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Induction of Labour with Vaginal Misoprostol and Incidence of Cesarean Delivery for MSL

Authors
Dr Jyoti Bindal[1], Dr Smita Soni[2]
[1]Professor and Head, [2]P.G. Student,
Department of Obstetrics and Gynaecology, G.R. Medical College, Gwalior (M.P.), India

Abstract

Aim: *Induction of labour with low lose of misoprostol (25 µg) and detecting the incidence of cesarean delivery for MSL.*

Design: *Prospective randomized control trial conducted at Kamla Raja Hospital, GRMC, Gwalior from 01 Jan. 2017 to 30 June 2017.*

Participants: *150 pregnant women requiring induction of labour.*

Methods: *The women were divided into two groups based on Bishop score as favourable and unfavourable cervix group, induction delivery interval, number of misoprostol doses, incidence of meconium stained liquor, incidence of meconium aspiration syndrome and rate of cesarean section for fetal distress due to meconium stained liquor.*

Results: *Among the outcomes compared between unfavourable and favourable cervix groups induction delivery interval, number of misoprostol doses and incidence of meconium stained liquor and meconium aspiration syndrome was more in unfavourable cervix group and thereby increases the rate of cesarean delivery. Long induction delivery interval and higher number of misoprostol doses were associated with higher incidence of meconium stained liquor in primigravida with unfavourable cervix group.*

Conclusion: *Misoprostol is an effective priming and labour inducing agent. Though incidence of meconium stained liquor is higher in misoprostol induced labour among women with unfavourable cervix thereby increasing the rate of cesarean delivery for meconium stain liquor and increasing maternal as well as fetal morbidity and mortality.*

Introduction

Cytotec, a prostaglandin synthetic, is the brand name for the drug misoprostol. It has been researched, developed, and approved only for use in the treatment of stomach ulcers. Cytotec is used to protect the inner lining of stomach in order to prevent ulcers.[1,2]

Because it is impossible to predict how each mother and baby will react to Cytotec, it is very dangerous to begin administration. Some of the most common adverse side effects of Cytotec use in pregnant women.[3]

On August 23, 2000, the manufacturer of misoprostol (Cytotec, Searle) distributed a letter to clinicians in the United States warning them against the use of misoprostol in pregnant women.[4]

The letter stated that Cytotec administration by any route is contraindicated in pregnancy because it can cause abortion. The manufacturers also cited reports of uterine rupture and maternal and fetal deaths when Cytotec was used to induce labor.[5]

Many hospitals removed misoprostol from their formularies, and pregnant women lost access to the drug for any indication.[6]

The controversy over the use of misoprostol for induction of labor continues as misoprostol is put

on trial by the media and in courtrooms around the country.[6]

Material and Methods

All women requiring induction of labour at term are assessed. Study included color doppler studies are normal, postdated pregnancy, PROM in greater than 37 weeks, PIH, IUGR and oligohydramnios.

BISHOP's prelabour scoring system was used to assess whether the cervix was favourable for induction of labour or not.

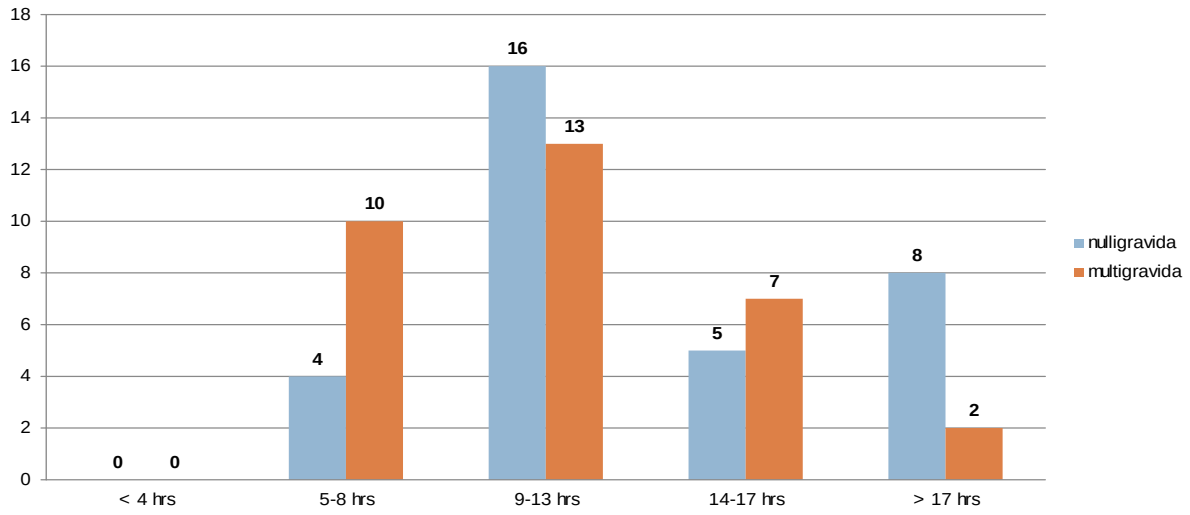
From 1 January 2017 to 30 June 2017, total of 150 women given consent both nulligravida and multigravida to participate in the trial and were randomized into 2 groups. Women with unfavourable cervix in group 1 and women with favourable cervix in group 2. Tablet misoprostol 25 µg placed every 4 hourly for a maximum of 6 doses.

