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"COMPARISON BETWEEN VAGINAL MISOPROSTOL VERSUS SEQUENTIAL USE OF INTRACERVICAL FOLEY CATHETER FOLLOWED BY MISOPROSTOL FOR INDUCTION OF LABOR IN TERM PREGNANCY AND IT'S FETOMATERNAL OUTCOME"

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ABSTRACT

Background and Objectives: Induction of labor is initiating labor before spontaneous onset of labor in a viable pregnancy, is often considered when the benefits of induction outweigh the risks of continued pregnancy. Induction is commonly advised to prevent the progression of maternal illness, neonatal morbidity, or foetal demise in response to a wide variety of medical indications. There are many factors which affect successful induction. Favourable factors include younger age, multiparity, body mass index (BMI) <30, favourable cervix and fetal birth weight <3500 gms,with the most importantly being favorability of cervix assessed by Bishop's score.

Methods: The study compared vaginal misoprostol with a sequential approach (Foley catheter followed by misoprostol) for inducing labor in 130 patients each (Group A and Group B) at Dr. Ram manoharlohia institute of medical sciences, Lucknow, uttarpradesh, india. The demographic characteristics including age, parity, indication for induction of labour,augmention, Bishop's score, no of doses of misoprostol, timing of intracervical foleys catheter, induction to delivery interval, mode of delivery and maternal / neonatal outcomes were evaluated.

Results: The time from induction to delivery did not significantly differ between the groups, despite numerical variations.Differences in the mode of delivery (LSCS, NVD, instrumental) were not statistically significant.Indications for LSCS, such as foetal distress and failure to progress, were similar in both groups.Instrumental delivery was infrequently needed in both groups .Group A had a trend towards more uterine hyperstimulation (2.31%) compared to none in Group B (p-value = 0.0815).Rates of non-reassuring foetal heart rate were comparable between the groups, suggesting consistent monitoring.APGAR scores below 7 at 1 minute and 5 minutes were similar in both groups, with no significant differences.Both induction methods (misoprostol alone and sequential approach) effectively induced labor, with outcomes influenced by patient characteristics.

Conclusion: Evaluation of effective methods for induction of labour, has a very important role in obstetrics as timely and safe induction can reduce maternal and neonatal morbidity and mortality.The study reflects standard obstetric practices, highlighting the need for individualized care and flexible induction protocols to decrease the maternal and neonatal morbidity n mortality risks providing maximum benefits and positive obstetric outcomes.

Keywords: Induction of Labor, Misoprostol, Intra cervical Foley Catheter

INTRODUCTION

Induction of labor is initiating labor before spontaneous onset of labor in a viable pregnancy, is often considered when the benefits of induction outweigh the risks of continued pregnancy .[1]

In the United Kingdom, the rate of induction of labor ranges from 6 to 25% with the average being about 20%. In the USA the average rate of induction of labor is approximately 13%[2,3], while in India it is 10%[4].

Induction is commonly advised to prevent the progression of maternal illness, neonatal morbidity, or foetal demise in response to a wide variety of medical indications.

Common indications of induction of labour include prelabour rupture of membranes, gestational hypertension, oligohydramnios, nonreassuringfetal status, postdated pregnancy, Intrahepatic cholestasis of pregnancy, and maternal medical conditions like chronic hypertension and diabetes mellitus [5]

The maternal contraindications for labour induction are abnormal placental implantations such as Placenta previa, some rare maternal infections like active phase of genital herpes infection, cervical cancer, malpresentations, cephalopelvic disproportion.

Ripening of the cervix is a prerequisite for an effective induction. An increased risk of induction failure is associated with an unripe cervix that has a lower Bishop score, whereas a timely delivery is substantially predicted by a cervix that is favourable. [6] The inducibility of labour is highly correlated with prelabor cervical status, and cervical maturation increases the efficacy of labour induction. [7]

There are many factors which affect successful induction. Favourable factors include younger age, multiparity, body mass index (BMI) <30, favourable cervix and fetal birth weight <3500 gms[8],with the most importantly being favorability of cervix.

