VOLUME-7, ISSUE-12, DECEMBER-2018 • PRINT ISSN No 2277 - 8160

Original Research Paper

Gynecology

COMPARITIVE STUDY OF 50 MCG ORAL VERSUS 25 MCG VAGINAL MISOPROSTAL ADMINISTRATION FOR INDUCTION LABOUR AT TERM

Dr. M. Hindumathi MS, Assoc. Professor, Santhiram Medical College & General Hospital Nandyal.

Dr. B. Tejaswi Prabhanjana* MS, Santhiram Medical College & General Hospital Nandyal. *Corresponding Author

Dr Karthiki Santhiram Medical College & General Hospital Nandyal.

ABSTRACT

BACKGROUND AND OBJECTIVES : Induction of labour is one of the most common obstetric procedures performed in the world. Among the various methods of induction of labour, the synthetic prostaglandin E1 analogue 'Misoprostol' has emerged as a promising agent for induction of labour. The present study aims to assess and compare the safety and efficacy of 50 µg oral misoprostol and 25 µg intravaginal misoprostol for induction of labour at term .

METHODOLOGY: This prospective randomized comparative study included 100 pregnant women at term with obstetric or medical indications for induction of labour. Women either took 50 µg misoprostol orally or had 25 µg of misoprostol inserted in the posterior vaginal fornix. In each group, misoprostol administration was repeated every four hours in the same dose until regular uterine contractions were established or to a maximum of six doses. Induction to delivery interval, number of doses of misoprostol required, need for oxytocin augmentation, outcome of labour, maternal and fetal complications for each group were compared.

RESULTS : The mean number of oral misoprostol doses required for induction was significantly shorter(1.78) compared to the mean number of vaginal misoprostol doses(2.9) with P=0.00002 .The mean induction to delivery interval was significantlyshorter in oral group compared to vaginal group (16.46h in oral group versus
21.38h in vaginal group with P=0.003).The percentage of cases requiring oxytocin
augmentationwas significantly more in vaginal group(76%)than oral group(42%).The improvement in Bishop score after 6 hours was also more in oral group than vaginal group. There were no significant differences between the groups with respect to mode of delivery, number of failed inductions, maternal complications and fetal outcome.

CONCLUSION : Oral misoprostol in dose of 50µg is as efficacious as 25µg vaginal misoprostol because of similar labour outcome with shorter induction delivery interval, smaller number of doses required for delivery, lesser requirement of oxytocin augmentation with similar maternal and fetal outcome. Oral route of administration is easy and convenient for both patients and caregivers.

KEYWORDS : Misoprostal ,vaginal route oral route, induction of labour

INTRODUCTION:

Induction of labour, the technique of artificially stimulating uterine contractions prior to the natural onset of labour to achieve vaginal delivery of the fetoplacental unit, is one of the most common obstetric procedures performed in the world. It is indicated when the fetal and maternal risks of early delivery are outweighed by the risks of prolonged pregnancy.

In fact, in the United States alone, the induction rates more than doubled from 9.5% to 22.8% between 1990 and 2012. The WHO Global Survey on maternal and perinatal health (including data from 24 countries and nearly 30,000 deliveries) showed that 9.6% of the deliveries involved labour induction. Overall, the survey found that African countries tended to have lower rates of induction of labour (lowest: Nigeria 1.4%) compared with Asian and Latin American countries(highest: Sri Lanka 35.5%).

The new synthetic prostaglandin E1 analogue 'Misoprostol' licensed primarily for prevention and treatment of non steroidal anti-inflammatory drug induced gastric ulcers, is a promising agent for induction of labour. Unlike oxytocin and prostaglandin E2 (Dinoprostone), misoprostol is conveniently administered through the oral,sublingual, buccal, rectal routes. Compared to oxytocin and prostaglandin E2 (Dinoprostone) which loose their efficacy unless preserved at correct temperature (between 2-8°C), misoprostol can be stored at room temperature with a long shelf life. It is inexpensive and has few systemic side effects. Therefore, it has been the major focus of attention for labour induction during the past 15 years.

Misoprostol could also be easily administered by unskilled attendants or the women themselves, thus making them available for women giving birth at home or in isolated areas. These are benefits that make it particularly appealing for developing poor Even though misoprostol has been established as a choice of drug for countries.(3)induction of labour, the ideal route, dose and frequency of administration are under investigation.(4) the dosage range is also widely variable for different obstetric indications, working as a con founder relating to safe dosages for re productive health indications.if unsafe dosage is used ,side effects are more prone to occure because they seem to be dose- related.(5) reasonable means of induction, there is a patient resistance to repeated digital.

