12% of cases and absent in remaining 88% of cases. Among the controls, labor complications were present in only 16% of cases and absent in remaining 84% of cases. The difference between the cases and controls was not statistically significant ($P = 0.4150$). As given in Table 5, vaginal delivery was seen in 80% of cases and 68% of controls. The difference between the cases and controls was not statistically significant ($P = 0.0531$). As given in Table 5, cesarean section was done in 20% of cases and 32% of controls. The difference between the cases and controls was not statistically significant ($P = 0.0531$).

As shown in Table 6, there was no difference between cases and controls with respect to need for augmentation. The *P* value is not significant ($P = 0.763$).

Table 4: Reason for induction

Reason for induction	Cases (induction by Foley's Catheter)	Controls (induction by PGE_2 gel)	*P*-value
Pregnancy induced by hypertension	46	52	0.641
Oligohydramnios	24	26	
Intrauterine growth retardation	19	14	
Bad obstetric history	11	08	
Total	100	100	

As shown in Table 7, there was a statistically significant difference between cases and controls in induction to delivery interval. The *P* value is significant ($P = 0.047$).

Neonatal Outcomes

As shown in Table 8, live birth was seen in all the 100 cases and 100 controls, no still births were present in both the groups. The difference between the cases and controls was not statistically significant ($P = 1.000$). As shown in Table 8, APGAR score at 5 min of <7 was observed in only 5% of cases and 6% of controls. This difference is statistically insignificant ($P = 0.7564$). As shown in Table 8, NICU admission was seen among 14% of neonates of cases and 17% of neonates of controls. The difference between the cases and controls was not statistically significant ($P = 0.5578$).

As shown in Table 9, the cost of Foley's catheter (Rs.180) is lesser when compared to PGE_2 gel (Rs.240).

DISCUSSION

Maternal Outcomes

In our study, as shown in Figure 1, maternal side effects were less in Foley's catheter group (17%) when compared to PGE_2 group (26%). However, the difference between the two groups is statistically insignificant ($P = 0.1214$). This is contrary to studies done by Baloch *et al.*[17] which revealed more side effects in PGE_2 group compared to Foley's catheter group. However, similar results to our study were seen in studies done by Alam and Ahmed[18]

As shown in Figure 2, labor complications were less in cases (12%) when compared to controls (16%). This finding of ours is similar to observations seen in a study done by Baloch *et al.*[17]

As shown in Figure 3, in our study vaginal delivery was seen in 80% of Foley's catheter group and in 68% of PGE_2 gel group. However, the difference between the two groups was statistically insignificant. Our study results were in accordance with studies done by Anupma *et al.*[19]

As shown in Figure 4, in our study, cesarean section was done in 20% of cases and 32% of controls. However, the difference

Table 5: Maternal outcomes

Parameter	Cases (induction by Foley's Catheter)			Controls (induction by PGE_2 gel)			*P*-value
	Present	Absent	Total	Present	Absent	Total	
Maternal side effects	17	83	100	26	74	100	0.1214
Labor complications	12	88	100	16	84	100	0.4150
Vaginal delivery	80	20	100	68	32	100	0.0531
Cesarean section	20	80	100	32	68	100	0.0531

Table 6: Maternal outcome-need for augmentation

Need for augmentation	Cases (induction by Foley's Catheter)	Controls (induction by PGE_2 gel)	*P*-value
Only ARM	22	20	0.763
Only oxytocin	27	34	
ARM+Oxytocin	40	36	
None	11	10	
Total	100	100	

Table 7: Maternal outcome-induction to delivery interval

Induction to delivery interval (h)	Cases (induction by Foley's Catheter)	Controls (induction by PGE_2 gel)	*P*-value
<12	22	38	0.047*
>12–24	66	52	
>24	12	10	
Total	100	100	