One quantifiable method used to predict labor induction outcome is the score described by Bishop (1964)[9].As favorability or Bishop Score decreases, the rate of induction to effective vaginal delivery also declines.

Maternal complications associated with labor induction are postpartum hemorrhage, uterine atony , chorioamnionitis, and uterine rupture.

Numerous studies have contrasted the two procedures—intravaginal misoprostol and intracervical Foley catheter—either separately or in combination [10,11]

Prostaglandins promote the maturational changes of cervical ripening by modifying collagen and altering the relative concentration of glycosaminoglycans in the cervix when applied directly to the cervix. [12]

Due to its favourable efficacy, affordability, and stability at ambient temperature, misoprostol (prostaglandin E1) is commonly employed in the field of obstetrics and gynaecology [13] The conventional mechanical technique, initially documented by Embrey and Mollison in 1967, involves the insertion of an intracervical Foley catheter (ICF) into the cervical canal. By gently tractioning the ICF outward, the catheter dilates the cervix just beyond the internal os, thereby stimulating prostaglandin (PG) and oxytocin secretion and facilitating direct cervix dilation. [14,15] Synergistic effects between the two distinct mechanisms have been postulated, as supported by the research of Al-Ibraheemi Z et al. and several other authors [16,17].

One of the main concerns of labor induction is on cesarean delivery. However, the true relationship between caesarean delivery and labour induction, upon closer inspection, there does not appear to be a statistically significant association between the two.

Furthermore, research has identified cervical examination status as a substantial effect modifier in this correlation; specifically, caesarean delivery rates

following labour induction were highest among women with an unfavourable cervix.

When comparing foetal and maternal outcomes, it is critical to take into account critical factors such as the rates of caesarean sections, neonatal admissions, and maternal complications. The selection among these approaches ought to be personalised, taking into account the particular circumstances surrounding the pregnancy.

Various studies have been done comparing different methods of induction but there is no consensus regarding which method for Induction of labor is more appropriate and effective, safe as well as cheaper.

Hence, this study aims to know the effectiveness of vaginal misoprostol and sequential use of intracervical foley catheter followed by misoprostol for induction of labor in term pregnancy and it's fetomaternal outcome.

AIMS AND OBJECTIVES

AIM:

To Compare the effect of Intravaginal Misoprostol alone with sequential use of Intra Cervical Foley Catheter followed by Intravaginal Misoprostol for Induction of labor

OBJECTIVES:

PRIMARY

1. To compare the Induction to delivery Interval in both the groups.
2. To compare the Mode of delivery and Indication of Caesarean section

SECONDARY

1.Adverse maternal outcomes- Various Adverse outcome can be there

- Tachysystole/PPH/Puerperal Sepsis/Uterine Rupture/NPOL

2. Adverse neonatal outcomes:

- Non reassuring fetal heart rate.
- Apgar scores <7 at 5 minute.
- Admission to the neonatal ward/NICU and its reason (suspected infection, infection proven by positive culture, other reasons for admission or intensive care).
- Meconium-Stained Liquor.

MATERIAL & METHODS

Type Of Study- Prospective Observational Study

Study duration: 18 months

Setting And Location – DR. Ram Manohar lohia Institute Of Medical Sciences , Lucknow

Sample size: (N) – 130 patients were included in 2 groups.

All women presenting for delivery and consenting to be part of this study shall be explained in detail about both the methods and their advantages & disadvantages, and to their husbands or primary caregivers coming with women. They would have a choice of choosing either of the methods based on the collective decision of the women & the husband/caregiver.

Divided into two groups –

Group A– should have participants using Intravaginal Misoprostol only

Group B- should have participants using Intracervical Foley Catheter followed by Intravaginal Misoprostol.

INCLUSION CRITERIA
1. Nulliparous **2.** Age 18-35 yrs **3.** Period of Gestation 37-42 weeks

4. Singleton gestation with Cephalic presentation
5. Intact membranes
6. Reactive Non-Stress Test
7. Modified Bishop Score <6
8. Antenatal pregnant women of 37-42 weeks gestation in whom induction of labour is indicated (other than exclusion criteria)

EXCLUSION CRITERIA

1. Multiparous
2. Period of gestation <37 weeks and >42 weeks
3. Women with Vaginal Infection
4. Antepartum bleeding
5. Intrauterine fetal death
6. Placenta Praevia
7. Cephalopelvic Disproportion
8. Non-Cephalic fetal presentation
9. Pregnancy with known congenital malformation of the fetus.

