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Original Research Article

Comparison of oral mifepristone with intracervical foleys catheterisation for induction of labour in term pregnancy: A randomized control trial

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ABSTRACT

Background: The purpose of this study is to compare the efficacy of oral Mifepristone with the efficacy of intracervical Foley catheterisation for induction of labour in term pregnancy. The primary outcome of this study is to compare both methods of induction of labour in terms of induction to delivery interval and the secondary outcome is to compare the two methods in terms of route of delivery, indications of caesarean section and the neonatal outcomes.

Materials and Methods: This study is a randomized control trial conducted from May 2022 to December 2022 in Department of Obstetrics and Gynecology, SSG Hospital, Baroda Medical College. 180 term pregnant patients were enrolled in this study based on a pre-established criteria. Patients were randomised into group A and B. Group A included patients who were given Tablet Mifepristone 200 mg PO followed by per vaginum Tablet Misoprostol and Group B included patients who underwent intracervical Foleys catheterisation followed by placement of per vaginum Tablet Misoprostol.

Results: The study concluded that there was significantly decreased induction-delivery interval in women induced with intracervical Foleys catheterisation (Group B) as compared to those given oral Tablet Mifepristone (Group A). There was no significant difference between the two groups in terms of the route of delivery, rate of C Sections and neonatal outcomes.

Conclusion: Mifepristone is effective for inducing indicated term pregnancies, despite no decrease in induction delivery interval. Incidence of fetal distress with oral Mifepristone is comparable to intracervical foley's catheterization. Further research is needed to assess tachysystole/hyperstimulation and fetal distress caused by Mifepristone.

1. Introduction

Induction of labour is the process of initiating labour artificially in situations where termination of pregnancy is indicated due to maternal or fetal compromise or when the fetus has crossed the period of viability. Over the past few decades, the incidence of induction of labour has increased owing to the detection of high risk pregnancies which often require prompt intervention to prevent perinatal and maternal morbidity and mortality.[1] These high risk pregnancies include but are not limited to complications like pregnancy induced hypertension, Overt/ Gestational diabetes mellitus, Rh alloimmunisation, fetal growth restriction and Oligohydramnios/Polyhydramnios.[2,3]

Misoprostol is a synthetic prostaglandin E1 analogue primarily introduced for the prevention and treatment of gastroduodenal ulcers that occurred as a side effect of non steroidal anti-inflammatory drugs.[4] Its off label use includes medical termination of pregnancy, induction of labour, cervical dilatation before hysteroscopic procedures and the

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prevention and management of post partum hemorrhage. In the initial trials, misoprostol for induction of labour in term pregnancy was kept per vaginally in doses of 100 mcg to 200 mcg which was then titrated to 25 mcg to 50 mcg owing to its various side effects. [5]

Mifepristone, RU 486, is an anti-progesterone which acts mainly on the cervix and accelerates its ripening process and sensitizes the uterus to the action of prostaglandins and oxytocin which helps in the initiation of uterine contractions. [6,7]

As a functional withdrawal of progesterone is responsible for the onset of uterine contractions, cervical ripening and dilation, mifepristone is used in this study as a means of induction of labour at term in indicated pregnancies. We have compared the efficacy of oral Tablet Mifepristone and the efficacy of intracervical foleys catheterisation for induction of labour in term pregnancy with respect to the induction-delivery intervals, route of delivery and neonatal outcomes. [8,9]

2. Materials and Methods

In this randomized control study, 180 full term pregnant women visiting Obstetrics and Gynecology OPD of Sir Sayajirao General Hospital (SSGH) were enrolled in the study which was conducted from May 2022 to December 2022 after approval from the Institutional Ethics Committee for Biomedical and Health Research (IECBHR), SSG Hospital, Vadodara.

All the women of the study were chosen based on a strict inclusion and exclusion criteria and unnecessary inductions were avoided.