Every 4th hour pelvis examination is done to note the progress of labour in terms of dilatation, effacement and descent of the presenting part, the dose is repeated. At about 3-4 cm of cervical dilatation if the membrane have not ruptured ARM was done and colour of liquor noted.

Depending on the colour women were subjected to cesarean section or allowed to continue for vaginal delivery. If there is fetal distress of tachysystole or hyperstimulation next of dose of misoprostol is deferred.

Results

Graph 1 : Induction of delivery time (group 1)



Graph 2 : Induction of delivery time (group 2)

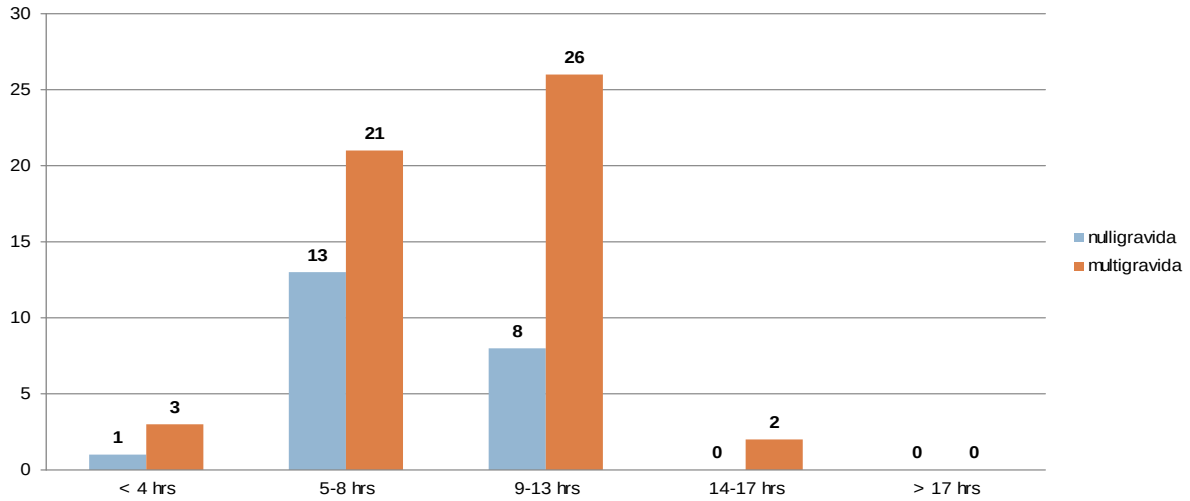


Table 1: Comparing group 1 and 2 (Induction to delivery time)

Time in hours	Unfavourable cervix (%)	Favourable cervix (%)
< 4	0	4 (5.3%)
5-8	16 (21.3%)	35 (46.6%)
9-13	27 (36%)	34 (45.3%)
14-17	20 (26.6%)	2 (2.6%)

P value is 6.528 and the 'p' value is < 0.05 significant.

The average time from induction to vaginal delivery was 11.87±3.65 in group 1 (unfavourable cervix) and 7.85±1.68 in group 2 (favourable cervix).

Table 2 : Number of doses of misoprostol (25 micrograms)

No. of doses	Unfavourable cervix (%)	Favourable cervix (%)
1 dose	12 (16%)	33 (44%)
2 doses	26 (34.6%)	34 (45.3%)
3 doses	30 (40%)	6 (8%)
4 and above doses	7 (9.3%)	2 (2.6%)

T test value is 6.088. p value < 0.05 (significant).