METHODOLOGY:

1. Ethical Clearance was taken before enrollment of the patient for study.
2. All pregnant women during their visit for ANC (Antenatal Care) fulfilling the inclusion criteria were included in the study after obtaining informed consent.
3. At 37-42 weeks, on follow-up, the patient requiring Induction of Labor was admitted and based on patient choice, they were divided into two groups
4. All Antenatal and relevant investigations were sent.
5. Maternal and Fetal Surveillance was done in the Labor room.
6. General Examination followed by Obstetrics Examination was done –

Per Abdominal Examination, Per Speculum Examination, Per Vaginal Examination (to assess Bishop Score).

7. Group A- Pregnant women were Induced by Intra vaginal misoprostol. A 25 micro gm of misoprostol was placed intravaginally and the dose was repeated every 4 hours up to 8 doses as per Bishop Score.

8. Group B- Pregnant Women were induced by Intracervical Foley Catheter. Under direct visualization, a 16-F Foley catheter was inserted into the endocervical canal. Once the catheter tip was inside the internal os, the balloon was inflated with 50-60 ml sterile saline solution and pulled against the internal os of the cervix.

9. The external end of the Foley catheter was taped with tension to the medial aspect of the maternal thigh. Cardiotocography was conducted after catheter insertion and hourly.

10. Foley catheter was kept insitu till one of the following happened: (1) spontaneous expulsion, (2) maximum period of 12 h was reached, and then 25 mcg misoprostol tablet was inserted in the posterior vaginal fornix immediately after removal of Foley catheter and every 4 h up to a maximum of 8 doses as per Bishop Score.

11. Hourly monitoring was done by Cardiotocography and maintaining partograph till delivery.

12. Once cervical ripening occurs or Bishop more than 6, we did Oxytocin Augmentation if Uterine contractions are inadequate.

13.PostPartum follow-up was done till discharge.

14. Analysis of outcome measures was done.

15.Data was entered in Microsoft Excel and analysed using statistical software SPSS version 26 (SPSS Inc., Chicago, IL, USA).

OBSERVATION & RESULTS

Table-1: Age distribution of the enrolled patients.

AGE (yrs)	GROUP-A (130)		GROUP-B (130)		P-VALUE
	N	%	N	%	
18-25	82	63.08%	90	69.23%	X=1.237 p=0.5387
26-30	33	25.38%	26	20.00%	
31-35	15	11.54%	14	10.77%	
MEAN±SD	28.94±7.94		29.88±6.84		t=1.541 p=0.8461

Table-2: Bishop score distribution of the enrolled patients among the groups.

BISHOP SCORE	GROUP- A (TOTAL-130)		GROUP B (TOTAL-130		P VALUE
	N	**%**	**N**	**%**	
1	28	21.54%	12	9.23%	X=14.74 **p=0.0053***
2	52	40.00%	56	43.08%	
3	25	19.23%	46	35.38%	
4	16	12.31%	10	7.69%	
5	9	6.92%	6	4.62%	

Indication for induction in two groups-

The below given pie chart displays the distribution of high-risk factors between Group A and Group B, with both groups consisting of the same number of participants (N=130). For each listed risk factor, the percentages of occurrence are similar between the two groups, with no statistically significant differences.