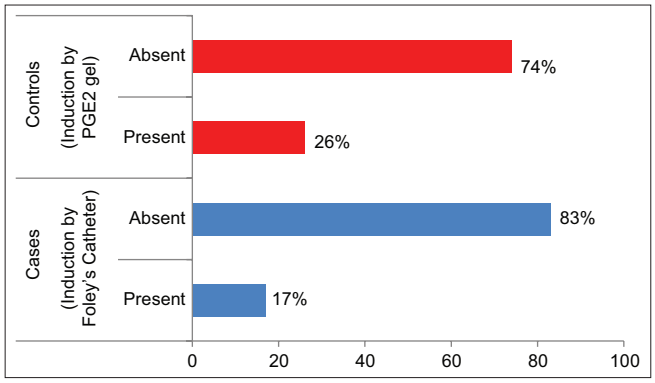

Figure 1: Maternal side effects

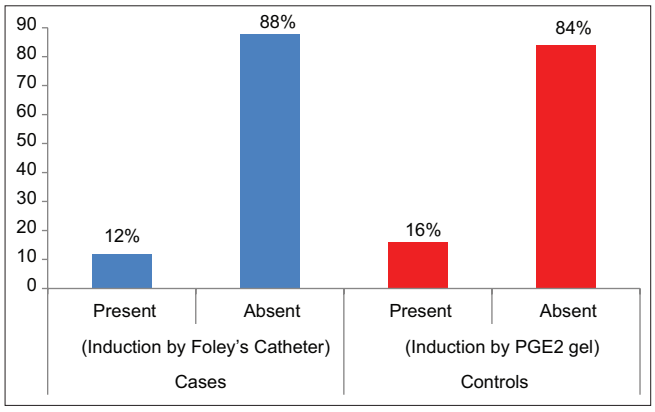

Figure 2: Labour complications

between the cases and controls was not statistically significant. Our study results were in accordance with studies done by Alam and Ahmed,[18] Anthony *et al.*,[20] and Pennell *et al.*[15]

In our study, in terms of need for augmentation of labor, as shown in Figure 5, 27 cases and 34 controls needed only oxytocin, while 22 cases and 20 controls needed only

