ORIGINAL RESEARCH

Comparison of Efficacy of Pervaginal Misoprostol, Intracervical Foley Catheter, Intracervical Dinoprostone on Induction of Labor

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Received on: 31 January 2023; *Accepted on:* 20 June 2023; *Published on:* XX XXXX XX

Abstract

Introduction: Induction methods are many such as intravaginal misoprostol, intracervical Foley catheter, intracervical dinoprostone, etc. Presently, a very limited number of studies are available for comparing all three popular methods intravaginal misoprostol, intracervical Foley catheter, and intracervical dinoprostone.

Aims and objectives: Comparison of efficacy of pervaginal misoprostol, intracervical Foley catheter, and intracervical dinoprostone on induction of labor and fetomaternal outcome.

Materials and methods: It is a prospective study conducted on 273 patients divided into 3 groups, and each group included 90 study subjects.

- Group I – Foley catheter of No. 18 introduced in the cervical canal. The Foley catheter balloon is filled with 50 mL of normal saline.
- Group II – Dinoprostone 2.5 mL of 0.5 mg injected into the cervical canal below the internal os under aseptic precautions.
- Group III – Tablet misoprostol 25-µg pervaginally put in the posterior fornix. Continuous observation of the patients will be done in all groups.

Results: Success of induction was 100% in the Foley catheter, 92.3% in dinoprostone gel, and 90% in the misoprostol group, respectively. Vaginal delivery occurred—83.51% in Foley catheter, 59.34% in dinoprostone gel, and 73.62% in the misoprostol groups, respectively.

The mean induction to delivery interval time was 16.78 ± 6.5 hours in the Foley catheter group, 12.87 ± 6.41 hours in the dinoprostone gel group, and 11.16 ± 5.97 in the misoprostol group.

Conclusion: Foley catheter is superior to dinoprostone gel and misoprostol in achieving vaginal delivery.

Keywords: Dinoprostone, Foley catheter, Misoprostol.

Journal of South Asian Federation of Obstetrics and Gynaecology (2023): 10.5005/jp-journals-10006-2358

Introduction

Induction of labor is defined as the stimulation of contractions before the spontaneous onset of labor with or without ruptured membranes. The incidence of induction of labor is 5–22%. Induction of labor is the most commonly and importantly done intervention in pregnancy. Induction of labor is a major obstetric challenge.[1,2]

Common indications for induction of labor are postdated and prolonged pregnancy, etc. Commonly used Methods for induction of labor are mechanical methods and pharmacological methods. Mechanical methods include sweeping of membranes, transcervical Foley catheter, and extra-amniotic saline infusion. Pharmacological methods use PGE_2, oxytocin, and misoprostol.[3]

Foley catheter method for induction of labor has increasing popularity due to its better safety profile lesser side effects and less close observation, monitoring of patients.[4–7] Induction with the Foley balloon catheter may result in a reduction of risk to the fetus, but with the caveat of a slower labor and an increased use of oxytocin.[8,9]

Complications of induction of labor are hyperstimulation, tachysystole, failure of induction of labor, prematurity, placental detachment, fetal pneumonia, neonatal jaundice. It is also more likely to require pain relief like epidural analgesia and assisted birth. Induction of labor places more strain on labor wards than spontaneous labor due to need of closed observations. Traditionally, induction is undertaken during daytime when labor wards are often already busy resulting in more burden.

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How to cite this article: Nipanal HV, Uppar P, Talawar SR, *et al*. Comparison of Efficacy of Pervaginal Misoprostol, Intracervical Foley Catheter, Intracervical Dinoprostone on Induction of Labor. J South Asian Feder Obst Gynae 2023;x(x):xx–xx.

Source of support: Nil

Conflict of interest: None

Presently very limited number of studies available for comparing all three popular methods that intravaginal misoprostol, intracervical Foley catheter, intracervical dinoprostone.

Aims and Objectives

Comparison of efficacy of pervaginal misoprostol, intracervical Foley catheter, intracervical dinoprostone on induction of labor and fetomaternal outcome.

Materials and Methods

It is a prospective hospital based interventional study cantered in department of obstetrics and gynaecology of Gadag Institute of Medical Sciences, Gadag, Karnataka, India from January 2021 to December 2022 and subjects sampling technique was by purposive sampling.

The study design was analytical study conducted on 273 patients will be studied for the study. Each group will include 90 study subjects. It is calculated by standard formula of proportion using previous study by Noor et al.[10] With 95% confidence interval, 5% level of significance with 4% desired precision and also applying 10% rule.