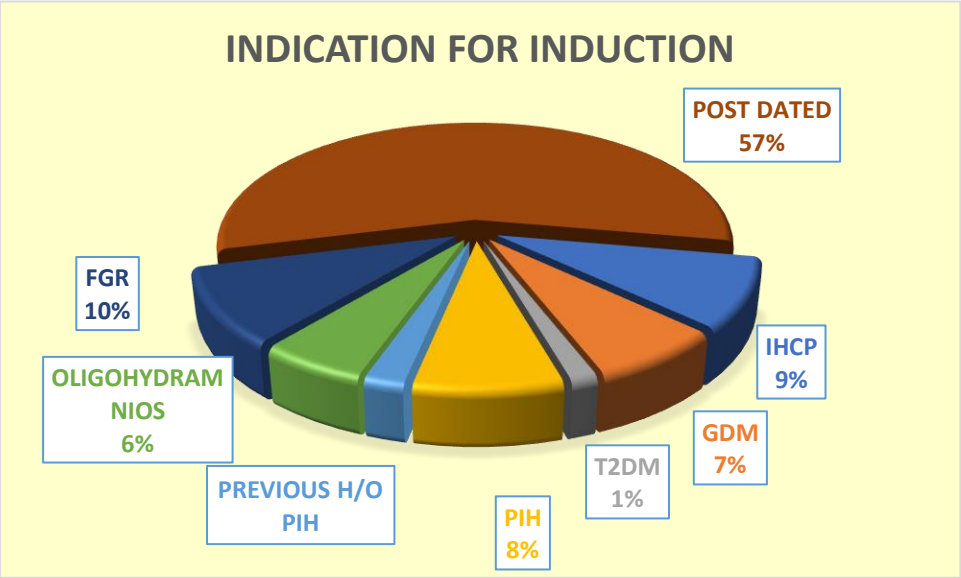

Figure-3: Graphical representation of the Indication for induction in two groupTable: 3- No. of dose of misoprostol given to the patients of groups-A.

NO. OF DOSE OF MISOPROSTOL ONLY	GROUP-A	
	N	%
1	3	2.31%
2	5	3.85%
3	24	18.46%
4	38	29.23%
5	31	23.85%
6	18	13.85%
7	5	3.85%

8	6	4.62%

Table-4: Duration of Intracervical Foley's Catheter in Group B -

DURATION OF FOLEY'S	GROUP-B	PERCENTAGE
<12 hrs	32	24.62%
12 hrs	98	75.38%

Table-5: No. of dose ofMisoprostolafter intracervicalfoley'sin Group B-

NO. OF DOSE OF INTRACERVIAL FOLEY'S F/B MISO	GROUP-B	
	N	%
1	22	16.15%
2	39	29.23%
3	32	23.85%
4	17	12.31%
5	9	6.15%
6	7	5.38%
7	4	3.08%
8	5	3.85%

Table-6: Distribution of patient who were augmented in Two groups-

AUGMENTATION	GROUP A (130)		GROUP B (130)		P-VALUE
	N	%	N	%	
YES	114	87.69%	119	91.54%	X=1.033 p=0.3094
NO	16	12.31%	11	8.46%	

Table-7: Induction delivery Interval in two groups.

INDUCTION TO DELIVERY INTERVAL	GROUP-A		GROUP-B		P-VALUE
	N	%	N	%	
≤12 hrs	6	4.62%	3	2.31%	X=4.611 p=0.0997
>12-24 hrs	80	61.54%	67	51.54%	
>24 hrs	44	33.85%	60	46.15%	

Table-8: Mode of Delivery Distribution in Two Groups -

MODE OF DELIVERY	GROUP-A		GROUP-B		P-VALUE
	N	%	N	%	

LSCS	55	42.31%	43	33.08%	X=3.672 p=0.1595
NVD	67	51.54%	82	63.08%	
INSTRUMENTAL	8	6.15%	5	3.85%	

Figure-9: Indication of LSCS Distribution in Two Groups

INDICATION OF LSCS	**GROUP-A (TOTAL LSCS-55)**		**GROUP-B (TOTAL LSCS-43)**		**P-VALUE**
	N	%	N	%	
2nd STAGE ARREST	7	12.73%	3	6.98%	X=4.158 p=0.5268
FAILED INDUCTION	6	10.91%	5	11.63%	
FAILURE TO PROGRESS	13	23.64%	12	27.91%	
FETAL DISTRESS (NONREACTIVE NST)	14	25.45%	15	34.88%	
FETAL DISTRESS (MSL)	12	21.82%	8	18.60%	
HYPERSTIMULATION	3	5.45%	0	0.00%	

Table-10: Indication of Instrumental Delivery among the groups.

