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COMPARATIVE STUDY OF CERVIPRIME GEL WITH ORAL MISOPROSTOL IN INDUCTION OF LABOUR FOR POST DATISM AND PIH AND IUGR

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ABSTRACT

BACKGROUND: Induction of labour implies the artificial initiation of uterine contraction after the period of viability by medical or surgical method for the purpose of vaginal delivery. It is an intervention that artificially initiates uterine contraction leading to progressive dilatation and effacement of cervix and expulsion of fetus prior to spontaneous onset of labour. It is indicated if the continuation of pregnancy is a risk either to the mother or fetus.Comparative study for the effect of oral misoprostol and cerviprime gel in induction of labour for post datism, **PIH** and oligohydromnios.

MATERIALS AND METHODS: A Prospective observational study of cerviprime gel and oral misoprostol solution was conducted in the department of obstetrics and gynaecology, government KAPV medical college in 100 patients from jan 2017 to march 2017.

The patients were distributed in two groups:

GROUP-1: 50 patients who underwent induction with oral misoprostol solution administered two hours apart.

GROUP 2: 50 patients who underwent induction with dinoprostone intra cervical gel (cerviprime)

Patients recruited in the study were primi gravida at term with obstetrics or medical indication for labour induction. These pts were either booked attending antenatal clinic regularly (had atleast 3 antenatal visits) or emergency admission in labour room.

RESULTS: Out of 100 patients who met with the inclusion and exclusion criteria were subjected to PGE1 (oral misoprostol) and PGE2 (dinoprostone gel) and the results were, the cases induced with PGE2 (DINOPROSTONE) as compared to PGE1(misoprostol) were associated with significantly shorter duration of initiation of labour after induction(table 1),shorter induction to delivery interval (table 2) and higher incidence of vaginal deliveries within first 24 hours (table 3). cerviprime gel is very much effective in achieving normal vaginal delivery within 24 hours. Less caesarean section rate (table 3 & 4) and lower uterine hyperstimulation syndrome with cerviprime gel. The most common indication for LSCS in misoprostol group was fetal distress and that in dinoprostone group was failed induction .

CONCLUSION: In this prospective observational study,50 cases induced with PGE1 were compared with 50 others induced by PGE2 which served as control. The cases induced with PGE2 as compared to PGE1 tablets were associated with higher incidence of vaginal deliveries within the first 24 hrs of induction and significantly shorter induction to delivery interval.Thus in conclusion, PGE2 gel appears to be safer and more efficacious for induction of labour as compared to misoprostol oral tablets.

KEYWORDS : induction of labour, cerviprime gel,oral misoprostol, induction delivery interval.

BACKGROUND:

Induction of labour implies the artificial initiation of uterine contraction after the period of viability by medical or surgical method for the purpose of vaginal delivery. It is an intervention that artificially initiates uterine contraction leading to progressive dilatation and effacement of cervix and expulsion of fetus prior to spontaneous onset of labour. It is indicated if the continuation of pregnancy is a risk either to the mother or fetus. For induction to be successful it should result in adequate uterine contraction and progressive dilatation of cervix. The drugs that are commonly used are misoprostol and dinoprostone. Cervical ripening is an essential pre requisite and its assessed with BISHOP scoring system. When BISHOP score exceeds 8, the likelihood of a successful vaginal delivery is more.

Prostaglandin analogue has been emerged for use in labour induction. prostaglandin alter the extracellular ground substance of cervix and increase activation of collagenase, elastase and glycosamino glycans and dermatan sulfate in cervix leading to collagen breakdown in cervical tissue. They also allow in increase in intracellular calcium level and modulation of cAMP levels causing myometrial contraction. It progressively increases the tone and amplitude of contraction

STUDY DESIGN: This is a prospective observational study

MATERIALS AND METHODS:

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The method of induction of labour was clearly explained to the patients and only those who gave consent were finally selected for the study.each patient's name, age and parity were noted. Systemic examination was done to rule out any diseases of heart, lungs and kidney. Per abdominal and per vaginal examination done. On per abdominal examination height of uterus, fetal lie, presentation and position were noted and fetal heart rate auscultated. Cervical effacement, cervical dilatation in centimetres, consistency, head station, position of the cervix, membrane status were evaluated in per vaginal examination.