Inclusion Criteria

Patient with

- Singleton,
- Cephalic,
- Term gestation,
- Intact membranes,
- Live fetus, and
- Absence of uterine contractions.

Exclusion Criteria

- Pregnancy induced hypertension,
- Fetal distress,
- Previous cesarean section,
- Uterine surgery,
- Intrauterine growth reduction,
- Malpresentation,
- Oligohydramnios [amniotic fluid index (AFI) <5 cm],
- Polyhydramnios,
- Diabetic mellitus.

Patients are screened for inclusion and exclusion criteria. Informed written consent is taken. Study subjects divided into three groups by investigator choice.

- Group I – Under aseptic precautions Bishop score will be assessed. Foley catheter of No. 18 introduced in the cervical canal. Foley catheter balloon is filled with 50 mL of normal saline. Catheter is tagged to right thigh. Will be waited for 24 hours to auto expel or deflate the balloon.
- Group II – Bishop score will be assessed. Dinoprostone 2.5 mL of 0.5 mg injected into the cervical canal below the internal os under aseptic precautions. Watch for uterine contractions and fetal heart rate. Will be followed by reassessment of the Bishop score after 6 hours. Dinoprostone can be repeated every 6 hours for maximum of 3 doses.
- Group III – Patient lied on supine position with legs semi-flexed. Bishop score will be assessed. Tablet misoprostol 25 microgram pervaginally put in the posterior fornix. Watch for uterine contractions and fetal heart rate. Will be followed by a reassessment the Bishop score after 4 hours. The dose can be repeated every 4 hours for a maximum of 6 doses.

Continuous observation of the patients will be done. If patients go for uterine hyperstimulation with fetal distress or failed induction, they are taken to other induction of labor or cesarean section. The outcome is measured in rate of vaginal delivery, rate of cesarean section, risk of hyperstimulation and fetal distress.

Success of Induction

Success of induction is defined as if patient has gone to active phase of labor (i.e., 4 cm cervical dilatation or adequate uterine contractions) within 48 hours of induction with or without oxytocin.

Failed Induction

If patient does not gone to active phase of labor (i.e., 4 cm cervical dilatation or adequate uterine contractions) within 48 hours of induction with or without oxytocin.

Statistical Method

Data were entered in the Microsoft Excel sheet. Data was analyzed using statistical package for the social sciences (SPSS) software, version 22.

Results

The present study was performed on 273 cases which are divided into three groups, namely, group I, group II, and group III each containing 91 cases. Group I had Foley catheter, group II had dinoprostone gel and group II had misoprostol as method of induction.

In our study with respect to age all groups were similar with a *p*-value of 0.7. The mean maternal age in group I was 23.74 years, in group II was 24.10 years, and 23.85 years in group III. The majority of women in this groups were between the age group of 20–30 years, constituting 83 (90%) in group I, 74 (81%) in group II and 83 (91%) in group III. Age with 30–40 years were 7 (7%) in group I, 11 (12%) in group II, and 6 (6.5%) in group III. With respect to parity also all the groups were similar with *p*-value of 0.71. Primigravida constitutes 65% in group I, 61% in group II, and 67% in group III. Multigravida constitutes 34% in group I, 41% in group II, and 32% in group III, respectively.

In our study with respect to gestational age, group II and group III were similar ($p = 0.09$) whereas group 1 and group II, group 1 and group III were not similar ($p < 0.05$). The mean gestational age in group I was 39.95 weeks, in group II was 39.60 weeks, and in group III was 39.28 weeks. Majority of the women in the study, were in the gestational age group of 40–41 weeks.

All groups were similar with respect to indication for induction with a *p*-value of 0.085. Majority of indications in all groups were postdated. With respect to preinduction Bishop score, group II and group III were similar whereas group I and group II as well as group I and group III were not similar with *p*-value > 0.05.

Majority of inductions were done in Bishop score of 0–4. Least common were 1, 6, and >6. Most common Bishop score was 2 and 3 in group I and group II while 2 and 4 in group III (Fig. 1).

Postinduction Bishop score in all the study groups were ranged from 3 to 13 in group I and II whereas it was 4–13 in group III. In comparison of postinduction Bishop score group I and group II, group 1 and group III were not similar whereas group II and group III were similar (Table 1).

Success was 91 (100%) in group I, 84 (92.3%) in group II, and 81 (90%) in group III. There was statistically significant difference found only between group I and group whereas rest were statistically not significant (Table 2).

In the present study with respect to meconium-stained liquor, all groups were similar with a *p*-value of 0.15, whereas with respect to hyperstimulation, there was statically significant difference between group I and group III ($p = 0.004$). There was also statically

significant difference between group I and group II in consideration of non-reassuring prenatal non-stress test (NST) ($p = 0.01$).

