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Comparative study of induction of labour with oral mifepristone and intracervical dinoprostone in primigravida

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Abstract
Background: Mifepristone (RU-486) in doses of 200-400 mg has shown to improve cervical ripening. Hence the sequential use of Mifepristone followed by Dinoprostone is more effective in induction of labour with less chance of failed induction and thereby decreasing the caesarean delivery rate.
Methods: A prospective comparative study was done for a period of 21 months from Oct 2021 to June 2020 in Dept. of OBG AIMS RC.170 primigravida with term gestation were included in the study.85 women (group A) were given 200 mg Mifepristone orally and 85 women (Group B) were induced with 0.5 mg intra cervical Dinoprostone gel. Bishop score was assessed after 6 hrs.
Results: After the 1st assessment Bishop score was < 6 in 35.7% in group A, 28.8% in group B. Induction delivery interval was 9.61 hours in group A, 5.21 hours in group B ($p \leq 0.001$). 71.7% had vaginal delivery and 28.2% required LSCS in group A and 52.9% had vaginal delivery and 47.1% required LSCS in group B. There was no fetal mortality in both the groups
Conclusion: Induction delivery interval was more in Group A compared to group B. However % of vaginal delivery was more in Group A compared to group B. Oral Mifepristone 200 mg can be used for cervical ripening during induction of labour, followed by intracervical Dinoprostone gel to reduce the number of caesarean deliveries.

Keywords: Induction of labour, mifepristone, dinoprostone gel, bishop score

Introduction
Human parturition has been termed 'labour' in recognition of the hard work that the parturient as well as the uterine myometrium have to perform in order to deliver the fetus. Labour refers to the onset of effective uterine contractions leading to progressive effacement and dilatation of the cervix resulting in the expulsion of the fetus, placenta and the membranes. Cervical ripening is a process by which the cervix becomes soft, compliant and partially dilated. It is due to a combination of biochemical, endocrine, mechanical and possibly inflammatory events [1].
Induction of labour means initiation of uterine contractions (after the period of viability) by any method (medical, surgical or combined) for the purpose of vaginal delivery. Generally induction of labour is indicated when the benefits of early delivery are greater than the risks of continuing the pregnancy. A successful induction is primarily dependent on the pre-induction Bishop's scoring of the cervix [2].
Various methods have been used for induction of labour which includes mechanical such as amniotomy, balloon-tipped catheters, and natural, synthetic laminaria. And medical methods include use of prostaglandins, oxytocin and Mifepristone. But an ideal inducing agent must be safe and easy to administer and acceptable to patient [3].
Various methods are available for the induction of labour, includes non-pharmacological and pharmacological methods. Presently, there is lot of difference in the choice of inducing agent. Choice of inducing agent depends upon the efficacy of agent, risk/benefit ratio, institutional protocol and FDA approval, availability of drugs, cost-effectiveness, and obstetrician choice. Commonly used drugs for the induction of labour are prostaglandin analogues such as dinoprostone and misoprostol. Mifepristone/RU-486, a new class of pharmacological agent (antiprogesterone), has been developed to antagonize the action of progesterone. It is the 19 nor-steroid, which has greater affinity for progesterone receptor than progesterone itself. It blocks the action of progesterone at the cellular level [4].

The most commonly used approved indications for Mifepristone in obstetrics include: termination of early pregnancy, cervical dilatation prior to surgical abortion, labour induction in case of fetal death in utero. Induction between 37-41 weeks has the potential to improve neonatal outcome. However, it is associated with a doubling in the caesarean delivery rate compared with spontaneous labour recent studies showed improvement in cervical score within 24-48 hr. with decline in the caesarean delivery rate. There is reduction in NICU admission and maternal complication after mifepristone induction in term and prolonged pregnancy [5].