Although, vaginal application of misoprostol has been validated as as examination and there is risk of ascending infection(6).For these reasons, oral administration of misoprostol has been introduced for cervical ripening and labour induction(7). This study aims to compare the safety and efficacy of oral application of misoprostol with vaginal application for cervical ripening and induction of labour.

AIMS & OBJECTIVES

To study the safety and efficacy of oral and vaginal applications of misoprostol as an inducing agent for induction of labour in 100 gravid women with term gestation in terms of
Induction to delivery interval
Number of Doses required for delivery
Need of Oxytocin augmentation for delivery
Mode of delivery
Maternal Outcome
Maternal Complications
Fetal Outcome
Meconium Stained Amniotic Fluid
NICU Admissions

METHODOLOGY

The present study "Comparative study of 50 µG oral versus 25 µG vaginal misoprostol administration for induction of labour at term"

is a clinical prospective study involving 100 gravid women with term gestation admitted in department of OBSTETRICS AND GYNAECOLOGY labour room, Santhiram Medical College, Nandyal from year January 2016 to june 2018 for induction of labour. The study was approved by the college Ethical committee.

Inclusion Criteria
37 weeks (or) more gestation
Singleton gestation
Bishop score less than 6
Intact or early rupture of membranes
Vertex Presentation

Exclusion Criteria
Cephalopelvic disproportion
Abruptio placenta
Placenta praevia, vasa previa
Malpresentation
Previous uterine scar
Active genital herpes

As shown in the proforma, assessment of the patient included a detailed history with reference to age, parity, socioeconomic and educational status, period of gestation and indication for induction of labour. Period of gestation was calculated from the first day of her last menstrual period (LMP), if her previous cycles were regular or from Ultra Sonogram(USG) reports of 1st or 2nd trimester.

Complete physical examination including per abdominal and pelvic examination was carried out in all cases. Laboratory investigations included urine for sugar, proteins and microscopy, blood for hemoglobin estimation, grouping, Rh typing and BT, CT, random blood sugar assessment, serology screening for HIV, HBsAg and VDRL was done. An USG and a Non-Stress Test at admission to labour room was done. Other investigations specific to the co-morbidities (anemia, pre-eclampsia, iugr, etc) like red cell indices, liver function tests, renal function tests, triple vessel Doppler were also done if needed.

The 100 gravid women in the study were randomized into Group A and GroupB. A written consent for induction of labour was taken.

Group A – 50 women received oral administration of 50 µg Misoprostol every 4th hourly, maximum of 6 doses.

Group B - 50 women received vaginal administration of 25 µg Misoprostol every 4th hourly, maximum of 6 doses.

In all the women the cervical status was assessed by using Bishops score prior to induction. Repeat Bishops score was assessed at 6th hr and then before every

Repeat dose
In case of oral administration 50µg misoprostal dose was repeated every 4th hourly until an adequate pattern of uterine contractionssets in. Maximum allowable dose was 300µg orally.In case of vaginal administration 25µg of misoprrostal was kept in posterior fornix .Same dose was repeated every 4th hourly until an adequate uterine contractions sets in .so maximum allowable dose by vaginal route is 150µg.

From the time of induction ofb labour the women were closely monitored for vital signs,progress of labour ,uterine contractions ,FHR was monitored by intermittent auscultation or cardio tocography according to need.Labour augumentation was done with amniotomy and oxytocin if needed once cervix is 3 cm and more dilated.Progress of labour wasn monitored with a partogram from 4 cm of dilatation to delivery.

If the women did not enter active phase of labour i.ecervical dilatation <4cmand cervical effacrment of <80% even after 24 hours of induction of labour,it was considered as failed induction and delivry was terminated by LSCS.In case woman has tachysystole i.e more than 5 contractions in 10 min period she was managed as per the following protocol

Stop oxytocin drip if on augmentation of labour
Inj. terbutaline 250mcg subcutaneously stat
Close monitoring of fetal heart rate and hasten delivery in case of fetal distress

In case of fetal distress, the following protocol was adopted :
Moving the mother to lateral position
Stop oxytocin drip {if on augmentation of labour}
Intravenous hydration with 500ml of Ringer lactate or 5D
Supplemental oxygen at 10L/min through a non breathing mask to mother Hasten delivery.