2.1. Inclusion criteria

1. Singleton pregnancy
2. Cephalic presentation
3. Intact membranes
4. If labour induction was indicated due to maternal/fetal complications which included pregnancy induced hypertension, GDM, Overt DM, IUGR, oligohydramnios, polyhydramnios and fetal congenital malformations.
5. Delivery could be postponed for 24 hrs
6. Women with unfavorable cervix (Bishop score less than or equal to 6)
7. Patients with a reactive NST

2.2. Exclusion criteria

1. Parity more than 4
2. Previous caesarean section
3. Suspected or confirmed cephalopelvic disproportion
4. Macrosomia
5. Malpresentation
6. Intrauterine fetal demise
7. Known hypersensitivity to prostaglandins or mifepristone
8. Impaired renal, hepatic or adrenal function and antepartum hemorrhage

All eligible women with obstetrical or medical indication for labour induction were enrolled in the study taking inclusion and exclusion criteria in consideration. Participants were briefed about the nature of the study, details of the treatment and a written informed consent was obtained after being explained about the risks and benefits of the study.

A thorough history including patients' menstrual history, obstetric history and any significant past/family/treatment history was taken and recorded. Complete systemic and obstetric examination was done in all patients. Baseline complete blood count, liver function test and renal function test along with fetal ultrasound with doppler were done in all patients. Per vaginum examination was done to assess the modified bishops score and pelvis.

Patients were randomized into two groups with group A including patients who were given Tablet Mifepristone 200 mg PO and group B including patients who were pre-induced with intracervical foleys catheterization.

Patients in Group A were assessed after 24 hours or after initiation of uterine contractions, whichever was earlier. If modified bishop's score was < 8, patients were induced with per vaginal insertion of Tablet Misoprostol 25 mcg or 50 mcg depending on parity and if the modified bishop's score was more than or equal to 8, augmentation was done with intravenous oxytocin (if uterine contractions were confirmed to be inadequate).

Patients in Group B were assessed after expulsion of intracervical foleys bulb. If modified bishop's score was < 8, patients were induced with per vaginal insertion of Tablet Misoprostol 25 mcg or 50 mcg depending on parity and if the modified bishop's score was more than or equal to 8, augmentation was done with intravenous oxytocin (if uterine contractions were confirmed to be inadequate).

Electronic fetal heart rate monitoring was performed in all patients in active labour. Artificial rupture of membranes was done when clinically indicated. Augmentation was delayed for six hours after administration of misoprostol. No epidural analgesia used in our study.

A maximum of 3 doses of Tablet Misoprostol 4 were allowed. If after 3 doses of per vaginum misoprostol regular uterine contractions failed to begin, the patient was given a choice of either waiting for the contractions to begin or undergoing emergency LSCS.

3. Results

Observations were made based on the age and parity of the study participants with specific focus on the following outcomes.

3.1. Primary outcome

The interval from administration of oral mifepristone/intracervical foleys catheterisation to vaginal delivery.

3.2. Secondary outcome

1. Mode of delivery,
2. Number and Indications of C sections,
3. Neonatal outcomes

Out of the total 180 study participants, 90 women were given Tablet Mifepristone 200 mg per orally and 90 women were induced with intracervical foley's catheterisation. The mean age of group A was 24.18 years and of group B was 24.06 years, as shown in Table 1, and thus are very closely comparable.

Out of 90 study participants in group A, 34 were Primigravida and 56 were Multigravida. Out of 90 study participants in group B, 43 were Primigravida and 47 were Multigravida as shown in Table 2.

As shown in Table 3 the study demonstrated a significant decrease in induction– delivery interval in Group B compared to Group A. The mean induction-delivery interval was 13.34 hours in Group B as compared to 21.82 hours in Group A. This difference in induction-delivery interval between the two groups was found to be statistically significant (p value <0.05).

As shown in Table 4, 87% of women delivered via vaginal delivery in Group A as compared to 77% in Group B. 13% women underwent C section in Group A as compared to 27% in Group B. The reduction in rate of C section between the two groups was statistically insignificant (p value > 0.05).

As shown in Table 5, out of the 11 women who underwent C section in Group A, 4 were because of fetal distress with thick MSL, 3 because of pathological CTG, 1 due to non progression in 1^{st} stage of Labour and 3 due to failed induction. As shown in Table 6, out of the 20 women who underwent C section in Group B, 5 were because of fetal distress with MSL, 7 due to pathological CTG, 2 due to non progression in 1^{st} stage of labour and 6 due to failure of induction. This difference in indications of C sections and their frequency was insignificant (p value > 0.05).