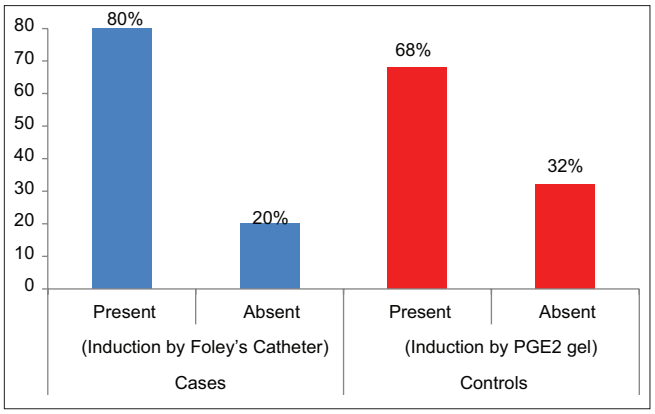

Figure 3: Vaginal delivery

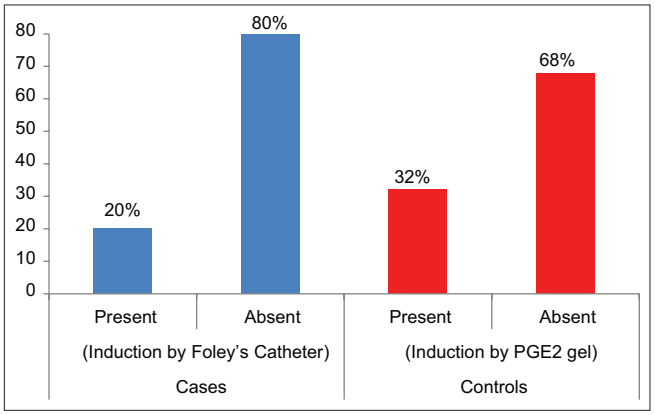

Figure 4: Cesarean section

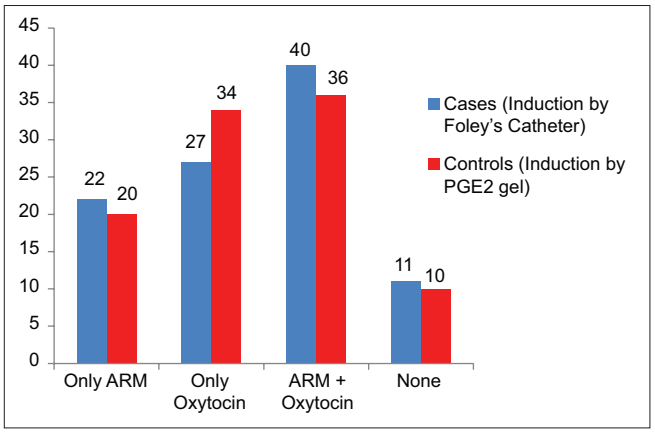

Figure 5: Need for augmentation

ARM and 40 cases and 36 controls needed both ARM and oxytocin for augmentation of labor. There was no need for augmentation in 11 cases and 10 controls. However, these differences were not statistically significant between cases and controls. Our study results were in accordance with studies done by Anupma *et al.*[19]

As shown in Figure 6, when comparing induction to delivery interval between two groups, induction to delivery interval was more in cases when compared to controls.

Table 8: Neonatal outcomes

Parameter	Cases (induction by Foley's Catheter)			Controls (induction by PGE_2 gel)			*P*-value
	Present	Absent	Total	Present	Absent	Total	
Still birth	0	100	100	0	100	100	1.000
APGAR score at 5 min (<7)	05	95	100	6	94	100	0.7564
Neonatal intensive care unit (NICU admission)	14	86	100	17	83	100	0.5578

Table 9: Cost of induction

Parameter	Cases (induction by Foley's catheter)	Controls (induction by PGE_2 gel)
Cost of induction (in INR)	180	240

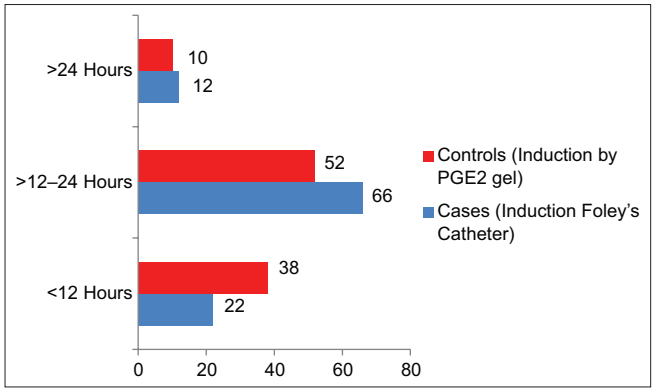

Figure 6: Induction to delivery interval

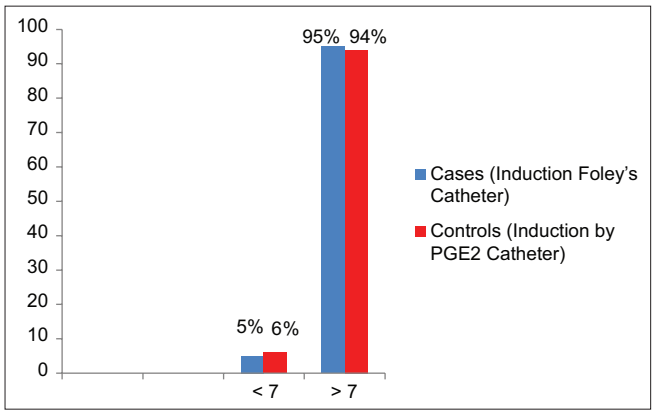

Figure 7: APGAR at 5 min

The difference between the two groups was statistically significant. Our study results were in accordance with studies done by Jozwiak *et al.*[16] and Kadam *et al.*[21]

Neonatal Outcome

As shown in Figure 7, in our study, data revealed that 5% of cases and 6% of controls had APGAR score at 5 min of <7. Hence, there is no statistically significant difference between Foley's catheter group and PGE_2 gel group in terms of APGAR score at 5 min. As shown in Figure 8, all the babies were born alive; there were no still births in both the groups. As shown in Figure 9, in our study, NICU

