



COMPARATIVE EVALUATION OF SAFETY AND EFFICACY OF SUBLINGUAL MISOPROSTOL WITH FOLEY'S CATHETER FOLLOWED BY OXYTOCIN FOR INDUCTION AND AUGMENTATION OF LABOUR IN TERM PREGNANCY

Gynaecology

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ABSTRACT

Good obstetric care requires averting caesarean sections with all associated complications. Foley's catheter has been successfully used since long for induction of labour. With the advent of prostaglandins there was growing interest in its use for the induction of labor. We have compared the safety and efficacy of sublingual misoprostol with Foley's catheter followed by oxytocin for induction and augmentation of labour in term pregnancy.

Method: This study was conducted over 214 women of over 18 years of age, with term gestation, having viable singleton fetus with cephalic presentation, with intact membranes and unfavourable cervix admitted for labour, carried out over a period of 2 years. Induction of labour was conducted in group I with Foley's catheter in extra amniotic space and oxytocin and in group II with misoprostol. Events of labour were graphically recorded.

Result: There was no significant difference in the mean Bishop score after induction of labour with catheter and misoprostol. 24.3% cases of group I and 34.57% of group II ended up with LSCS. Indications being fetal distress 38.4%, failed induction 29.6% in group I and failed induction 77.67% in group II. Complications such as hyperstimulation, retro placental clots, need for blood transfusions and diarrhea were significantly more in group II. There was 1.86% perinatal mortality in group II. Distribution of perinatal morbidity and their percentages in both groups were nonsignificant.

Conclusion: Foley's catheter followed by oxytocin is better and more physiological as compared to sublingual misoprostol for induction and augmentation of labour.

KEYWORDS

caesarean section, Foley's catheter, hyperstimulation, induction of labour, misoprostol, oxytocin

Introduction:- The art of good obstetric care requires averting caesarean sections with all its complications. It is now well accepted that ripening of cervix by a variety of methods can decrease rates of induction failure. An ideal method must be efficacious and safe for the mother and fetus. It should have a short procedure- delivery interval. It must have minimal side effect and should be convenient for patients and medical staff.

Foley's catheter has been used successfully since long. With the advent of prostaglandins there was growing interest in the use of it for the induction of labor. Misoprostol (PgE1) acts as uterotonic as well as acts locally to soften cervix. Because of this quality, it has been used for induction of labor. The present study entitled was done in the department of Obstetrics & Gynecology Dr. B.R.Ambedkar Memorial Hospital Raipur (C.G.)

Methods and material

This study was conducted over carefully selected 214 women of over 18 years of age, with term gestation, having viable singleton fetus with cephalic presentation, with intact membranes and unfavourable cervix, admitted for labour. A detailed history of the cases was taken. The study was carried out over a period of 2 years. Women with hypersensitivity to any of the products used, history of caesarean section, ante partum bleeding, IUFD, genital herpes infection were excluded. Selected patients were explained about the study, an informed consent for inclusion in the study was taken from the patient.

Group I- Foley's catheter+ oxytocin

Group II- Misoprostol

Date and time for induction of labour was noted. Indication for

induction was recorded and pre-induction bishop score noted.

In Foley's group, Foley catheter was inserted into extra-amniotic space via endocervical canal & balloon was inflated with 30 ml saline. The catheter was checked for extrusion of the balloon from the cervix every 4 hours by cervical examination. If the balloon had not been extruded, the catheter was adjusted to continue gentle traction. Each subject underwent cardiotocography for 20 min after Foley catheter placement. Then she was allowed to ambulate with intermittent fetal heart rate (FHR) assessment every 30 minutes. The position and traction of the balloon were checked once or twice each hour.

Immediately following expulsion, or when the Bishop score attained a value of >6, for acceleration of labour, oxytocin was begun if necessary. The group assigned misoprostol had 25 µgm of misoprostol placed sublingual, every 4 hours for a maximum 5 doses. Subsequent doses were withheld if tachysystole, uterine hyper stimulation or non-reassuring FHR developed.

During each P/V examination bishop score was noted.

All events of labour were graphically recorded in the form of partogram. If labor did not end within 24 hours spontaneously, it was considered as failure of induction of labor.

Results and analysis:

A total of 214 women were included in the study.

Group I: women induced with transcervical Foley catheter followed by oxytocin

(n=107) Group II: women induced with sublingual misoprostol (n=107). In the present study maternal baseline characteristics in both

the groups were similar.

Table 1: Mean Bishop score after induction of labour in two groups in relation to duration since induction.

S.no		Foley's catheter	Misoprostol	P value
1	0 hour	3.21 ± 1.33	3.31 ± 1.18	NS
2	4 hours	7.48 ± 2.2	7.98 ± 2.4	NS
3	8 hours	10.13 ± 2.56	10.18 ± 2.85	NS
4	12 hours	11.5 ± 2.39	11.7 ± 2.05	NS
5	16 hours	9.79 ± 2.61	12.71 ± 0.49	NS
6	20 hours	1.9 ± 2.4	-	-
7	24 hours	1.9 ± 2.4	-	-

Table 2: Distribution of cases according to number of LSCS with time

S.No	Time taken	Foley's group N=26	Misoprostol group n=37
1	0-4 hr	0	0
2	4-8 hr	3	25
3	8-12 hr	6	10
4	12-16 hr	8	1
5	16-20 hr	1	1
6	20 -24 hr	1	0
7	>24 hr	7	0

Table 3: Distribution of cases according to indications of caesarean sections

S.No	Indication	Foley's group		Misoprostol group		P Value		
1	Failed induction	7	29.6%	0	-	S/0.001	26.88	0
2	Fetal distress	10	38.4%	29	77.67 %	S/0.0032	38.40	78.3
3	Non progress of labour 1	4	15.3%	5	13.51 %	NS	16.40	13.5
4	Non progress of labour 2	4	15.3%	3	8.1%	NS	15.40	8.1
5	Severe preeclampsia with antepartum eclampsia	1	0.93%	0	-	NS	3.84	0

Table 4: Distribution to complications of cases according groups developed in two groups.