The results were interpreted as mean and standard deviation and modified 't' test and chi-square test were applied to know the statistical significance.

RESULTS
The results observed while comparing the effect of 50 micrograms oral misoprostol versus 25 micrograms vaginal misoprostol for induction of labour at term pregnancy in 100 women belonging to selection criteria will be discussed below..

OBSEVATION AND RESULTS:-
Table no. 1 Distribution of cases According to Gestational Age

G A(in weeks & days)	GROUP A (ORAL)	GROUP B(VAGINAL)
37-40weeks 6 days	47	46
41-42 weeks	03	4
Total	50	50
Mean gestational age	39.89 +_0.88	40.03+0.89

The mean gestational age in group Awas39.89±0.88 weeks and in group B was 40.03±0.89 weeks.

Distribution of cases according to parity

Parity	Group A (oral)		Group B(vaginal)	
Primi	32	64%	33	66%
multi	18	18%	17	17%
Total	50	100%	50	100%

The parity based distribution of cases shows that out of the total 50 cases
under group A, 32(64%) cases are primigravida and 18(36%) cases are multigravida.
In group B, 33(66%)cases are primigravida and 17(34%)cases are multigravida

Table 3 : Distribution of cases based on indications for induction among cases

Indication	Group A (oral)		Group B (vaginal)	
Post dated	33	66%	35	70%
Rh –ve Preg	5	10%	6	12%
Preeclampsia	4	8%	3	6%
P R O M	6	12%	4	8%
Oligohydromnious	2	4%	2	4%

Distribution of indications for induction of labour was similar in both the groups with post dated pregnancy(>40 weeks) being the most common indication in both group A and group B

Table no. 4 Distribution of cases based on no. of Doses required for Delivery

No. of Doses	Group A (oral)		Group B (vaginal)	
1	21	42%	8	16%
2	21	42%	8	16%
3	7	14%	19	38%
4	0	0%	11	22%
5	1	2%	4	8%
6	0	0%	0	0%
Mean ± S D	1.78± 0.82		2.9 ±1.16	

In Group A, maximum number of cases i.e. 21(42%) and 21(42%) required 1 and 2 doses respectively and 7 cases(14%) required 3 doses. Only 1 case required 5 doses In Group B, majority of the cases i.e. 19 cases(38%) required 3 doses and 11 cases (22%) required 4 doses. 1 and 2 doses were sufficient to induce labour in 8 cases (16%) each and 4 cases (8%) required 5 doses.

Mean Number of doses needed for induction of labour is significantly less in Group A (1.78 +0.82) compared to Group B (2.9 +1.16) with P=0.00002.

Table no. Response to drug in terms of Bisphops Score

Bishops Score	Group A (oral)	Group B (vaginal)
Pre induction B S	3.22 ± 1.23	2.76± 1.22
6 hrs after induction B S	6.22 ± 1.45	4.98 ± 1.52

In Group A, the mean pre-induction Bishop score was 3.22 ± 1.23 and mean Bishop score after 6 hours was 6.22 ± 1.45

In Group B, the mean pre-induction Bishop score was 2.76 ± 1.22 and mean . Bishop score after 6 hours was 4.98 ± 1.52.

The Bishop score improvement after 6 hours was better in Group A compared to group B

Table no. Distribution of cases based on requirement of oxytocin Augmentation

Augumentation c oxytocin	Group A(oral)		Group B(vaginal)	
Yes	21	42%	38	76%
No	29	58%	12	24%
Total	50	100%	50	100%

In Group A, 21 cases(42%) required augmentation with oxytocin while 29 cases(58%) did not require it.

In Group B, majority of the cases i.e. 38 cases(76%) required oxytocin augmentation while rest 12 (24%) did not need it.

This difference is statistically significant with P=0.0005

Table no. Distribution of cases based on Induction to delivery Interval (IDI)

IDI interval	Group A		Group B (vaginal)	
< 12 hr	6	12%	4	8%
12- 24	40	80%	28	56%
> 24 hrs	4	8%	18	36%
total	50	100%	50	100%
Mean ± S D	16.46 ± 4.64		21.38 ± 5.27	

While analyzing the results based on IDI out of the total 50 cases Belongimg to GROUP A, majority of the cases i.e 40 cases are in 12-24 IDI and another 6 cases are in < 12 hrs IDI , and only 4 cases are in >24 hrs IDI. In the Group B 28 cases are in 12-24 hrs of IDI followed by 18 cases and 4 cases in > 24 hrs and < 12 hrs Of IDI respectively.

