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A COMPARATIVE STUDY OF ADDING FIRST DOSE OF INTRACERVICAL DINOPROSTONE IN MISOPROSTOL REGIMEN AND SUBLINGUAL MISOPROSTOL ALONE FOR INDUCTION OF LABOUR

Dr. Juhi Goyal	Senior residents, Department of Obstetrics and Gynecology, Mahatma Gandhi Memorial Medical College Indore, Madhya Pradesh, India.
Dr Deepa Joshi	Associate Professor, Department of Obstetrics and Gynecology, Mahatma Gandhi Memorial Medical College Indore, Madhya Pradesh, India.
Dr Sheetal Hedau*	Assistant Professor, Department of Obstetrics and Gynecology, Mahatma Gandhi Memorial Medical College Indore, Madhya Pradesh, India. *Corresponding Author
Dr. Nilesh Dalal	Professor and Head, Department of Obstetrics and Gynecology, Mahatma Gandhi Memorial Medical College Indore, Madhya Pradesh, India.
Dr. Neha Rajput	Senior Resident, Department of Obstetrics and Gynecology, Mahatma Gandhi Memorial Medical College Indore, Madhya Pradesh, India.

ABSTRACT

Background: Induction of labor is characterized as the course of misleadingly animating the uterus to begin labor. In around 5 to 25% of pregnancies, there comes a stage when the embryo or the mother would be better if the birth is directed. Prostaglandins change the extracellular principal substance of the cervix, mature the cervix & furthermore increment the movement of collagenase in the cervix. They additionally permit an increment in intracellular calcium levels, causing withdrawal of the myometrial muscle. As of now, there are two prostaglandin analogs accessible for cervical aging: Misoprostol & Dinoprostone Gel. The method of administration that has been explored thoroughly is endocervical Dinoprostone or prostaglandin E2. Though this is widely used, it is expensive and required refrigeration for storage with warming before use. It was only a matter of time before a comparably cheap, safe and effective vaginally administered Prostaglandin with limited side effects would be available and Misoprostol or PGE1 tablet fitted those criteria admirably. **Material And Methods:** The present study is a case control study done in the Department of Obstetrics and Gynecology, M.G.M Medical College and M.Y Hospital, Indore, over a period of 1 year from August 2020 to August 2021. All cases induced in Department of Obstetrics and Gynaecology, M.G.M Medical College and M.Y Hospital, Indore. The study will include prospective cases for 1 year from ethics committee with Sample Size of 400 patients.

1. 200 patient with an indication for labour induction received with 25ug of sublingual misoprostol & repeated for a maximum of 6 doses every 4 hours as needed.
2. 200 patients with an indication for induction of labour received 0.5 mg intracervical dinoprostone gel followed by 25ug of sublingual misoprostol & repeated for a maximum of 4 doses every 4 hours as needed.

Results: During the study period maximum induction were done in the age group of 21-23 years booked patients, in multiparas, at 39 weeks gestation, with common indications of postdated pregnancy, PROM, hypertensive disorders of pregnancy, with BISHOPS score < 4. More than 80% patients achieved vaginal delivery in both groups, however in group 2 fetal distress was more common. **Conclusion:** study concluded that adding dinoprostone gel to misoprostol regime was safe; led to increased induction delivery interval as compared to misoprostol regime without adding additional risk to the mother or fetus; with additional benefit of reducing the risk of tachysystole in mother; led to less fetal distress with need of operative intervention; led to increased induction delivery interval but the APGAR scores were comparable in both the groups.

KEYWORDS : induction of labour, dinoprostone gel, misoprostol, APGAR score, BISHOPS score

INTRODUCTION

Induction of labour is an obstetric procedure, designed to pre-attempt the natural process of labour by initiating its onset artificially, before this occurs spontaneously. The aim of successful induction is to achieve vaginal delivery when continuation of pregnancy presents a threat to the life or well being of the mother or her unborn child. The infant should be delivered in a good condition, in an acceptable time frame and with minimum material discomfort or side effects.

In order to be successful, induction of labour must fulfil three criteria. First, it should result in labour namely adequate uterine contractions and progressive dilation of the cervix. Second, this labour should result in vaginal delivery, as there is little purpose in bringing about labour as a mere preparation for caesarean section.

Third, in viable pregnancies these aims must be achieved with minimal risk to both mother and fetus.

The method of administration that has been explored thoroughly is endocervical Dinoprostone or prostaglandin E2. Though this is widely used, it is expensive and required refrigeration for storage with warming before use. It was only a matter of time before a comparably cheap, safe and effective vaginally administered Prostaglandin with limited side effects would be available and Misoprostol or PGE1 tablet fitted those criteria admirably.

In this study, cervical ripening with endocervical prostaglandin E2 gel as first dose in sublingual misoprostol regimen, and sublingual prostaglandin E1 tablet alone are compared with regard to efficacy and safety.

METHODS

After informed consent has been obtained, the patients selected for the study will be evaluated initially by modified Bishop's score and admission test for fetal wellbeing. Patients with a modified bishops score <6 and a positive admission test will be induced.