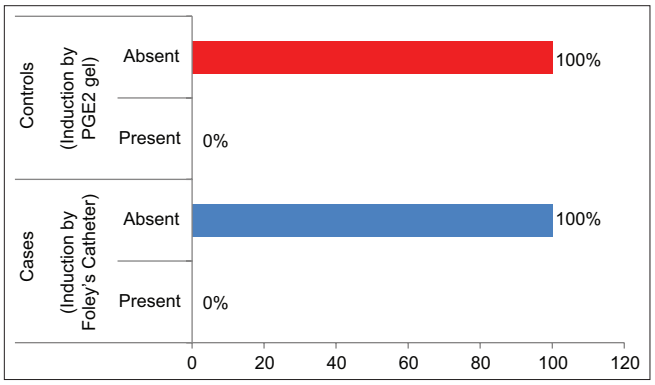

Figure 8: Still birth

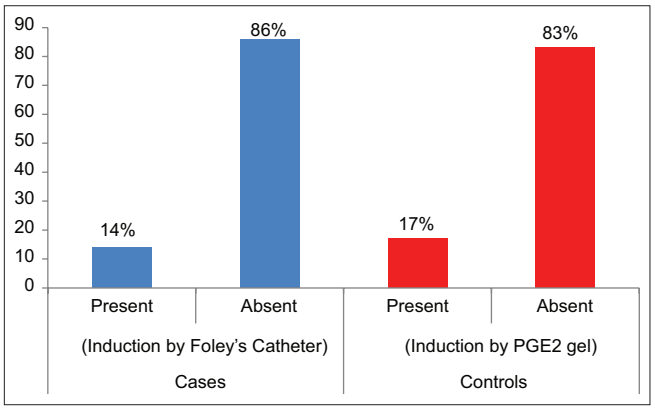

Figure 9: Neonatal intensive care unit admission

admission was seen in 14% of cases and 17% of controls. This meager increase of 3% among PGE_2 group had no statistical significance when compared to Foley's catheter group. All these neonatal outcomes were similar to studies done by Anupma *et al.*[19]

The average cost of induction was more in PGE_2 group (Rs.240) when compared to Foley's catheter group (Rs.180). This was consistent with studies done by Dewan *et al.*[22] Dahiya *et al.*,[23] and Dharmavijaya *et al.*[24]

CONCLUSION

Majority of the outcomes between the two groups were comparable and similar except for the induction to delivery interval. This duration was shorter for PGE_2 group when compared to Foley's catheter group. However, this outcome

alone does not make PGE_2 better than Foley's catheter in cervical ripening for IOL. In light of these results, in terms of maternal and neonatal outcomes in our study, we conclude that both Foley's catheter and PGE_2 gel had proved to be equally effective methods for pre-induction ripening for unfavorable cervix.