The mean IDI in Group A , is calculated as 16.46 ± 4.64 hrs and in Group B 21.38 ± 5.27 this difference was statistical significant with P = 0.003

Table no. 8 Failed Inductions

Failed induction	Group a oral		Group B VAGINAL	
Yes	2	4%	4	8%
No	48	96%	46	92%
total	50	100%	50	100%

2 cases in group A and 4 cases in group Bfailed to have significant cervical changes after 24 hours of induction with p=0.399 which is not significant.

Table no 9 Mode of delivery

Mode of delivery	Group A		Group B	
Normal	43	86%	43	86%
Forceps/vacuum	1	2%	0	0%
LSCS	6	12%	7	14%
Total	50	100%	50	100%

The mode of delivery in terms of normal vaginal instrumental and LSCS was similar in both groups.

Table no 10 Distribution of cases based on character of liquor

Character of liquor	Group A		Group B	
Clear	39	78%	42	84%
Meconium	11	22%	8	16%
Total	50	100%	50	100%

In both the groups meconium staining liquor was not statistically significant.

Table no 11 Maternal complications

Maternal complication	Group A		Group B	
Uterine tachysystole	0	0%	1	2%
Nil	50	100%	49	98%
Total	50	100%	50	100%

This difference in both groups not statistically significant.

Table no 12 Distribution of cases based on APGAR score at 1and 5

APGAR score	Group A Oral		Group B Vaginal	
1min <7	5	10%	6	12%
>7	45	90%	44	88%
Total	50	100%	50	100%
5 min <7	1	2%	1	2%
>7	49	98%	49	98%
Total	50	100%	50	100%

Table no 13 Mean APGAR scoreat 1 min and 5 min

Mean APGAR score	Group A	Group B
At 1 min	7.54±0.91	7.48±0.93
At 5 min	8.78±0.68	8.82±0.59

The APGAR score <7 at 1 min in both groups was not statistically significant with p value0.749

Table no 14 Distribution of cases based on NICU admission

NICUadmission required	**GroupA**		**GroupB**	
Yes	5	10%	5	10%
No	45	90%	45	90%
Total	50	100%	50	100%

Number of babies needing NICU admission is same in both the groups

Table no 15 Distribution of cases based on indication of LSCS

Indication for LSCS	Group A		Group B	
Failed induction	2	33.3%	4	57.1%
Fetal distress	2	33.3%	3	42.9%
Deep transverse arrest	1	16.7%	0	0%
Arrest of labour	1	16.7%	0	0%
Total	6	100%	7	100%

In group A 6 patients had LSCS and in group B 7 patients had LSCS .

DISCUSSION;

Distribution according to gestational age and parity and indication for induction

There was no statistically significant difference in both groups with respect to gestational age and parity. The groups were also similar with respect to indications for labour induction, with postdates being the most common indication in both the groups.

Number of doses of drug required for delivery

In the present study, the mean number of doses of 50 micrograms oral misoprostol every 4th hourly for induction of labour was 1.78±0.82 which was significantly less compared to the mean number of doses required for induction in the vaginal group i.e. 2.9±1.16 with 25 micrograms of misoprostol being administered vaginally every 4th hourly, with P=0.00002.

In a similar study conducted by **Hafizur Rahman et al. (2013)8** the mean number of doses of misoprostol required orally and vaginally for induction of labour was the same i.e. in the oral group was 2.33 ± 1.18 and in the vaginal group was 2.42 ± 1.28 with P=0.59 .

Another study by **Kambhampati Komala et al. (2013)9 also** found that there was no significant difference in the mean number of doses of misoprostol required orally and vaginally with P=0.11.

This is attributed to pharmacokinetics of misoprostol which is different for each route. Although the bioavailability of vaginal misoprostol is greater, the peak plasma concentration attained by oral misoprostol is higher than the peak attained by vaginal route. Also misoprostol is rapidly absorbed orally with the time for onset of action being shorter for oral route(8min) compared to vaginal route(20 min). There is also a great variation in bioavailability between women with vaginal administration of misoprostol.