S.No	Complications	Foley's group		Misoprostol group		P value
1	Hyperstimulation	1	0.93%	13	12.14%	S
2	Vomiting	2	1.86%	9	8.41%	NS
3	Pyrexia	4	3.73%	10	9.3%	NS
4	PPH	2	2.46%	1	1.42%	NS
5	Retro-placental clots	0	0	6	8.57%	S
6	Blood transfusions	0	2.8%	12	11.21%	S
7	Diarrhea	0	0	6	5.60%	S

Table 5: Distribution of newborns according to perinatal morbidity and mortality

Morbidity	Foley's		Misoprostol		P
NICU admission	19	17.7%	21	19.82%	NS
Hyperbilirubinemia	16	14.9%	11	10.2%	NS
Meconium aspiration syndrome	1	0.93%	7	6.54%	NS
Birth asphyxia	1	0.93%	5	4.67%	NS
Hypoglycemia	1	0.93%	1	0.93%	NS
Nevirapine Therapy	1	0.93%	2	0.93%	NS
Perinatal mortality	0	0	2	1.86%	NS
1 min apgar score	8.93± 1.75		8.34±1.36		S/0.0066
5 min apgar score	9.3 ±0.99		8.71±1.56		S/0.003

Discussion:-

There was statistically significant difference in both the groups in term of Bishop Score after 4 hours or 8 hours. Foley's catheter is better in the improvement of bishop score in 4 hours. A study by Agnieszka et al reported a significant change in the total Bishop score, with a mean difference of 3.85 points ($p < 0.00001$). They found the most significant changes in cervical dilatation and effacement by Foley's catheter. ($p < 0.00001$). In contrast to our observation another recent study done by Owlabi AT(1) conducted that a 50 µg dose of misoprostol is more effective than a balloon catheter in inducing labour. In our study, Foley's group was having lower induction to active phase interval as compared to misoprostol group but difference was statistically insignificant. Our study revealed that misoprostol and Foley's catheter were similarly effective to reduce the induction to delivery interval with no significant difference. Similar finding was also by reported by Mandana Mansour Ghanaie (2), Swapan Das (3), Sedigheh Ayati et al (4), Bouchra Fakhir et al (5), Thakur A (6). We observed that the incidence of LSCS was more in misoprostol group than in Foley's catheter group. Many of the studies reported insignificant difference in number of caesarean deliveries in both the groups (Chung J H (7) Culver strass RA (8) Saleem S(9) Chandrashekhar Jindal promila (10) Halaabdelftahali (11) A Dhanya Mackeen (12) Goonewardene M (13). In present study in both the groups maximum patients underwent LSCS due to fetal distress. But observation shows that the incidence of fetal distress was significantly higher in misoprostol group 29/37 (78.37%) in contrast to 10/26 (38.4%) in Foley's group (P value 0.03/S). The second common indication for caesarean was failure of induction in Foley's group 7/26 (30.7%) vs none of the patient in misoprostol group (P value 0.03/S) which was the most significant finding. **OB Moraes Filho et al** also reported three times higher rate of failure of induction in Foley's group and higher number of dystocia in misoprostol group. **Sujara et al** reported high incidence of fetal distress in her study with misoprostol. Contrary finding of increased fetal distress with Foley's catheter induction was reported by Jindal Promilla et al. 4 out of 29 preeclampsia patients had accidental abortion in misoprostol group as compared to none in foley's group. In a study by Fonteno MT in 2005 done among patients with preeclampsia, a higher incidence of abortion placenta i.e. 13.7% found in misoprostol group. Martinez de Tajada B in 2010 concluded that the use of misoprostol in preeclamptic women appears to be safe as compared to other prostaglandins in terms of abortion (1.3% vs 5.4%). In present study, during first stage of labour, significantly higher number of women suffered from hyperstimulation i.e. 13/107 (12.14%) in contrast to 1/107 (0.93%) women in Foley's group (P value < 0.05/S). This is because of the reason that oxytocin has a short half-life and whenever hyperstimulation develops its infusion can be stopped immediately whereas in the case of misoprostol, by the time hyperstimulation develops it has entered the circulation by sublingual absorption and it can't be removed from the circulation. Similar finding were reported by chung, jindal promila, chandrashekhar. The presence of higher number of meconium passage and retro-placental clots suggest that strong myometrial contractility induced by misoprostol result in decreased blood flow to fetus resulting in asphyxia which resulted in meconium passage and accidental separation of placenta which adds on to the asphyxia in fetus and results in abortion placenta. Hala et al, rezvan et al and N nor et al report higher apgar in Foley's group in 1 and 5 minutes than misoprostol group similar to our study. Overall the neonatal outcome was better in Foley's group as compared to misoprostol group. Similar outcomes were reported by Niromanesh et al (14), Owlabi et al (15), Cromi et al (16) and Prager et al (17).

Conclusion :- Ideally, the method which we are using for induction of labour should be the one which would cause the same physiological change in the cervix i.e. effacement and softening without uterine contractility compatible with active labour with low cost, simplicity safety and lack of systemic and serious side effects.

It has been observed that induction of labour by intracervical Foley's catheter followed by oxytocin is a safe, effective, simple, low cost method without any systemic serious side effects.

Thus, we can conclude that Foley's catheter followed by oxytocin is better and more physiological as compared to sublingual misoprostol for induction and augmentation of labour.

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