In dinoprostone gel group 23 (25%) cases required repeated application. Out of which 20 (22%) required second application and 3 (3%) required third application. In misoprostol group, 23 (25%) cases required multiple doses, out of which 20 (22%) cases were required 2 doses, 3 (3%) cases were required 3 doses.

In the present study with respect to vaginal delivery, group I and group II were statistically significant with a *p*-value of 0.001. Vaginal delivery was occurred in 76 (83.51%) subjects of group I whereas in group II, it was 54 (59.34%). In group III, vaginal delivery was occurred in 67 (73.62%) subjects. The number of lower (uterine) segment cesarean section (LSCS) were more in group II 37 (40%) followed by group III 24 (26.37%) (Table 3).

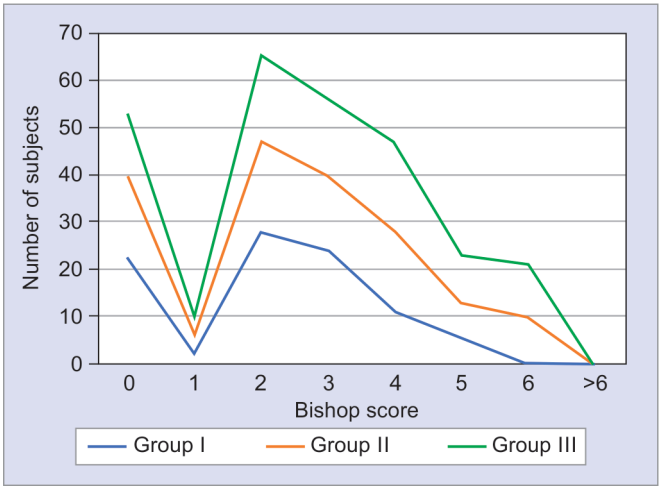

Fig. 1: Preinduction Bishop score distribution of subjects

Most of the cases underwent LSCS with the indications of non-reassuring NST. Least were found to be failed induction.

In our study with respect to mean induction, to delivery interval time was statically significant in group I comparing with both group II and group III with *p*-value of 0.00 whereas there is no significant difference between group II and group III.

The mean interdelivery interval (IDI) time was 16.78 ± 6.5 hours in group I and 12.87 ± 6.41 hours in group II, and 11.16 ± 5.97 in group III (Fig. 2).

Majority of new born babies had appearance, pulse, grimace, activity, and respiration (APGAR) score more than 7 in all groups. Only 2 (2.20%) newborns in group II and group III were had APGAR score less than 7 which is statistically not significant with a *p*-value of 0.4. There were no fetal complications.

Side effects are more commonly seen in group II and group III. Vomiting 10 cases (4%) in group III. Atonic postpartum hemorrhage was seen in 21 (7.69%) cases of which 5 (5.49%) in group I, 8 (8.79%) in group II, and 8 (8.79%) cases in group III. Among 21 cases, 15 were managed by medical method whereas 6 required compression sutures 2 in group II and 4 in group III, respectively, in subjects of LSCS. Hyperstimulation was more in group III 10 (10.98%) cases followed by group III 6 (6.59%) cases.

Discussion

The mean maternal age in group I was 23.74 years which is comparable with Leigh et al.[8] In group II, our study mean age

Table 1: Postinduction Bishop score distribution of subjects

Postinduction Bishop score	*Group I (Foley catheter)*	*Group II (Dinoprostone gel)*	*Group III (Misoprostol)*	*Total*
<5	1	5	3	12
5–10	77	51	58	185
>10	13	35	30	76
Total	91	91	91	273
Mean ± SD	8.56 ± 2.0	9.52 ± 2.6	9.75 ± 2.23	9.15 ± 2.4

Significance: 0.001

Table 2: Success of induction of labor

Group	*Group I (Foley catheter)*	*Group II (Dinoprostone gel)*	*Group III (Misoprostol)*	*Total*
Success*	91 (100%)	84 (92.3%)	81 (89%)	257 (94.13%)
Failure	0 (0%)	7 (7.69%)	10 (11%)	16 (5.87%)
Total	91 (100%)	91 (100%)	91 (100%)	273 (100%)

*Success of induction of labor depends on achieving cervical dilatation of more than 4 cm or good uterine contractions as per FOGSI guidelines