As seen in Table 7, 20% of Primigravida in Group A and 25% of Primigravida in Group B underwent C-Section whereas 7% of Multigravida underwent C-Section in Group A as compared to 19% in Group B. This difference was, however, not statistically significant. (p value > 0.05)

As shown in Table 8, no neonate born in Group A had APGAR score of <7 whereas 2 neonates of Group B were found to have an APGAR score <7 at 1 minute out of which 1 neonate had persistent APGAR score of <7 at 5 minutes and was admitted to the NICU. In Group A, all 90 neonates had APGAR score more than or equal to 7 at 1 minute and 5 minutes whereas 88 neonates in Group B had an APGAR score of more than or equal to 7 at 1 minute and 5 minutes.

Table 1: Distribution of patients according to age

	Induction type	N	Mean	SD
Age	Group A	90	24.18	1.92
	Group B	90	24.06	1.93

Table 2: Distribution of patients according to parity

	Type of Induction	
	Group A	Group B
Primi gravida	34 (37.78%)	43 (47.78%)
Multi gravida	56 (62.22%)	47 (52.22%)

Table 3: Association of induction-delivery interval with the type of induction

Induction to Delivery Interval	Induction type	N	Mean	STD deviation
	Group A	90	21.82	9.64
	Group B	90	13.34	5.91

P < 0.0001 (Statistically Significant)

Table 4: Association of route of delivery with type of induction

Type of Induction	Route of Delivery	
	Normal Delivery	C-section
Group A	79 (87.78%)	11 (12.22%)
Group B	70 (77.78%)	20 (22.22%)

Chi-square = 2.494, P = 0.1143 at df = 1 (Not statistically significant)

4. Discussion

Our study was conducted at the Department of Obstetrics and Gynaecology, SSG Hospital, Baroda Medical College between May 2022 and December 2022 and included 180 patients out of which 90 patients were given tablet mifepristone 200 mg per orally and 90 were induced with intracervical foleys catheterisation.

Among the study participants 77 women were primigravida and 103 were multigravida.

The mean age of the women in the study group was 24.10 years.

The mean duration of induction-delivery interval was 21.8 hours in Group A whereas it was 13.3 hours in Group B. This difference was statistically significant and was markedly different from the results in the study conducted by Kannan Yelikar.[10,11]

87% of women delivered by vaginal delivery in Group A whereas 77% women delivered by vaginal delivery in Group B. 13% women underwent C section in Group A

Table 5: Indications for C section (Group A)(Chi-square = 0.19, P = 0.65 at df = 1 (Statistically not significant)

Indication of C Section	Mode of induction	Parity	
	Tablet mifepristone	Primigravida	Multigravida
Fetal distress with MSL	4	2	2
Fetal distress with pathological CTG	3	1	2
Non progression in 1st stage of labour	1	1	0
Failure of induction	3	3	0

Table 6: Indications for C section (Group B)

Indication of C Section	Mode of induction	Parity	
	Intracervical foleys catheterisation	Primigravida	Multigravida
Fetal distress with MSL	5	2	3
Fetal distress with pathological CTG	7	4	3
Non progression in 1^{st} Stage of labour	2	1	1
Failure of induction	6	4	2

Chi-square = 0.81, P = 0.84 at df = 1 (Statistically not significant)

Table 7: Comparison of parity with C-section rate in both groups

Parity		Primi			Multi	
	Total	C-Section	%	Total	C Section	%
Group A	34	7	20%	56	4	7%
Group B	43	11	25%	47	9	19%

Chi-square = 2.146, P = 0.14 at df = 1 (Statistically not significant)

Table 8: Comparison of neonatal outcomes

	Group A	Group B
APGAR <7		
1 Min	0	2
5 Min		1
APGAR more than or equal to 7		
1 Min	90	88
5 Min	90	88

and 27% underwent C section in Group B. These results were comparable to the results obtained in various studies conducted by Lata G et al, Rutuja Athawale, Wing DA.[11–13]