Sample size was 400 in which 200 patient with an indication for labour induction received with 25ug of sublingual misoprostol & repeated for a maximum of 6 doses every 4 hours as needed. And 200 patients with an indication for induction of labour received 0.5 mg intracervicaldinoprostone

gel followed by 25ug of sublingual misoprostol & repeated for a maximum of 4 doses every 4 hours as needed.

Inclusion Criteria:
1. Singleton fetus with cephalic presentation.
2. Over 39 weeks of gestation.
3. Reactive fetal heart pattern
4. Unfavorable cervix Bishop score <6.
5. No contraindication to vaginal delivery

Exclusion Criteria:
1. Previous L.S.C.S or any uterine surgery
2. Mal presentation
3. Grand Multi-parity
4. Abnormal fetal heart rate pattern
5. Allergy to Prostaglandins

After drug insertion, patients will be monitored for signs of labor maternal vital signs, fetal heart rate and progress of labor. The fetal heart rate is going to be monitored by intermittent auscultation and continuous fetal heart rate monitoring. A partogram will be strictly maintained in all patients induced.

Oxytocin will be started depending on the modified Bishop's score and in the absence of adequate uterine contractions after 6 hours of the last dose, or for augmentation of labor in case of an arrest of dilation. Oxytocin will be started at the dose of 2 mu / min with increments of 2 mu/ min every 30 minutes up to a maximum of 20 mu/ min.

Membranes will be ruptured, when the cervix becomes favorable or at onset of active stage of labor.

The data collection includes demographic details of the patient, indication for induction, booked/ unbooked case, maternal age, parity, gestational age, modified Bishop's Score at time induction, induction delivery interval, oxytocin augmentation, type of delivery, Apgar score of the baby, maternal and neonatal complications.

The results observed will be subjected to statistical analysis by Students t test, odds ratio, chi-square test and a 'p' value of < 0.05 was considered as significant.

RESULTS AND DISCUSSION

The study comprised of 400 labour induction cases done after dividing in Group I and Group II. There were specific inclusion and exclusion criteria. Patients who didn't give consent were excluded. [7]

Out of 400 patients, 59% belonged to age group of 21-23 years, followed by 26.5% in the 24-26 years and 13.25% in the age group of <20 years, while 1.25% of patients were in 27-30 years age group. Maximum inductions were done in age groups of 21-23 years both in Group I and Group II. In the study, 36.5% patients were nulliparas and 63.5% were multiparas. In Group I and II, 34% and 39% respectively were nulliparas and 66% and 61% respectively were multiparas. [8] Among 400 patients, the common indications for induction of labour were postdated pregnancy (43.75%), followed by Pre-labor Rupture of Membranes (22.25%) and Hypertensive Disorders of Pregnancy (19%). In 15% patients, there were other indications like intrauterine growth retardation, oligohydramnios and maternal medical disorders (e.g. diabetes mellitus).

In Group I, 43% patients had indication of postdated pregnancy, 23% Pre-labor Rupture of Membranes, 18% Hypertensive Disorders of Pregnancy, 8.5% intrauterine growth retardation, 4% oligohydramnios and 3.5% maternal medical disorders (e.g. diabetes mellitus).

In Group II, 44.5% patients had indication of postdated pregnancy, 21.5% Pre-labor Rupture of Membranes, 20% Hypertensive Disorders of Pregnancy, 4% intrauterine growth retardation, 8% oligohydramnios and 2% maternal medical disorders (e.g. diabetes mellitus). In the study, 82% patients were booked and 18% were unbooked. In Groups I and II, 83% and 81% respectively were booked and 17% and 19% respectively were unbooked. [9]

Maximum induction (56.75%) was done in 39 weeks of gestation, 43.25% at >40 weeks of gestation. In Group I, Bishop Score was <4 in 64% patients and between 4 and 6 in 36%. In Group II, the score was <4 in 73% patient and between 4 and 6 in 27% patients. Overall, Bishop score was <4 in 68.5% patients and between 4 and 6 in 31.5% patients.

In Group I, 84% patients had vaginal delivery, while LSCS rate was 16%while in Group II, 81% patients had vaginal delivery and LSCS rate was 19%. The difference in mode of delivery in two groups was statistically not significant (The p-value is .429795. The result is not significant at $p < .05$).

In Group I, LSCS rate was 16% with indications of fetal distress (7%), Secondary arrest of dilation (7%) and deep transverse arrest (2%). In Group II, LSCS rate was 19% with indications of fetal distress (11.5%), Secondary arrest of dilation (6%) and deep transverse arrest (1.5%).[10]

The difference in mode of delivery in two groups was statistically not significant however fetal distress was more seen in group II than group I and the results are statistically significant (The p-value is < 0.00001. The result is significant at $p < .05$).