Table 3: Mode of delivery distribution of patient

Mode of delivery	*Group I (Foley catheter)*	*Group II (Dinoprostone gel)*	*Group III (Misoprostol)*	*Total*
Vaginal	70 (76.92%)	46 (50.54%)	59 (64.83%)	175 (64.10%)
Instrumental (vacuum/forceps)	6 (6.59%)	8 (8.79%)	8 (8.79%)	22 (8.05%)
Toal vaginal deliveries	76 (83.51%)	54 (59.34%)	67 (73.62%)	197 (72.16%)
LSCS	15 (16.48%)	37 (40.65%)	24 (26.37%)	76 (27.83%)
Total	91 (100%)	91 (100%)	91 (100%)	273 (100%)

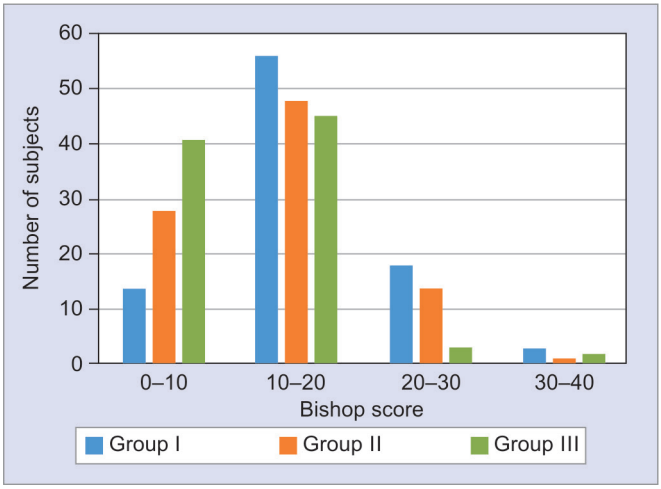

Fig. 2: Induction to delivery interval time of subjects

was 24.10 years which is similar to that of the study by Madaan et al.[11] In group III, our study mean age was 23.85 years whereas that of Dasgupta Ellora and Gurneesh Singh[12] was 21.6 years.

The number of primigravida were 65.93% in group I which is comparable with Chowdhary et al.[13] In group II, primigravida were 61.53% which is similar to Madaan et al.[11] In group III, primigravida was 65.93% whereas in Young DC et al.,[14] it was 62%.

The mean gestational age in group I was 39.9 weeks which is comparable with Noor et al.[10] In group II, our study mean gestational age was 39.6 which is similar to Young et al.,[14] Bennett et al.,[15] Madaan et al.[10] study.

In group I, mean preinduction Bishop score was 2.18 whereas 2.5 in Chia et al.[4] and Cazorla et al.[16] study, 3.1 in Ghanaie et al.[17] study. In group II, mean preinduction Bishop score was 2.95 whereas it was 2.9 in the study by Henry et al.[18] and it was 4.2 in the study by Young et al.[14] study. In group III, mean preinduction Bishop score was 3.12 whereas it was 3 in the study by Bhatiyani et al.[19]

In group I, mean postinduction Bishop score was 8.5 whereas it was 6 in the study by Anqa Chowdhary et al.[13] In group III, mean postinduction Bishop score was 9.7 whereas it was 10 in Binti R Bhatiyani et al.[19]

In group I 83.51% of subjects were delivered by vaginally which is comparable with the study by Garba et al.,[20] Hamdan et al.,[21] and Deshmukh et al.[22] whereas it was 76% in the study by de Vaan et al.;[7] 75% in the studies by Chowdhary et al.[13] and Ghanaie et al.[17] In group II, 59.34% of subjects were delivered by vaginally whereas it was 65% in the study by Ghanaie et al.,[17] it was 72.7% in the study by Young et al.,[14] it was 76% in the study by Benalcazar–Parra et al.,[23] it was 83% in the study by de Vaan et al.[7] In group III, 73.62% of subjects were delivered by vaginally whereas it was 68.6% in the study by Young et al.[14]

The mean integrated discharge team (IDT) in group I was 16.7 hours whereas it was 15.3 hours in the study by Deshmukh et al.[22] and 14 hours in the study by Leigh et al.[8] The mean IDT in group II was 12.8 hours whereas it was 14.2 hours in the study by Deshmukh et al.,[22] it was 14.9 hours in the study by Madaan et al.,[11] it was 18.9 hours in the study by Ghanaie et al.,[17] and it was 20 hours in the study by Chia et al.[4]

Conclusion

Foley catheter is superior to dinoprostone gel and misoprostol in achieving vaginal delivery as well as success of induction. Although induction to delivery interval time is more but it has got other advantages like less painful, less chance of failure of induction with good perinatal outcome, minimum chance fetal distress and negligible hyperstimulation.[24,25] Hence, Foley catheter is a good method of induction of labor which is effective, safe, economical, easy to store, readily available, with less side effects.[26,27]

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