Response to Drug in terms of Bishop Score

Before induction of labour, cervical scoring was done by Bishop's score and for both the groups, next cervical scoring was done after 6 hours.

Mean pre-induction bishop score for Oral group was 3.22±1.23. For vaginal group, the mean value was 2.76±1.22 which was statistically just significant (P=0.046). After 6 hours, the bishop score for oral group had a mean of 6.22±1.45 and for vaginal group, the mean was 4.98±1.52, which was statistically very much significant (p=0.00002). It indicates that the improvement in cervical score was significantly more in oral group as compared to the vaginal group after the 6 hours.

Requirement of Augmentation with Oxytocin

In the present study, it was found that 21 cases (42%) in Group A and 38 cases (76%) in Group B required augmentation with oxytocin. The difference was statistically significant, with P=0.0005.

This finding is consistent with the study by **Shi-Yann Cheng** 10 which showed, only 10.9% (11 of 101) of patients in the titrated oral misoprostol group needed oxytocin augmentation, which was a far lower percentage than the 53.8% (57 of 106) in the vaginal misoprostol group (RR 0.11, 95% CI 0.05– 0.22).In the study conducted by **Hafizur Rahman et al.(2013)8,** 30 out of 110 cases(27.27%) in the oral misoprostol group required augmentation with oxytocin and 26 out of 110 cases(23.64%) in the vaginal group required oxytocin augmentation for labour with P=0.64 which is not statistically significant.

Induction to delivery interval

The mean induction to delivery interval in the present study was found to be 16.46±4.64 hours in Group A(oral) which was significantly less compared to 21.38±5.27 hours in Group B(vaginal) with P=0.003.

Shi-Yann Cheng 10 study showed, completed vaginal delivery occurred within 12hours in 75 (74.3%) women in the titrated oral group and 27 (25.5%) women in the vaginal group (relative risk (RR) 8.44, 95% confidence interval (CI) 4.52–15.76).

In another study by **Kambhampati Komala et al.(2013)9,**oral group had a shorter induction to delivery interval of 12.92 hours as compared to 14.04 hours in vaginal group.

In the study conducted by **Hafizur Rahman et al.(2013)8,** mean induction-to-delivery interval in women who delivered vaginally was similar in oral and vaginal groups(21.22 hours in oral group versus 20.15 hours in vaginal group; P = 0.58).

In the study by **Khadija bano et al (11)**, mean induction-delivery (I-D) interval were similar in both groups; vaginal (9.09 ±3.4 hours) and oral (9.81±4.43 hours p=0.33).

Failed Induction

In this study number of cases who did not progress to active labour after 24 hours of induction was considered as failed induction. There was no statistical difference with respect to this outcome with 2 cases(4%) in Group A(oral)and 4cases(8%) in Group B of failed induction with P= 0.399

This finding was consistent with the study by **Hafizur Rahman et al.(2013)(8)** where 19 out of 110 cases(17.2%) in oral group and 22 out 110 cases(20%) in vaginal group were declared as failed induction with P= 0.73.

In the study by **Kambhampati Komala et al.(2013)(9)**, failed induction rate was more in vaginal group, which had a 6% rate as compared to oral group, which had a rate of 2%.

Shi-Yann Cheng (10)study showed induction failure did not occur in any patient in the titrated oral group but occurred in 11 (10.4%) women in the vaginal group (RR 0.04, 95% CI 0.00–0.70).

Mode of delivery after induction

Number of patients who had normal delivery was 43 (86%) both in Group A(oral) and Group B(vaginal), one(2%) from Group A had instrumental delivery in view of failed maternal efforts. Six (12%) from Group A and seven (14%) from Group B underwent emergency caesarean section. Indications for caesarean section in Group A was two cases in view of fetal distress, two cases in view of failed induction and one case in view of secondary arrest of labour and one in view of deep transverse arrest. Indications for caesarean section in Group B was fetal distress for three cases and failed induction for four cases. The mode of delivery in terms of normal vaginal, instrumental (forceps/vacuum) and LSCS was similar in both groups in the present study.

This finding is consistent with a similar study by **Hafizur Rahman et al.(2013)(8)** who found no significant difference in the number of vaginal, instrumental and caesarean delivery rates between oral and vaginal misoprostol groups.