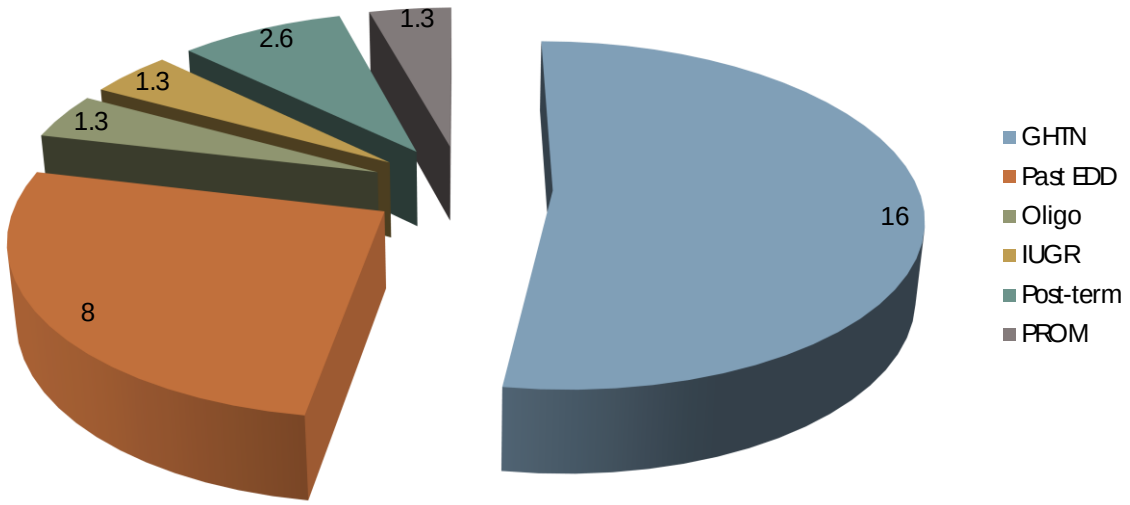
Table 3: Comparing Group 1 and Group 2 (Mode of delivery)

Mode of delivery	Unfavourable cervix (%)	Favourable cervix (%)
Spontaneous vaginal delivery	52 (69.3%)	63 (84%)
Cesarean section	23 (30.6%)	12 (16%)

T test value is - 2.542. p value < 0.05 (significant).

Statistical analysis was performed comparing nulligravida and multigravida. T test value is 2.542 and p value is 0.012 which is significant.

Graph 3 : Incidence of MSL (Group 1)



Graph 4 : Incidence of MSL (Group 2)

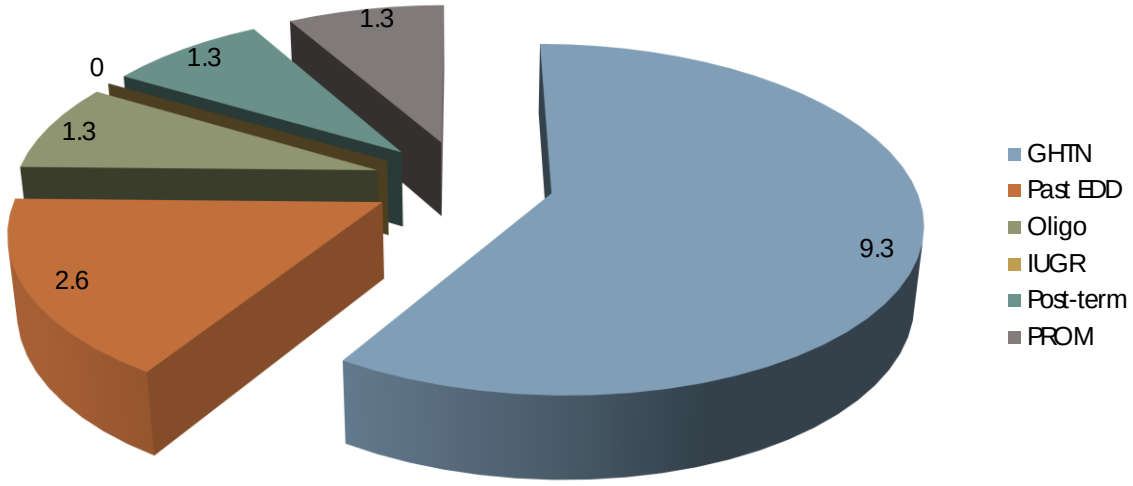


Table 4 : Incidence of meconium stained liquor based on parity (group 1 and group 2)

Parity	Group 1	Group 2
Nulligravida	18 (39.4%)	7 (17.2%)
Multi gravida	5 (15.3%)	5 (13.9%)

In group 1, T test value is 2.545 and p value is 0.013 which is found statistically significant. In group 2, T test value is 1.320 and p value >0.05 which is found statistically insignificant.