REFERENCES

1. Mozurkewich E, Chilimigras J, Koepke E, Keeton K, King VJ. Indications for inductions of labour; A best-evidence review. BJOG 2009;116:626-36.
2. National Institute for Health and Clinical Excellence (NICE). Induction of Labour. London: National Institute for Health and Clinical Excellence (NICE); 2008.
3. Sullivan AC, Benton LW, Roach H, Smith LG, Martin RW, Morrison JC. Combining medical and mechanical methods of cervical ripening. Does it increase the likelihood of successful induction of labor? J Reprod Med 1996;41:823-8.
4. Beta J, Issat T, Nowicka MA, Jakimiuk AJ. Risk factors for cesarean section after using the foley catheter for labor induction. Ginekol Pol 2013;84:359-62.
5. Vrouenraets FP, Roumen FJ, Dehing CJ, Van den Akker ES, Aarts MJ, Scheve EJ. Bishop score and risk of cesarean delivery after induction of labor in nulliparous women. Obstet Gynecol 2005;105:690-7.
6. Vardo JH, Thornburg LL, Glantz JC. Maternal and neonatal morbidity among nulliparous women undergoing elective induction of labor. J Reprod Med 2011;56:25-30.
7. Mishanina E, Rogozinska E, Thatthi T, Uddin-Khan R, Khan KS, Meads C. Use of labour induction and risk of casarean delivery: A systematic review and metanalysis. CMAJ 2014;186:665-73.
8. Hedegaard M, Lidegaard O, Skovlund CW, Mørch LS, Hedegaard M. Reduction in still births at term after new birth induction paradigm: Results of a national intervention. BMJ Open 2014;4:e005785.
9. Klefstad OA, Okland I, Lindtjørn E, Rygh AB, Kaada K, Hansen ML, *et al.* A more liberal approach towards induction of labour in prolonged pregnancy does not result in an adverse labour outcome. Dan Med J 2014;61:A4913.
10. Wood S, Cooper S, Ross S. Does induction of labour increase the risk of caesarean section? A systematic review and meta-analysis of trails in women with intact membranes. BJOG 2014;6:674-85.
11. Gulmezoglu AM, Crowther CA, Middleton P, Heatley E. Induction of labour for improving birth outcomes for women at or beyond term. Cochrane Database Syst Rev 2012;6:CD004945.
12. Jindal P, Gill BK, Tirath B. A comparison of vaginal misoprostol versus foley's catheter with oxytocin for induction of labour. J Obstet Gynaecol India 2007;57:42-7.
13. Hofmeyr GJ, Gulmezoglu AM, Alfirevic Z. Misopostol for induction of labour: A systematic review. Br J Obstet Gynaecol 1999;106:798-803.
14. Nasreen N, Mehket AS, Manazir A. Comparison of vaginal misoprostol and foley's catheter for cervical ripening. Intl J Sci Res 2013;4:475-8.
15. Pennell CE, Henderson JJ, O'Neill MJ, McChlery S, Doherty DA, Dickinson JE. Induction of labour in nulliparous women with an unfavourable cervix: A randomized controlled trial comparing double and single ballon catheter and PGE_2 gel. BJOG 2009;116:1443-52.
16. Jozwiak M, Rengerink KO, Benthem M, Van Beek E, Dijksterhuis MG, De Graaf IM, *et al.* Foley catheter versus vaginal prostaglandin E2 gel for induction of labour at term (PROBAAT trial): An open-label, randomized controlled trial. Lancet 2011;378:2095-103.
17. Baloch R, Muhabat Q, Waheed F, Ahmed W. Comparative effects of ballooning intracervical catheter and prostaglandin pessary on cervical ripening. Open J Obstet Gynecol 2016;6:525-33.
18. Alam A, Ahmed EA. A comparative study of intra-cervical foley's catheter and PGE_2 gel for pre-induction cervical ripening. Int J Reprod Contracept Obstet Gynecol 2016;5:2644-7.
19. Anupma, Karya U, Gaikwad HS, Anamika, Shalini A. A comparative study of transcervical foley's catheter with intracervical PGE2 gel for pre-induction cervical ripening. Int J Reprod Contracept Obstet Gynecol 2020;9:2581-6.
20. Sciscione AC, McCullough H, Manley JS, Shlossman PA, Pollock M, Colmorgen GH. A prospective, randomized comparison of foley catheter insertion versus intracervical prostaglandin E2 gel for preinduction cervical ripening. Am J Obstet Gynecol 1999;180:55-60.
21. Kadam DA, Kshirsagar NS, Patil SK, Patil Y. Comparative study of extra amniotic foley's catheter and intracervical PGE_2 gel for pre-labour cervical ripening. J Evol Med Dental Sci 2015;4:1672-80.
22. Dewan F, Ara AM, Begum A. Foley's catheter versus prostaglandin for induction of labour. Singap J Obstet Gynaecol 2001;32:56-63.
23. Dahiya K, Malik K, Dahiya A, Nanda S. Comparison of the efficacy of foley catheter balloon with dinoprostone gel for cervical ripening at term. Int J Clin Med 2012;3:527-31.
24. Dharmavijaya MN, Umashankar KM, Kavita G, Angure AG. Comparative study of intra-cervical Foleys catheter and PGE_2 gel for pre-induction ripening. Int J Basic Appl Med Sci 2013;3:247-53.

How to cite this article: Rashmi M, Sangeetha TM. Comparative Study on Transcervical Foley's Catheter and Intracervical PGE_2 Gel for Cervica Ripening for Induction of Labor. Int J Sci Stud 2022;10(4):14-20.

Source of Support: Nil, **Conflicts of Interest:** None declared.