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A COMPARATIVE STUDY OF LOW DOSE ORAL MISOPROSTOL VERSUS VAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR

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ABSTRACT

INTRODUCTION: Misoprostol is a new promising agent for cervical ripening and induction of labour. The ideal dose, route and frequency of administration of misoprostol are still under investigation. Although, vaginal application of misoprostol has been validated as a reasonable mean of induction, there is a patient resistance to digital examination and there is a risk of ascending infection. For this reason, oral administration of misoprostol for cervical ripening and labour induction has been tried.

AIMS: To compare the effect of low dose oral misoprostol with vaginal misoprostol administration for induction of labour at term.

MATERIALS AND METHODS: This study was conducted in the Department of Obstetrics and Gynaecology of Maharani Laxmi Bai Medical College, Jhansi, Uttar Pradesh (India) from September 2017 to July 2019. The study was approved by the college Ethical.

RESULTS: There were 220 women in the oral and 180 women in the vaginal misoprostol groups. The mean induction to delivery interval in this study was found to be in Group I mean was 13.83 hours with in Group II mean was 11.9 hours.

CONCLUSION: Oral and vaginal route of administration of misoprostol for induction of labour are equally effective for induction of labour, Number of doses of misoprostol used in vaginal route of administration, was significantly lesser compared to oral route, There was no difference in induction to delivery interval between the two routes of administration of misoprostol, There was no difference in fetal and maternal complications in both groups., There was no difference in outcome of labour in both groups.

KEYWORDS : Induction Of Labor, Prostaglandins, Uterine Contractions

INTRODUCTION

Induction of labour is one of the most common procedures in obstetrics. Generally, labour induction is indicated when the benefits of delivery to the mother or fetus outweigh the potential risks of continuing the pregnancy[1-2]. The most appropriate timing for labour induction is the point at which the maternal or perinatal benefits are greater if the pregnancy is interrupted, than if the pregnancy is continued. Ideally, most pregnancies should be allowed to reach term, with the onset of spontaneous labour being the signal for physiologic termination of pregnancy[3]. Occasionally, however, a woman must deliver before the spontaneous onset of labour.

AIMS AND OBJECTIVES

AIMS:

To compare the effect of low dose oral misoprostol with vaginal misoprostol administration for induction of labour at term.

OBJECTIVES:

- To compare induction delivery intervals by oral and vaginal routes of misoprostol administration.
- To evaluate maternal outcomes after oral and vaginal routes of administration
- To compare neonatal outcome in terms of APGAR score, meconium stained liquor and admission to NICU.

MATERIALS AND METHODS:

This study was conducted in the Department of Obstetrics and Gynaecology of Maharani Laxmi Bai Medical College, Jhansi, Uttar Pradesh (India) from September 2017 to July 2019. The study was approved by the college Ethical.

On an average 90 antenatal patient come to our department including OPD and emergency department.

After applying inclusion and exclusion criteria ~1-2 patient I get daily.

It take approximately 36-40 month for me to get 400 patients for my study.

As it is a randomized clinical trial so in order to avail raising from both observer and participant.

A simple method of randomisation is applied. I have devided patients into two groups –

- Group A – Vaginal misoprostol
- Group B – Oral misoprostol

For randomization after selecting patients I use to see OPD ticket number and patients with odd ticket number were given vaginal misoprostol and those having even OPD ticket number are given oral misoprostol.

By applying this method finally in group A 220 patients and group B – 180 patients were selected for the study.

INCLUSION CRITERIA:

1. Primigravida
2. Gestation age between 37-42weeks
3. Age between 18-35 years
4. Singleton fetus
5. Cephalic presentation
6. Intact or early rupture of membranes (<6 hrs)

7. Bishop's score <6
8. Normal admission cardiotocography

EXCLUSION CRITERIA:

1. Age <18 and >35 years
2. Malpresentations
3. Fetal distress
4. Previous uterine scar
5. Placenta previa, vasa previa, active genital herpes

METHODOLOGY:

ORAL MISOPROSTOL REGIMEN:

1. Initially 25 mcg is given orally
2. After 4 hrs if uterine contractions are adequate further dose will be withheld
3. If uterine contractions are inadequate and if cervical bishop score is unfavourable, 20mcg will be given and repeated every 4hrs till adequate contractions 4 contractions lasting for 40 seconds in 10 minute period or bishop score improves(>6), evaluated once in 4 hours.
4. Labour augmentation may be done with amniotomy and oxytocin, once cervix is 5cm and more dilated.

VAGINAL MISOPROSTOL REGIMEN:

1. Initially 25mcg will be kept in posterior vaginal fornix after moistening with two drops of saline.
2. After 4hrs if uterine contractions are adequate no further action is taken
3. If uterine contractions are inadequate or bishop score is unfavourable, 25mcg will be given and repeated every 4hrs till adequate contractions 4 contractions lasting for more than 40 seconds in 10 minutes period or bishop score improves(>6), evaluated once in 4 hours.
4. Labour augmentation may be done by amniotomy and oxytocin, once cervix is 5cm or more dilated.

MANAGEMENT OF TACHYSYSTOLE:

In case patient has tachysystole, i.e. more than 6 contractions in 10 minutes period ,patient will be managed as per the following protocol

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

STUDY DESIGN:

A randomized clinical trial to compare the effects of titrated low dose oral misoprostol regimen with vaginal misoprostol administration for induction of labour at term.

METHOD OF DATA ANALYSIS:

The data was collected and entered in Microsoft excel sheet and later on excel sheet is transported to the SPSS 15.0 and appropriate statistical test student t-test are applied.