In group 1: each patient received misoprostol vaginal tablet in the dose of 25 micrograms in the posterior fornix.the dose was repeated every 4 hours, until adequate uterine contractions were achieved (atleast 3 contractions lasting 30-45 secs in 10 minutes). Maximum total dose of misoprostol was 150 micrograms or 6 tablets. If labour did not ensure after 4 hours following the last dose it was considered a failed induction.

In group 2: patient was asked to evacuate the bladder and in lithotomy position, the dinoprostone gel 0.5mg in a preloaded syringe is instilled into the cervical canal. If the bishop score remained <7 after 6 hours, reapplication was done.when the score remained <7 after 6 hours of second application or evidence of fetal compromise then it was taken as a failed induction.

Patients undergoing induction of labour after 36 weeks of pregnancy in PIH, oligohydromnios and post datism. Delivery within 24 hrs after cerviprime gel or misoprostol was the primary outcome.

INCLUSION CRITERIA:

- Primigravida
- Live singleton fetus in cephalic presentation
- Pregnancy between 36-42 weeks of gestation
- Reactive NST
- Post dated pregnancy
- Intra uterine death of fetus
- Premature rupture of membranes
- No h/o uterine surgery
- Modified BISHOP score >5
- Clinically adequate pelvis

EXCLUSION CRITERIA:

- Grand multipara
- Known hypersensitivity or contraindication to oral misoprostol
- Patients refusal to give consent
- ØCephalopelvic disproportion
- Major degree of placenta praevia
- Malpresentation
- Multifetal gestations
- Previous caesarean delivery
- Previous myomectomy
- Situation requiring caesarean section
- Renal, hepatic or cardiovascular diseases
- Non reactive NST

RESULTS:

In our study conducted in MGMGH ,Trichy from jan 2017 to march 2017, out of 1895 deliveries, 100 patients who met with the inclusion and exclusion criteria were subjected to PGE1 (oral misoprostol) and PGE2 (dinoprostone gel) and the results were, the cases induced with PGE2 (DINOPROSTONE) as compared to PGE1(misoprostol) were associated with significantly shorter duration of initiation of labour after induction(table 1),shorter induction to delivery interval (table 2) and higher incidence of vaginal deliveries within first 24 hours (table 3). cerviprime gel is very much effective in achieving normal vaginal delivery within 24 hours. Less caesarean section rate (table 3 & 4) and lower uterine hyperstimulation syndrome with cerviprime gel. The most common indication for LSCS in misoprostol group was fetal distress and that in dinoprostone group was failed induction .

TABLE 1:INTIATION OF LABOUR AFTER INDUCTION:

	GROUP I	GROUP II	TOTAL
< 6 hrs	28 (56%)	43 (86%)	71
>6 hrs	22 (44%)	7 (14%)	29
Total	50	50	100

TABLE 2: INDUCTION-DELIVERY INTERVAL:

	GROUP I	GROUP II	TOTAL
<12hrs	8 (21.6%)	20 (47.6%)	28
12-24hrs	20 (54%)	18 (42.8%)	38
>24 hrs	9(24.3%)	4 (9.2%)	13
total	37	42	79

TABLE 3: OUTCOME OF INDUCTION OF LABOUR:

	GROUP I	GROUP II	TOTAL
Successful	37 (74%)	42 (84%)	79
unsuccessful	13(26%)	8 (16%)	21
total	50	50	100

TABLE 4: MODE OF DELIVERY:

	GROUP I	GROUP II	TOTAL
Vaginal (including assisted vaginal deliveries)	37 (74%)	42 (84%)	79
LSCS	13 (26%)	8 (16%)	21
total	50	50	100

In particular there were no significant difference in neonatal and maternal morbidity between the two groups.