INDICATION OF INSTRUMENTAL DELIVERY	**GROUP-A**		**GROUP-B**		**P-VALUE**
	N	%	N	%	
POOR MATERNAL BEAR DOWN EFFORT WITH FETAL DISTRESS	8	6.15%	5	3.85%	X=0.7287 p=0.3933

IN 2nd STAGE OF LABOR					

Table-11: Uterine Hyperstimulation In Two Groups-

HYPERSTIMULATION	GROUP-A		GROUP-B		P-VALUE
	N	%	N	%	
YES	3	2.31%	0	0.00%	X=3.035 p=0.0815
NO	127	97.69%	130	100.00%	

Table-12: Non-Reassuring Fetal Heart Rate among the groups.

NONREASSURING FHR	GROUP-A		GROUP-B		P-VALUE
	N	%	N	%	
YES	14	10.77%	15	11.54%	X=0.03881 p=0.8438
NO	116	89.23%	115	88.46%	

Table-13: APGAR score at the 1 and 5 min among the groups.

	GROUP A		GROUP B		P-VALUE
	N	**%**	**N**	**%**	
APGAR <7 at 1 min	15	11.54%	13	10.00%	X=0.1601 p=0.6891
APGAR <7 at 5 min	9	6.92%	6	4.62%	

Table-14: Need of Resuscitation in the patients among the groups.

NEED OF RESUSCITATION	GROUP-A		GROUP-B		P-VALUE
	N	%	N	%	
NO	115	88.46%	117	90.00%	X=0.1601 p=0.6891
YES	15	11.54%	13	10.00%	

Table-15: NICU admission of the enrolled patients among the groups.

GROUP-A (11)				**GROUP-B (8)**			
N (11)	Diagnosis	NICU Stay	OUTCOME	N (8)	Diagnosis	NICU Stay	OUTCOME
6	Meconium Aspiration Syndrome	2 for 1 day 2 for 3 days 1 for 4 days 1 for 12 days	5 discharged In satisfactory condition 1baby expired after 12 days (ARDS)	4	Meconium Aspiration Syndrome	1 for 1 day 1 for 3 days 1 for 5 days 1 for 6 days	All Discharged in satisfactory condition
3	Acute Respiratory Distress Syndrome	1 for 4 days 1 for 6 days 1 for 9 days	2 discharged In satisfactory condition 1 expired on day 6 (ARDS)	3	Acute Respiratory Distress Syndrome	1 for 2 days 1 for 4 days 1 for 7 days	2 Discharged In satisfactory condition 1 expired on day 4 (ARDS)
1	Sepsis	1 for 7 days	Discharged in satisfactory condition	1	Sepsis	1 for 9 days	Discharged in satisfactory condition
1	Hypoxic ischemic encephalopathy	For 7 days	baby expired on day 7 (HIE grade 3)	0	-	-	-

	grade-3						

Table-16: Outcome of the baby in the NICU among the groups.

OUTCOME OF BABY IN NICU	GROUP- A (11)		GROUP- B (8)		P-VALUE
	N	%	N	%	
Discharged in satisfactory condition	8	72.73%	7	87.50%	X=0.6081 p=0.4355
Mortality	3	27.27%	1	12.50%	

Table-17: Maternal post-operative complications in the enrolled patients.

MATERNAL POST OP COMPLICATION	GROUP-A		GROUP-B		P-VALUE
	N	%	N	%	
PPH	8	6.15%	3	2.31%	X=2.373 p=0.1234
HYPERSTIMULATION	3	2.31%	0	0.00%	X=3.035 p=0.0815
UTERINE RUPTURE	0	0.00%	0	0.00%	--
PUERPERAL SEPSIS	0	0.00%	0	0.00%	--
OTHERS	0	0.00%	0	0.00%	--

DISCUSSION

A prospective observational studywas done in, department of obstetrics and gynaecology

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from a period of October 2022 to April 2024.

All women presenting for delivery and consenting to be part of this study, had a choice of choosing either of the methods for induction of laborand weredevided into two groups-

Group A (130 participants)– Intravaginal Misoprostol only
Group B(130 participants)– Intracervical Foley Catheter followed by Intravaginal Misoprostol.