When the cervix is favourable the usual method of induction is amniotomy and oxytocin, whereas with an unfavourable cervix vaginal prostaglandins are commonly used. Dinoprostone is a synthetic analogue of Prostaglandin E2 (PGE2).Mifepristone is also called as RU (RousselUclaf) - 486. It is 19 norsteroid with potent competitive anti progesterone and significant antiglucocorticoid activity. Mifepristone is used as a pretreatment to prime the cervix adequately. Various studies conducted on induction of labour in live term pregnancies with mifepristone in doses of 200-400 mg has shown to improve cervical ripening and rates of spontaneous labour with no apparent maternal or fetal side effects [2].

However, in late pregnancy, the uterus is sensitized by Mifepristone to prostaglandins and promotes cervical dilatation which induces labour. Hence the sequential use of Mifepristone followed by Dinoprostone is more effective in induction of labour with less chance of failed induction and thereby decreasing the caesarean delivery rate. There are no apparent maternal or neonatal side effects. The pharmacokinetics of Mifepristone is characterized by rapid absorption and a long half-life of 25-30 h [6].

Aims and Objectives

1. To study and compare the efficacy of Mifepristone and Dinoprostone as a cervical ripening and priming agent for induction of labour in primigravidae.
2. To study and compare the feto-maternal outcome among both agents.

Materials and Methods

A prospective comparative study was done for a period of 21 months from October 2018 – June 2020 in Adichunchanagiri Institute of Medical Sciences. 170 primigravidae with term gestation were included in the study. 85 women (Group A) induced with Mifepristone and 85 women (Group B) induced with Dinoprostone intracervical gel.

Inclusion criteria

Primigravidae with singleton pregnancy, cephalic presentation and term gestation (37 wks to 41 wks) with intact membranes, reactive FHR pattern, mild IUGR, Polyhydramnios, unfavourable cervix (Bishop score ≤ 4). Gestational hypertension with pre eclampsia, fetal congenital anomalies, intrauterine fetal demise.

Exclusion criteria

Malpresentation, cephalo-pelvic disproportion, bad obstetric history or recurrent pregnancy loss, any uterine surgery, gestational diabetes, hypersensitivity to Mifepristone or Dinoprostone, medical disorders, oligohydramnios, premature rupture of membranes, antepartum hemorrhage, abnormal fetal heart rate pattern, chorioamnionitis.

Ethical clearance was obtained from institutional ethical committee. Informed consent was taken from the participant and relatives after explaining the purpose of study. Data was collected from selected patients admitted to labour ward and inpatient ward. Detailed history was taken from patients regarding period of gestation along with the reports of investigations done during antenatal period. General physical and obstetric examination was done. Following findings were noted, fundal height, engagement of presenting part, amount of liquor, expected fetal weight, palpable uterine contractions, fetal heart rate. Per vaginal examination was done to assess cephalo pelvic disproportion and Bishops score.

Group A patients were given 200 mg Mifepristone orally and followed up to 24-36 hrs. For progress of labour. Bishop score was assessed at the end of 24 hrs. (First) and 36 hrs. (second). And if no change was observed then appropriate intervention was undertaken such as instillation of Dinoprostone gel, if required artificial rupture of membranes and oxytocin drip.

Group B patients were induced with 0.5 mg intra cervical Dinoprostone gel. Bishop score was assessed after 6 hrs. Maximum 3 gels were used and each assessment was done 6 hrs after each instillation. Fetal condition was assessed before each instillation with CTG.

Duration of latent phase of labour was measured and patients with inadequate uterine contractions were augmented with ARM and oxytocin drip. The course of labour in all patients was recorded on partogram. Decision on course of labour was made on clinical grounds. Inference was noted based on induction delivery interval (IDI), interventions required, mode of delivery and feto-maternal outcome.

Results

75.9% in group A and 77.8% group B of women in the study group were in the age group of 21-30 yrs. 2.8% group a, 0.9% group B belonged to age group of 30 - 40 yrs.