The neonatal outcome is listed as

- Meconium stained amniotic fluid in gel: 2%
- Meconium stained amniotic fluid in misoprostol: 2%

DISCUSSION: Induction of labour is the initiation of contractions in a pregnant woman who is not in labour to help her achieve a vaginal birth within 24 to 48 hours(SOGC GUIDELINES 2013). It is an intervention that artificially initiates uterine contraction leading to progressive dilatation and effacement of cervix and expulsion of fetus prior to spontaneous onset of labour. It is indicated if the continuation of pregnancy is a risk either to the mother or fetus. pregnancy, for the mother or the fetus, exceeds the risk associated with induced labour and delivery. The indication must be convincing, compelling, consented to, and documented. The reason for and method of induction should be discussed between the care provider and the woman in order to obtain clear consent. These conditions are not met when induction is proposed solely for the convenience of the care provider or patient. Induction should be prioritized by the health care team according to the urgency of the clinical situation and the availability of resources. The following list of indications for induction of labour is not meant to be exhaustive or absolute: High Priority indications being

- Preeclampsia ≥ 37 weeks
- Significant maternal disease not responding to treatment
- Significant but stable antepartum haemorrhage
- Chorioamnionitis
- Suspected fetal compromise
- Term pre-labour rupture of membranes with maternal GBS colonization

Contraindications

placenta or vasa previa or cord presentation ● abnormal fetal lie or presentation (e.g. transverse lie or footling breech) ● prior classical or inverted T uterine incision ● significant prior uterine surgery (e.g. full thickness myomectomy) ● active genital herpes ● pelvic structural deformities invasive cervical carcinoma ● previous uterine rupture

For induction to be successful it should result in adequate uterine contraction and progressive dilatation of cervix. The drugs that are commonly used are misoprostol and dinoprostone. Cervical ripening is an essential pre requisite and its assessed with BISHOP scoring system.

SCORE	0	1	2	3
Cervical dilatation (cm)	<1	1-2	3-4	>5
Length of cervix (cm)	>2	1-2	3-4	>5
Station of presenting part (cm)	-3	-2	-1,0	+1,+2
consistency	firm	medium	soft	
position	posterior	central	anterior	

When BISHOP score exceeds 8, the likelihood of a successful vaginal delivery is more.

Prostaglandin analogue has been emerged for use in labour induction. prostaglandin alter the extracellular ground substance of cervix and increase activation of collagenase, elastase and glycosamino glycans and dermatan sulfate in cervix leading to collagen breakdown in cervical tissue. They also allow in increase in intracellular calcium level and modulation of cAMP levels causing myometrial contraction. It progressively increases the tone and amplitude of contraction. Misoprostol (15-deoxy 16-hydroxy 16-methyl PGE1) was the first synthetic prostaglandin made available for the treatment of peptic ulcer disease. SANCHEZ RAMOS in 1993 used it for the management of obstetric condition after seeing its stimulant action on uterus. USG and Doppler and medical conditions in mother warrant an urgent termination of pregnancy. So the elective induction is increased now a days.

As per the recommended protocol 0.5mg / dose is kept endocervical upto a maximum of 3 doses 6 hours apart.

The improvement of another 2-3 points within 6 hours and by 7-8 points within 12 hours was found after instillation of gel. 93% patients went into spontaneous labour and 7% required re-installation. The incidence of failed induction was 1.4 %. The duration of latent phase was 10.2 hours. Induction delivery interval was 15.2 hours.69% of the patients required augmentation of labour and 31% patients did not require augmentation of labour.

In our study conducted in MGMGH ,Trichy from jan 2017 to march 2017, out of 1895 deliveries, 100 patients who met with the inclusion and exclusion criteria were subjected to PGE1 (oral misoprostol) and PGE2 (dinoprostone gel) and the results were, the cases induced with PGE2 (DINOPROSTONE) as compared to PGE1(misoprostol) were associated with significantly shorter duration of initiation of labour after induction(table 1),shorter induction to delivery interval (table 2) and higher incidence of vaginal deliveries within first 24 hours (table 3). cerviprime gel is very much effective in achieving normal vaginal

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