In our study ,the age distribution analysis of patients in Group A and Group B did not reveal statistically significant differences across the analysed age ranges (18-25yrs, 26-30yrs, and 31-35 yrs). Specifically, Group A has 82 patients (63.08%) aged 18-25 years, compared to 90 patients (69.23%) in Group B, yielding a non-significant p-value of 0.5387 with a test statistic X=1.237 (Jozwiak et al., 2012). Similarly, for the 26-30 age range, Group A has 33 patients (25.38%) while Group B has 26 patients (20.00%), and for the 31-35 age range, the numbers are 15 (11.54%) and 14 (10.77%) for Groups A and B, respectively, suggesting random variation rather than systemic differences between groups**.** Similarly, **Jozwiak et al., 2012** [18]found no significant differences in age distribution between groups undergoing labour induction with various methods.

In present study conducted, baseline Bishop Scores were <6 in both the groups.In Group A, 28 individuals (21.54%) scored 1, while in Group B, 12 individuals (9.23%) scored the same, showing a statistically significant difference with a p-value of 0.0053 and a test statistic X=14.74. For scores 2 to 5, there are varying percentages of participants in each group, but no significant differences are indicated

According to **Teixeira, et al., 2012** [19] fifty-nine studies found that higher Bishop Scores increase the likelihood of vaginal delivery and this also highlights the Bishop Score's importance in predicting successful labour induction outcomes.

Indications for induction of labor are evenly distributed in both the groups in present study, majority of participants were induced for post-dated pregnancy in both the groups (57%), other indications are conditions such as Intrahepatic Cholestasis of Pregnancy (9%), Gestational Diabetes Mellitus (7%), Pregnancy-Induced Hypertension (8%), Type 2 diabetes mellitus(1%), oligohydramnios(6%) and FGR(10%).

The distribution of misoprostol doses in Group A highlights the prevalent use of incremental dosing strategies to achieve cervical ripening and labour induction effectively. Report by **Aishwarya et al., 2023** [20]affirm that this type of dosing maintains a balance of effectiveness and safety.

In Group B, the duration of intracervical Foley catheter placement reveals a preference for longer durations, with a substantial majority of patients (98) catheterized for 12 hours or more.. Reports by **Tsakiridis et al., 2020** [21], also highlight how adjusting catheter duration can improve outcomes in labour induction.

The distribution of doses of intracervical Foley's catheter followed by misoprostol administration in Group-B, comprising 130 participants, shows varied dosing patterns. The most common number of doses administered was 2, received by 39 participants (29.23%), followed by 3 doses, received by 32 participants (23.85%). This indicates that a significant proportion of patients required 2 to 3 doses for effective induction. Additionally, 22 participants (16.15%) received only 1 dose, suggesting that a subset of patients responded sufficiently with minimal intervention. On the other end of the spectrum, smaller proportions of participants required more extensive dosing, with 4 doses

given to 17 participants (12.31%), 5 doses to 9 participants (6.15%), 6 doses to 7 participants (5.38%), 7 doses to 4 participants (3.08%), and 8 doses to 5 participants (3.85%) This distribution reflects the individualized nature of induction protocols, where the combination of mechanical and pharmacological methods is tailored to each patient's response to treatment.**Hofmeyr et al., 2010** [22]**,** support the use of misoprostol for labour induction, aligning with our study's approach.

In present study Patient augmentation in Group A and Group B shows that the majority in both groups underwent augmentation during labour. Specifically, 114 individuals (87.69%) in Group A and 119 individuals (91.54%) in Group B received augmentation, indicating a high prevalence of augmentation in both groups but the difference between the two groups in terms of augmentation rates does not reach statistical significance, with a p-value of 0.3094.These results are comparable to those reported by **Fareed et al**[23].