The mean induction-delivery interval was 15.26 hours in Group I with a range of 8.05 hours (min.) to 28.52 hours (max.) and 12.67 hours in Group II with a range of 7.42 hours (min.) to 27.60 hours (max.). There were no complications in maximum number of patients. In group I, 3.5% patients experienced postpartum hemorrhage, 2% experienced tachysystole whereas in group II, 4% patients experienced postpartum hemorrhage, 4.5% experienced tachysystole for which the results were statistically significant (The chi-square statistic is 198.7495. The p-value is < 0.00001. The result is significant at $p < .05$).

Other complications like diarrhea, fever, hyperstimulation, vomiting, etc were similar in both groups and results are statistically insignificant. There were no baby complications in maximum number of patients. In group I, 0.5% newborns experienced birth asphyxia, 2% experienced meconium aspiration syndrome whereas in group II, 4.5% newborns experienced birth asphyxia, 4.5% experienced meconium aspiration syndrome for which the results were statistically not significant (The chi-square statistic is 2.7559. The p-value is .252096. The result is not significant at $p < .05$). [11]

In the present study, Apgar score <5 in new born babies at 5 minute was found in 1.5% patients in Group I and 0.5% in Group II. The difference between the two groups was statistically not significant (The chi-square statistic is 1.0101. The p-value is .314879. The result is not significant at $p < .05$).

CONCLUSION

From this case control study we concluded that Adding dinoprostone gel to misoprostol regime was as safe as the use of misoprostol regime alone and also by Adding dinoprostone gel to misoprostol regime led to increased induction delivery interval as compared to misoprostol regime with additional benefit of reducing the risk of tachysystole in mother and fetal distress.

DECLARATIONS

Funding: *No funding sources*
Conflict Of Interest: *None declared*

Ethical Approval: *This study was approved by the institutional ethical committee*

Table 1: Demographic Characteristics Of The Study Group

		Induction of labour with dinoprostone gel followed by sublingual misoprostol		Induction of labour with 2 doses of sublingual misoprostol	
S. No.	**Demography**	**No.**	**Percentage**	**No.**	**Percentage**
	Age Group				
1	18-20	31	15.5	22	11
2	21-23	115	57.5	121	60.5
3	24-26	50	25	56	28
4	27-30	4	2	1	0.5
	Gravida/Parity				
1	Nullipara	68	34	78	39
2	Multipara	132	66	122	61
	Gestational Age				
1	39 weeks 0 day to 06 days	115	57.5	112	56
2	40 weeks 0 day to 06 days	85	42.5	88	44
	BOOKED/ UNBOOKED				
1	Booked	166	83	162	81
2	Unbooked	34	17	38	19
	Modified Bishops score				
1	Less than 04	128	64	146	73
2	44716	72	36	54	27

Table 2: Indication Of Induction

		Induction of labour with dinoprostone gel followed by sublingual misoprostol		Induction of labour with 2 doses of sublingual misoprostol		Total	
S. No.	**INDICATION OF INDUCTION**	**No.**	**Percentage**	**No.**	**Percentage**	**No.**	**Percentage**
1	Hypertensive Disorders of Pregnancy	36	18	40	20	76	19
2	Intrauterine Growth Restriction	17	8.5	08	04	25	6.25
3	Maternal Medical Disorders (e.g. Diabetes Mellitus)	07	3.5	04	02	11	2.75
4	Oligohydramnios	08	04	16	08	24	6
5	Post-dated Pregnancy	86	43	89	44.5	175	43.75
6	Pre-labor Rupture of Membranes	46	23	43	21.5	89	22.25

Table 3: Type Of Delivery

		Induction of labour with dinoprostone gel followed by sublingual misoprostol		Induction of labour with 2 doses of sublingual misoprostol		
S. No.	**TYPE OF DELIVERY**	**No.**	**Percentage**	**No.**	**Percentage**	**P Value**
1	LSCS	32	16	38	19	.429795
2	Vaginal	168	84	162	81	

Table 4: Indication Of Failed Induction

		Induction of labour with dinoprostone gel followed by sublingual misoprostol		Induction of labour with 2 doses of sublingual misoprostol		
S. No.	**INDICATION OF FAILED INDUCTION**	**No.**	**Percentage**	**No.**	**Percentage**	**P Value**
1	Deep Transverse Arrest	04	02	03	1.5	< 0.00001
2	Fetal Distress	14	07	23	11.5	
3	NA	168	84	162	81	
4	Secondary Arrest of Dilation	14	07	12	06	

Table 5: Induction- Delivery Interval (In Hours)

Statistics	**Induction of labour with dinoprostone gel followed by sublingual misoprostol**	**Induction of labour with 2 doses of sublingual misoprostol**
No.	200	200
Mean	15.2604	12.6765
Std. Deviation	3.92818	3.47961
Minimum	8.05	7.42
Maximum	28.52	27.60

Table 6: Apgar Score

		Induction of labour with dinoprostone gel followed by sublingual misoprostol		Induction of labour with 2 doses of sublingual misoprostol		
S. No.	**Apgar Score**	**No.**	**Percentage**	**No.**	**Percentage**	**P Value**
1	Less than 05	03	1.5	01	0.5	.314879
2	05-08	197	98.5	199	99.5	

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