RESULTS:

Parameters	Group A [Vaginal misoprostol] (N=220)		Group B [Oral misoprostol] (N=180)	
	Number	Percentage	Number	Percentage
Age groups (in years)				
• 16-25	168	76.6%	112	62.2
• 26-32	52	23.6%	68	37.7
Gestational Age (in weeks)				
• 37-39	188	85.5	146	81.1
• 40-42	32	14.5	34	18.8
Indication of induction				
• Post pregnancy	84	36.2%	61	33.89%
• Gestational hypertension	37	16.8%	27	15.0%
• PROM	35	15.91%	14	7.75
• Preeclampsia	27	12.27%	31	17.22%
• Other	37	16.87%	47	26.11%
Number of dose				
• 1	22	10.0%	9	5.0%
• 2	39	17.7%	27	15.0%
• 3	44	20.0%	30	13.8%
• 4	75	34.1%	29	18.8%
• 5	28	72.7%	53	29.4%
• 6	12	6.6%	32	17.8%
Side effects				
• Nausea/ vomiting	18	8.2%	22	12.2%
• Diarhoea	25	11.4%	17	9.4%
• Headache	17	7.7%	14	7.78%
• Fever	12	5.45%	4	0.22%
• Uterine hyperstimulation	22	10.0%	24	18.89%
Mode of delivery				
• Vaginal	187	88.0%	139	77.22%
• LSCS	33	12.0%	41	22.78%
Delay time (in hours)				
• <5 hours	20	9.17%	16	8.33%
• 6-10 hours	47	21.4%	22	12.22%
• 11-15 hours	74	37%	27	15.0%
• 16-20 hours	45	20.5%	55	30.55%
• >20 hours	34	15.5%	61	33.9%
Apgar score At 1 minute				
• <7	59	26.82%	63	35%
• >7	161	73.18%	117	65%
At 5 minute				
• <7	31	14.1%	41	21.58%
• >7	189	85.9%	139	78.42%

DISCUSSION:

400 women were enrolled for study who were belonging to selection criteria. They were divided into 2 groups:

- Group I: 200 women for oral misoprostol administration of 25mcg every 4 hourly
- Group II: 180 women for oral misoprostol administration of 25mcg every 4 hourly

DOSES OF DRUG REQUIRED FOR DELIVERY:

Mean number of doses required in Group I was 3.85 to Group II which was 7.0. Mean number of doses difference statistically more in Group II compared to Group I

REQUIREMENT OF AUGMENTATION WITH OXYTOCIN:

In my study, it was found that 39.3% in Group I and 57.4% in Group II required augmentation with oxytocin. The difference was statistically significant. Means more augmentation needed with oxytocin needed in oral route[4-5].

INDUCTION TO DELIVERY INTERVAL:

The mean induction to delivery interval in this study was found to be in Group I mean was 13.83 hours with in Group II mean was 11.9 hours[5].

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. Grop A 79.6% failed induction while group B have 28.33 mean more failed induction in oral route[4-5].

MODE OF DELIVERY AFTER INDUCTION:"

Number of patients who had normal delivery was, 80.6% in

Group A, compared to 71.6% in Group B. 19.5% from Group A and 28.33% from Group B underwent emergency caesarean section. Indications for caesarean section in Group A was two cases in view of fetal distress, one case in view of failed indu ction and one case in view of arrest of descent. Indications for three cases in Group B was fetal distress, one case in view of failed induction and one case in view of deep transverse arrest. The mode of delivery in terms of normal vaginal, instrumental (forceps/vacuum) and LSCS was similar in both groups with P=0.430[4-5].

CHARACTERISTICS OF LIQUOR:

In the present study, 75% cases from group A and 67.22% from groip B had clear liquor and 26% cases from group A and 32% cases from group B had meconium coloured liquor. Cases of meconium stained liquor from oral group one was thick meconium stained, and underwent LSCS in view of non-reassuring CTG and the other case had thin meconium stained liquor in view of arrest of labour underwent LSCS. Both the neonates did not require NICU admission and none developed respiratory distress syndrome. Cases of meconium stained liquor from vaginal group had thick meconium stained liquor and both cases underwent LSCS in view of non-reassuring CTG. Both neonates did not require NICU admi ssion and none developed respiratory distress syndrome[4,6].

MATERNAL COMPLICATIONS:

In the present study, only one case from Group B complication in 45% cases, this difference was not statistically significant. Other common adverse effects of misoprostol like, nausea, vomiting, watery diarrhea, fever were not encountered in pres ent study[4,7].

One case which developed hyperstimulation, was given injection terbutaline 250mcg subcutaneously.

BISHOP SCORE:

In both groups bishop score is between 2-5 and is comparable in both groups.

APGAR SCORE AT 1 AND 5 MINUTES:

In both the groups, 1 minute APGAR <7 was seen in 26.82% neonates. In Group A both babies were admitted to NICU in view of respiratory distress syndrome[4,7].

In Group B 36% neonates had APGAR score <7 at 1 minute and did not require NICU admission.

Neonates in both the groups had APGAR score < 7 at 5 minutes are 31% and 21% respectively in group A and group B.

NEONATAL OUTCOME IN TERMS OF NICU ADMISSION:

In the present study, 13.3% cases in group A and 23.3% cases in grop B required NICU admission in view of respiratory distress syndrome and none from Group B[4-5].

CONCLUSIONS

1. Oral and vaginal route of administration of misoprostol for induction of labour are equally effective for induction of labour.
2. Number of doses of misoprostol used in vaginal route of administration, was significantly lesser compared to oral route.
3. There was no difference in induction to delivery interval between the two routes of administration of misoprostol.

There was no difference in fetal and maternal complications in both groups. 5) There was no difference in outcome of labour in both groups.

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