The induction to delivery interval in Group A and Group B reveals numerical differences in distribution but no statistically significant disparities between the groups. In Group A, 6 individuals (4.62%) experienced an induction to delivery interval of less than 12 hours, compared to 3 individuals (2.31%) in Group B. Although this numerical difference may initially seem noteworthy, statistical analysis indicates it is not significant, with a p-value of 0.0997 and a test statistic X=4.611. For intervals ranging from greater than 12 to 24 hours, the majority of participants in both groups fell into this category, with 80 participants (61.54%) in Group A and 67 participants (51.54%) in Group B. Similarly, for intervals exceeding 24 hours, 44 participants (33.85%) in Group A and 60 participants (46.15%) in Group B experienced this duration. Despite variations in distribution between the groups, none reached statistical significance, indicating no substantial difference in the induction to delivery interval between Group A and Group B.

Similarly a Prospective randomized controlled trial was conducted by **Judith H Chung et al , 2023**[24] , a total of 146 patient were enrolled , 49 were asigned for misoprostol group , 54 for foley group and 43 for combination group . Induction to delivery interval in misoprostol group 17.5±9.3 hrs, in foley catheter group 19.5± 9.4 hrs and in combination group 16.6±8.2 hrs but these differences are not statistically significant.

The mode of delivery distribution between Group A and Group B shows numerical differences in the percentages of individuals undergoing different delivery methods, but these differences are not statistically significant. In Group A, 55 individuals (42.31%) underwent Lower Segment Caesarean Section (LSCS), compared to 43 individuals (33.08%) in Group B. The statistical analysis yielded a p-value of 0.1595 and a test statistic X=3.672, indicating that this difference is not statistically significant. For Normal Vaginal Delivery (NVD), 67 participants (51.54%) in Group A and 82 participants (63.08%) in Group B underwent this mode of delivery. Additionally, 8 participants (6.15%) in Group A and 5 participants (3.85%) in Group B had an instrumental delivery. Again, while there are variations in the distribution of delivery modes between the two groups, none of these differences reached statistical significance.

Similar to our study ,In previously mentioned study by **Judith H Chung et al , 2023**[24] there were no statistically significant differences in vaginal delivery rates (63.3% in misoprostol group, 57.4% in foley group, and 58.1% in combination group p value = 0.81) and there were no statistically significant differences in cesarean section rate(36.7% in misoprostol group, 42.6% in foley group, and 41.9% in combination group p value = 0.81).

In our study the distribution of indications for Lower Segment Caesarean Section (LSCS) between Group A and Group B ,In both groups, the most common indications for LSCS were "Fetal Distress (Nonreactive NST)" and "Failure to Progress." In Group A, these indications accounted for 25.45% and

23.64% of cases, respectively, while in Group B, they constituted 34.88% and 27.91% of cases, respectively. Similar to present study , in the study by**El-Kelani et al.2019**[25] indication for LSCS were fetal distress in 3.33% and failure to progress in 6.67% of LSCS in group A and 5.45% and 8.65% respectively in group B.

In present study other indications such as 2nd Stage Arrest (group A-12.73%, group B-6.98%),Failed Induction (group A-10.91%, group B-11.63%),Fetal Distress (MSL)(group A- 21.82%, group B-18.60%), and Hyperstimulation (group A-5.45%,group B-0.00%) had lower frequencies but still contributed to the overall distribution.**Paramasivan et al., 2024** [26] discusses the factors influencing the decision for LSCS, including maternal health, Fetal status, progress of labour, and clinical judgment.

The comparison for instrumental delivery between Group A and Group B shows that in both groups, a minority of individuals were indicated for this procedure due to "Poor Maternal Bear Down Effort with Fetal Distress in 2nd stage of labor." Specifically, in Group A, 8 individuals (6.15%) were indicated, compared to 5 individuals (3.85%) in Group B. In addition ,our results were in agreement with the study done by **Al-Ibraheemi et al 2017** [10] who reported that instrumental delivery were needed in 4 patient (5%) in sequential group and in 3 patients (4%) in concurrent group.