In the study by **Kambhampati Komala et al. (2013)(9)** caesarean rate in oral group was 6% and in vaginal group, it was 14%.Major indication for operative delivery rates in both the groups was non-reassuring CTG. The incidence of instrumental delivery was same in both the groups.

Shi-Yann Cheng 10 study showed, Eighteen (17.0%) patients in the vaginal group underwent cesarean delivery compared with only four (4.0%) patients in the titrated oral group (RR 0.20, 95% CI 0.07–0.62).

Characteristics of liquor

In the present study, 39(78%) cases from Group A and 42(84%) cases from Group B had clear liquor and 11(22%) cases from Group A and 8(16%) cases from Group B had meconium coloured liquor indicating no significant difference with respect to character of liquor in both the groups.

Three cases out of the 11 cases of meconium stained liquor from oral group were thick meconium stained, and two cases out of the three showed a non-reassuring CTG and underwent LSCS for fetal distress. All the three babies were admitted in NICU for respiratory distress.

Four cases out of the eight cases of meconium stained liquor from vaginal group had thick meconium and out of the four, three cases

showed non-reassuring CTG and underwent LSCS for fetal distress. All the four cases had NICU admission three for respiratory distress and one for observation.

Similar findings were observed by **Hafizur Rahman et al. (2013)8** where 18.18% in oral group and 23.64% in the vaginal group developed meconium stained liquor.

In the study by **Kambhampati Komala et al. (2013)9**, incidence of meconium stained liquor was more in vaginal group (20 out of 78) as compared to that in oral group (14 out of 86) but there was no significant difference. The major cause in both the groups was a prolonged pregnancy.

Maternal complications

In the present study5, only one case from Group B(vaginal) developed tachysystole(2%), this difference was not statistically significant. Other common adverse effects of misoprostol like, nausea, vomiting, watery diarrhea, fever were not encountered in present study.Various studys with similar methodological design,compared doses of 50 micro gram verses25 micrograms,via different routes, of viso prostal for induction at term. The incidents of tachysystole was significantly higher in the 50 micro grams groops than in the 25 micro grams groops,with out significant different with respective to incidence of hyper stimulation syndrome ,and no ruptured uterus.(12-14).

In the study by **Hafizur Rahman et al. (2013)8** adverse effects like nausea,vomiting, diarrhea and fever were encountered but the incidence was similar in both oral and vaginal groups. Tachysystole developed in two women (1.8%) in the oral misoprostol group and six women (5.5%) in the vaginal misoprostol group.

In the study by **Kambhampati Komala9 et al. (2013)**, the rate of hyperstimulation in vaginal group was only 1%, where caesarean section was done immediately and it was nil in oral group. Gastrointestinal side-effects were reported more in oral group and incidence of hyperpyrexia was also more in oral group in this study.

APGAR score at 1 and 5 minutes

In the present study 1 minute APGAR <7 was seen in 5 babies in GroupA(oral) and NICU admission was required in all 5, three for respiratory distress and two for observation.

In Group B(vaginal) 6 babies had APGAR score <7 at 1 minute and five required NICU admission, three for respiratory distress and two for observation.

One baby in both the groups had APGAR score < 7 at 5 minutes.

This indicates similar fetal outcome with respect to APGAR score at 1 and 5 minutes in both oral and vaginal groups with P=0.749 at 1min and P=0.475 at 5min.

comparable neonatal outcomes were found with both doses in terms of assigned Apgar score at 1 and 5 minites ,meconium strained amniotic fluid,birth weight and referrel of the infants to the paediatrition .(12-14) In the study by **Hafizur Rahman et al. (2013)** 8 out of 110 in oral group and 15 out of 110 in vaginal group had APGAR score less than 7 at 5 minutes indicating no significant difference between the two groups with respect to this outcome with P=0.19.In the study by **Kambhampati Komala et al. (2013),** 24 cases out of 74 in vaginal group and 14 cases out of 86 in oral group had low 5 minutes APGAR scores of 6-8 with overall good neonatal outcome in both the groups.

Fetal outcome in terms of NICU admission

In the present study, similar outcome in both the groups was observed with respect to fetal NICU admissions with five babies from both the groups requiring NICU admission, three out five for respiratory distress and two for observation.