Table 1: Showing mean Bishop score pre induction and after 1st & 2nd assessment

Group	Pre induction	1st assessment	2nd assessment
A	3.84±0.77	6.04±1.16	6.87±0.83
B	3.88±0.79	6.15±1.11	7.24±0.83

Favourability of cervix after the 1st assessment Bishop score was < 6 in 35.7% in group A, 28.8% in group B. Bishop score was ≥ 6 in 64.3% in group A, 71.2% in group B. After the 2nd assessment Bishop score was more than 6 in 100% in both the groups. Cervical ripening was found to be better with Mifepristone than Dinoprostone. PGE 2 gel was required in 28.2% in group A and 100% in group B and was not required in 71.8% in group A and 0% in group B.

Table 2: Showing number of PGE2 gel requirement among both groups

SL No	Gel required	Group A	Group B
1	1	11(12.9%)	41(48.2%)
2	2	12(14.1%)	32(37.6%)
3	3	01(1.2%)	12(14.1%)
4	None	61(71.8%)	0

Table 3: Showing mode of delivery and number of PGE2 gel required among both groups

SL No	Mode of delivery	None	1 Gel	2 Gel	3 Gel
1	FTND AB	39.8%	2.8%	2.8%	0
		-	21.3%	9.2%	0.9%
2	AVD AB	10.2%	0.9%	-	-
		-	4.6%	3.7%	1.8%
3	LSCS AB	6.5%	6.5%	8.3%	0.95
		-	12%	16.7%	8.3%

Induction delivery interval was 9.61 hours in group a, 5.21 hours in group B ($p \leq 0.001$). Induction delivery interval was more in group A and less in group B.71.7% had vaginal delivery and 28.2% required LSCS in group A. 52.9% had vaginal delivery and 47.1% required LSCS in group B. Percentage of vaginal delivery was more group A compared to group B.

Table 4: Showing mode of delivery in both groups

SL No	Mode of delivery	Group A	Group B
1	FTND	49 (57.6%)	34 (40.0%)
2	AVD	12 (14.1%)	11 (12.9%)
3	LSCS	24 (28.2%)	40 (47.1%)

The mean birth WT of babies was 2.92 kg in group a, 3.06 kg in group B.

APGAR score was normal in 96.5% in group A, 89.4% in group B. Abnormal in only 3.5% in group A, 10.6% in group b. NICU admission was needed in 3.5% in group A, 10.6% in group B. There was no fetal mortality in both the groups.

Discussion

In the present study 82 women in group A and 84 women in group B were between the age group of 20 to 30 yrs. and others were in age group >30 yrs. Gomathy, *et al.* [7] reported a similar study of 78 primigravida (Gr A 39 + Gr B 39), all women in group A were between 20 to 30 yrs. and 35 women in group B between 20 to 30 yrs. of age and 4 women were more than 31 yrs. Manoj Kumar, *et al.* [5] reported a study of 112 pregnant women, (56 in Group A, 56 in Group B). 43 women were in the age group of 20 to 29 yrs. in group A and 72 women in group B. There were 7 women in group A belonged to above 30 yrs.

Table 5: Comparison of Bishop score - pre induction (I) and after 24 hrs. (II)

Group	Manoj Kumar, *et al.* [5]		Rajibpal, *et al.* [2]		Gomathy, *et al.* [7]		Present study	
	I	II	I	II	I	II	I	II
A	3.58 ± 0.6	6.4 ± 1.64	5.04 ±0.81	7.96 ± 1.01	3.08 ±0.7	6.4 ± 0.91	3.84 ±0.77	6.04 ±1.16
B	3.4 ± 0.49	5.26 ± 1.85	5.06 ±0.71	8.32 ±1.08	2.77 ±0.74	5.6 ±1.4	3.88 ±0.79	6.15 ±1.11

There is significant change in Bishop score pre induction and after 24 hrs. in the studies compared here. In a study done by Rajibpal, *et al.* [2] pre induction score was 5 in both groups and 8 after 24 hrs.