In Group A, the incidence of fetal respiratory distress was 7% as compared to 13% in Group B. There were no significant changes in neonatal outcomes in studies by Hapangama and Byrne et al.[14,15]

5. Conclusion

Taking into account the observations we made in this study, we come to the following conclusions:

1. Due to its significant effect on mode of delivery and neonatal outcome, and despite no decrease in induction delivery interval, Mifepristone may be used as an inducing agent in indicated term pregnancies.
2. The incidence of fetal distress in patients given oral mifepristone as compared to patients induced with intracervical foleys catheterization was found to be insignificant.
3. Further study is required to efficiently assess the incidence of tachysystole/ hyperstimulation and fetal distress caused by Mifepristone.

6. Strengths of Study

1. Randomization was done so selection bias was avoided.
2. Inter observer bias was also avoided.

7. Limitations of Study

1. This study was conducted on a small scale with limited time, resources and sample size and the results obtained need to be proved by multiple, randomized studies.
2. There was no control group in our study.

8. Source of Funding

Nil.

9. Conflict of Interest

Nil.

10. Ethical Approval

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References

1. ACOG Practice Bulletin No. 107: Induction of labor. *Obstet Gynecol*. 2009;114(2 Pt 1):386–97.
2. Hofmeyr GJ, Gülmezoglu AM, Alfirevic Z. Misoprostol for induction of labour: a systematic review. *Br J Obstet Gynaecol*. 1999;106(8):798–803.
3. Hamza A, Herr D, Solomayer EF, Meyberg-Solomayer G. Polyhydramnios: Causes, Diagnosis and Therapy. *Geburtshilfe Frauenheilkd*. 2013;73(12):1241–6.
4. Tang OS, Schweer H, Seyberth HW, Lee SWH, Ho PC. Pharmacokinetics of different routes of administration of misoprostol. *Hum Reprod*. 2002;17(2):332–6.
5. Garris RE, Kirkwood CF. Misoprostol: a prostaglandin E1 analogue. *Clin Pharm*. 1989;8(9):627–44.
6. Deepika N, Kumar A. Mifepristone for cervical ripening and induction of labour . *Indian J Obstet Gynecol Res*. 2018;5(1):15–29.
7. Perusquía M, Espinoza J, Navarrete E. Nongenomic uterine relaxing effect of RU 486 (mifepristone) prior to its antiprogesterone activity in the human pregnancy. *Steroids*. 2009;74(10-11):825–31.
8. Schaff EA. Mifepristone: ten years later. *Contraception*. 2010;81(1):1–7.
9. Radzinsky VE, Startseva NM, Startseva OK, Teplov KV, Borisova AV. Mifepristone versus balloon catheter for labor induction: a cohort study. *J Matern Fetal Neonatal Med*. 2022;35(25):9331–5.
10. Yelikar K, Deshpande S, Deshpande R, Lone D. Safety and Efficacy of Oral Mifepristone in Pre-induction Cervical Ripening and Induction of Labour in Prolonged Pregnancy. *J Obstet Gynaecol India*. 2015;65(4):221–5.
11. Lata G, Rana N, Mittal R, Kumar S. Mifepristone for cervical ripening and induction of labour . *Int J Reprod Contracept Obstet Gynecol*. 2018;7(12):5041–4.
12. Athawale R, Acharya SN, Hariharan SC. Effect of mifepristone in cervical ripening forinduction of labour. *Int J Reprod Contracept Obstet Gynecol*. 2013;2(1):35–8.
13. Wing DA, Fassett MJ, Mishell DR. Mifepristone for preinduction cervical ripening beyond 41 weeks' gestation: a randomized controlled trial. *Obstet Gynecol*. 2000;96(4):543–8.
14. Hapangama D, Neilson JP. Mifepristone for induction of labour . *Cochrane Database Syst Rev*. 2009;2009(3):CD002865. doi:10.1002/14651858.CD002865.pub2.
15. Byrne JD, Wing DA, Fraser M, Fassett MJ, Goodwin TM, Challis JRG. Mifepristone: effect on plasma corticotropin-releasing hormone, adrenocorticotropic hormone, and cortisol in term pregnancy. *J Perinatol*. 2004;24(7):416–20.

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