In the study by **Hafizur Rahman et al.(2013)** 5 out of 110 in oral group and 9 out of 110 in vaginal group required NICU admission with P=0.41 showing no significant difference.Shi-Yann Cheng study showed, number of cases who required NICU admissions was nil in titrated oral group compared to titrated vaginal group six(5.7%).

CONCLUTION:

This study concludes that oral misoprostol in a dose of 50 µg has the potential to induce labour as safely and effectively as 25 µg vaginally administered misoprostol because of similar labour outcome with significantly shorter induction delivery interval, lesser number of doses required for delivery, more improvement in Bishop score after 6 hours of induction, lesser requirement of oxytocin augmentation with similar maternal and fetal outcome.

A limitation of our study is the lack of blinding after randomization. The clinicians involved in the study were aware of the allocated treatment. Further, the present study had a relatively small sample size. There is a need for a greater number of appropriately designed randomized controlled trials (preferably double blinded) with a larger sample size to validate the efficacy and safety of 50 µg oral misoprostol in comparison with 25 µg vaginal misoprostol as oral use of the drug is easier and more convenient for both patients and caregivers. Also misoprostol compared to other methods of induction of labour has good safety profile with predictable side effects, has low cost, long shelf life, lack of need for refrigeration and worldwide availability

REFERENCES:

1. Martin JA, Ventura SJ. Births: preliminary data for 2012.Natinal vital statistics report: from the Centre for Disease Control and Prevention, National Centre for Health Statistics. Nat Vital Stat.2013;62:1-20.
2. WHO Global Survey on Maternal and Perinatal Health. Induction of labour data. Geneva, World Health Organisation, 2010.
3. Elati A, Weeks AD. The use of misoprostol in obstetrics and gynaecology. BJOG 2009; 116 (Suppl 1): 61-69. Blanchard K, Clark S, Winikoff B, Gaines G, Kabani G, Shannon C. Misoprostol for women s health: a
4. review. Obstet Gynecol 2002; 99(2):316- 332.
5. Tang OS, Gemzell- Danielsson K, Ho PC. Misoprostol: pharmacokinetic profiles, effects on the uterus and side- effects. Int J Gynaecol Obstet 2007; 99 (Suppl 2):S160–167. Alfirevic Z, Weeks A. Oral misoprostol for induction of labour. Cochrane
6. Database Syst Rev 2006, Issue 2. Art. No.: CD001338. DOI:10.1002/14651858. CD001338.pub2.
7. Ngai SW, To WK, Lao T, Ho PC. Cervical priming with oral misoprostol in pre-labour rupture of membranes at term. Obstet Gynaecol 1996;87:923–6.
8. Hafizur Rahman, Anup Pradhan, Latha Kharka, Prachi Renjhen, SumitKar Sudip Dutta. Comparative Evaluation of 50 Microgram Oral Misoprostol and 25 Microgram Intravaginal Misoprostol for Induction of Labour at Term:A Randomized Trial. JObstet Gynaecol Can 2013;35(5):408–416.
9. Kambhampati Komala, Meherlatha Reddy, Iqbal Jehan Quadri, Suneetha B, Ramya. Comparative Study of Oral and Vaginal Misoprostol for Induction of Labour, Maternal and Foetal Outcome. Journal of Clinical and Diagnostic Research. 2013 Dec, Vol-7(12): 2866-2869.
10. Shi-Yann Cheng, MD, Ho Ming, MD, and Jui-Chi Lee, MD. Titrated Oral Compared With Vaginal Misoprostol for Labour Induction. Obstet Gynecol 2008;111:119–25
11. Khadija Bano, Mahjabeen, Shereen Zulfiqar Bhutta. Oral versus Vaginal misoprostol for induction of labour at term. Journal of Surgery Pakistan (International) 14 (1) January - March 2009.
12. Eroglu D, Oktem M, Yanik F, Kuscu E. Induction at term: a comparison of the effects of 50 microg and 25 icrog vaginal misoprostol. Clin Exp Obstet Gynecol 2007; 34(2): 102-105.
13. Paisarntantiwong R, Getgan M. A comparison between single dose of 50 microg oral misoprostol and 25 microg vaginal misoprostol for induction. J Med Assoc Thailand 2005; 88 (Suppl 2): S56- 62.
14. Elhassan EM, Mirghani OA, Adam I. Cervical ripening and induction with 25 microg vs. 50 microg of intravaginal misoprostol. Int J Gynaecol Obstet 2005; 90 (3):