According to study reported by Manoj Kumar, *et al.* [5] 70% in group A and 95% in group B had vaginal delivery. And 30% in group A and 32% in group B required LSCS. According to study reported by Gomathy, *et al.* [7] among the 39 cases in group A, 35 had vaginal delivery and 4 required LSCS. And among 39 cases in group B, 24 delivered vaginally and 15 required LSCS. In the present study 71.7% in group A and 53% in group B delivered vaginally. And 28.2% in group A and 47.1% in group B required LSCS.

Table 6: Showing comparison of mode of delivery

Outcome	Manoj Kumar, *et al.* [5]		Rajibpal, *et al.* [2]		Gomathy, *et al.* [7]		Present	
	A	B	A	B	A	B	A	B
LSCS	15(30%)	16(32%)	13	17	4	15	24 (28.2%)	40 (47.1%)
FTND	30(60%)	29(85%)	36	31	35	24	49 (57.6%)	34 (40%)
AVD	5(10%)	5(10%)	1	2			12 (14.1%)	11 (12.9%)

P value for the induction delivery interval was not significant in studies reported by Manoj Kumar, *et al.* [5l] and Gomathy, *et al.* [7]. P value was significant in the present study and study reported by Rajib Pal [2].

Table 7: Comparison of induction delivery interval

Manoj Kumar, *et al.* [5]		Rajibpal, *et al.* [2]		Gomathy, *et al.* [7]		Present	
A	B	A	B	A	B	A	B
39.06±15	41.3±17.4	28.72±3.24	10.3±2.42	10.9±1.86	10.56± 3.79	27.1± 9.61	11.9± 5.21
P = 0.493		$p < 0.001$		P = 0.597		$p < 0.001$	

Conclusion

Induction delivery interval was more in group a compared to group B. However % of vaginal delivery was more in group a compared to group B. Oral Mifepristone 200 mg can be used for cervical ripening during induction of labour, followed by intracervical Dinoprostone gel to reduce the number of caesarean deliveries.

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Conflict of Interest

Not available

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References

1. Sanghamitra Mohapathra, Samarpita. A Comparative study on the role of Mifepristone and endocervical Prostaglandin as preinduction cervical ripening agent. IJRCOG. 2021 Jan;10(1);215-221.
2. Dr. Rajib Pal, Tufan Khalua. Comparative analysis of Safety, Efficacy and fetomaternal outcome – in term live

pregnancy for Induction of Labour with oral Mifepristone and Intracervical Dinoprostone Gel.IOSR J of Dental and Medical Sciences, (IOSR – JDMS) E- ISSN: 2279-0853. P-ISSN: 2279-0861. 2018 April;17(4):77-81.
3. Anu Pathak, Saroj Singh, Shikha Singh, Rajesh Kumar, Arpita Tyagi. Comparative study to evaluate the efficacy and safety of oral Mifepristone versus intracervical Dinoprostone gel for induction of labour and their effects on fetomaternal outcome. IJRCOG. 2019 July;8(7):2678-2682.
4. Sandhya Kumari, Vandana Solanki, Urmila Singh, Seema Mehrotra. Comparative Study of Mifepristone with Dinoprostone gel in Induction of Labor in full term pregnancy: An open – label Randomized controlled Trial. Journal of South Asian Federation of Obstetrics and Gynaecology. 2021 May-Jun;13(3):98-102.
5. Manoj Kumar Sah, Saraswati M Padhye. Mifepristone versus intracervical ProstaglandinE2 gel for cervical ripening in Primigravid patients at term. IJRCOG. 2018 March;7(3):824-828.
6. Sailatha R, Famida AM, Vinoth Gnana Chellaiyan D, Vijayalaksmi K, Sathia S, Renuka S. Misoprostone: An alternate to Dinoprostone in induction of labor. IJRCOG. 2017 May;6(5):1880-1884.
7. Gomathy E, Neha BS. A Prospective study to compare oral Mifepristone and Dinoprostone gel in induction of labour in primigravida. Indian J of Obst and Gynae Research. TH Deepika, H Nagabhushan R. 2022;9(2):204-207.

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