In current study, in Group A, 3 individuals (2.31%) experienced hyperstimulation, whereas noindividual(0.00%)experienced hyperstimulation in Group B. The statistical analysis yielded a p-value of 0.0815 and a test statistic X=3.035, indicating a trend towards significance but not reaching it. **Al-Ibraheemi et al 2017** [10] showed similar results with hyperstimulation in 2 patient (3%) in sequential group and 5 patient (6%) in concurrent group .**Judith H Chung et al , 2023**[24] found hyperstimulation 33.3% in misoprostol group, 11.1% in foley catheter group and 16.3% in combination group.

In our study, comparing the incidence of non-reassuring Fetal heart rate (FHR) between Group A and Group B shows that in Group A, 14 individuals (10.77%) experienced non-reassuring FHR, while in Group B, 15 individuals (11.54%) had the same experience. Non-reassuring FHR is a critical indicator during labour, suggesting potential Fetal distress and prompting clinical interventions to ensure Fetal well-being**.** Study by **Oyelese et al., 2021** [27]highlights the importance of monitoring non-reassuring FHR during labour as an indicator of potential Fetal distress and the need for clinical interventions.

In this study APGAR scores at 1 minute and 5 minutes between Group A and Group B shows similar incidences of low APGAR scores, with no statistically significant differences between the two groups. At 1 minute, 11.54% of individuals in Group A had APGAR scores below 7, compared to 10.00% in Group B. Similarly, at 5 minutes, 6.92% of individuals in Group A had APGAR scores below 7, while 4.62% in Group B had the same. The p-value for this comparison was 0.1601, with a test statistic X=0.1601, indicating no significant difference in the incidence of low APGAR scores at 5 minutes between the groups. NICU admission was needed in 11 neonates in group A and 8 neonates in group B.

Similar results were reported by **Judith H Chung et al , 2023**[24] , at 1 minute, 24.5% of neonates in misoprostol group had APGAR scores below 7, 31.50% in foley group and 20.9% in combination group had APGAR scores below 7 at 1 min. Similarly, at 5 minutes, 10.2% of neonates in in misoprostol group had APGAR scores below 8, 16.7% in foley group and 9.3% in combination group had APGAR scores below 8 at 1 min. And NICU admission were 10.2% , 9.3% and 4.7% in misoprostol , foley catheter , and combination group respectively.

These findings suggest that while there are numerical differences in clinical outcomes between Group A and Group B, such as instrumental delivery

rates and incidences of uterine hyperstimulation or non-reassuring FHR, these differences do not reach statistical significance. This implies that overall, both groups experienced similar obstetric management and outcomes despite some variations in specific clinical parameters.

CONCLUSION

- The study compared vaginal misoprostol with a sequential approach (Foley catheter followed by misoprostol) for inducing labor in 130 patients each at Dr. Ram manoharlohia institute of medical sciences, Lucknow, uttarpradesh, india
- There were no significant age differences between the groups, indicating random variation rather than systematic differences.
- Group A had significantly more patients with a Bishop score of 1 (21.54%) compared to Group B (9.23%).
- High-risk factors for induction, like IHCP, GDM, and PIH, were evenly distributed between the groups.
- In Group A, most patients received 4 or 5 doses of misoprostol, reflecting common dosing practices.
- Group B typically had the Foley catheter placed for 12 hours or more to enhance cervical ripening.
- Misoprostol doses in Group B varied widely, with 2 or 3 doses being most common, reflecting individual responses.
- Both groups showed high rates of labor augmentation (Group A: 87.69%, Group B: 91.54%).
- The time from induction to delivery did not significantly differ between the groups, despite numerical variations.

- Differences in the mode of delivery (LSCS, NVD, instrumental) were not statistically significant.
- Indications for LSCS, such as foetal distress and failure to progress, were similar in both groups.
- Instrumental delivery was infrequently needed in both groups .
- Group A had a trend towards more uterine hyperstimulation (2.31%) compared to none in Group B (p-value = 0.0815).
- Rates of non-reassuring foetal heart rate were comparable between the groups, suggesting consistent monitoring.
- APGAR scores below 7 at 1 minute and 5 minutes were similar in both groups, with no significant differences.
- Both induction methods (misoprostol alone and sequential approach) effectively induced labor, with outcomes influenced by patient characteristics.
- The study reflects standard obstetric practices, highlighting the need for individualized care and flexible induction protocols.

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