Table 5: Incidence of meconium aspiration syndrome in neonates based on parity in group 1 and group 2

Parity	Group 1	Group 2
Nulligravida	10 (13.3%)	2 (2.7%)
Multi gravida	5 (6.7%)	1 (1.3%)

Discussion

Misoprostrol has been shown to be effective drug for induction of labour at term with a viable fetus. Previous studies have shown, uterine stimulation associated with fetal heart rate changes was more common in the group of women receiving misoprostol than in women receiving either oxytocin or PGE2. Cesarean delivery rate data were conflicting with the trend towards decrease cesarean for failure to progress in labour and increased cesarean delivery for fetal distress due to meconium passage in the misoprostol group.[5,7,8]

In the current study, a dosage of 25 microgram of misoprostol has been used intravaginally every 4 hrs. for the maximum of 6 doses. (over 24-hr period). This dose of misoprostol (25 micrograms, 4th hrly, max – 6 doses) was found to be safe, efficacious and has low incidence of side effects with maternal and fetal outcome. In this prospective study 150 women randomly recruited. All these cases, 150 women were induced with 25 mcg misoprostol 4th hrly. Among 150 cases, 75 women were included in the unfavorable cervix group (group 1) and 75 were included in favorable cervix group (group 2). Among the total number of cases after 8 hrs. of induction, only 14 cases were having poor Bishop's score. Among these, 12 cases were nulligravida. This indicates that misoprostol is very effective agent for cervical ripening. The average time from induction to vaginal delivery was 14.95 hrs. in nulligravida and 10.05 hrs. in multigravida in group 1. In Group 2 induction delivery interval is 8.68 hrs. in nulligravida and 6.64 hrs. in multigravida, overall induction delivery interval is 13.87 hrs. in Group 1 and 7.85 hrs in Group 2. Induction delivery interval is longer in unfavorable cervix group and in nulliparous women. This might be one of the contributing factors in incidence of MSL.[9,10]

Therefore increased incidence of cesarean delivery for fetal distress Average number of misoprostol doses required for vaginal delivery in case of nulligravida and multigravida are 3.90 and 3.38 respectively in Group 1. Average number of doses required for vaginal delivery case of nulligravida and multigravida are 2.90 and 2.38 respectively in Group 2. Average number of misoprostol doses required is higher in unfavorable cervix group and nulliparous women. This might also be one of the contributing factors in incidence of MSL. Therefore cesarean section in unfavourable cervical group.9 The total incidence of meconium stained liquor is 30.6% in group 1 and 16% in group 2, which is statistically significant. In group 1, incidence of MSL is 16%, 8%, 1.3%, 1.3%, 2.6% and 1.3% in PE/GHTN, PEDD, Oligo, IUGR, post-term and PROM cases respectively and in group 2, incidence of MSL is 9.3%, 2.6%, 1.3%, 0%, 1.3% and 1.3% in PE/GHTN, PEDD, Oligo, IUGR, post-term and PROM cases respectively.

In group 1, incidence of MSL based on parity is 39.4% and 15.3% in primigravida and multigravida respectively. In favorable cervix group, incidence of MSL based on parity is 17.2% and 13.9% in primigravida and multigravida respectively which is responsible for more number of cesarean section for misoprostol induced labour in unfavourable cervical group.

In group 1, the meconium aspiration syndrome in nulligravida was 13.3% and in multigravida was 6.7% and in group 2, the meconium aspiration syndrome in nulligravida was 2.7% and in multigravida was 1.3%.

In our study, the cesarean rate following meconium stained liquor following misoprostol induction was 30% in group 1 and 16% in group 2 which concludes that however misoprostol is an effective drug for induction of labour at term but meconium passage due to uterine hyperstimulation should not be ignored which indirectly increases the incidence of fetal and maternal morbidity and mortality thereby increases the incidence of cesarean delivery and increases the unnecessary fetal complications like meconium aspiration syndrome and obstetric complication such as in mother such as uterine extension, obstetric hysterectomy and bladder injury.

Conclusion

Overall, misoprostol appears to be more effective than conventional methods of cervical ripening and labour induction. But, incidence of meconium stained liquor is higher in misoprostol induced labour among women with unfavourable cervical group. The studies were not sufficiently large to exclude the possibility of uncommon serious adverse effects.

In particular the increase in uterine hyperstimulation with fetal heart rate changes following misoprostol is a matter for concern which increases the incidence of cesarean delivery for fetal distress and risk of serious adverse events in mother. It is possible that, if sufficient numbers are studied, an unacceptably high number of serious adverse events including uterine rupture and asphyxial fetal deaths may occur.

The data at present are not robust enough to address the issue of safety. Thus, though misoprostol shows promise as a highly effective, inexpensive and convenient agent for labour induction, it cannot be recommended for routine use at this stage. Lower dose misoprostol regimens should be investigated further.

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