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### Original Article

# Misoprostol (PGE1) Versus Dinoprostone gel (PGE2) in Induction of Labour in Late Intra Uterine Fetal Death with Unfavourable Cervix: A Prospective Comparative Study.

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#### ABSTRACT

**Objectives:** To compare the efficacy, safety and tolerance of misoprostol versus dinoprostone gel in induction of labour in the case of late Intra Uterine Fetal Death (IUFD) with unfavourable cervix. **Materials and methods:** This prospective study included a consecutive series of 40 women gravid up to fourth with IUFD after 28 weeks of gestation between March 2013 to Feb 2014. Women were divided into two groups. Each group consisted of 20 women. First group of women received 100µg of misoprostol per vaginally at four hourly intervals (maximum 600µg in 24 hours). Second group of women received dinoprostone gel 0.5 mg intracervically at every 6 hours, maximum 2 doses in 24 hours. Oxytocin was given for augmentation if needed. **Results:** The induction-to-delivery interval was significantly shorter with the misoprostol ( $8.13 \pm 1.62$  hrs vs.  $14.32 \pm 2.46$  hrs;  $p < 0.001$ ) group. The total dose of misoprostol needed was significantly lower than the group pre-treated with dinoprostone gel ( $1.78 \pm 0.80$  vs.  $3.50 \pm 1.12$ ;  $p < 0.001$ ). The two groups did not differ as regards complications experienced during labor and delivery significantly. **Conclusion:** Both regimens, misoprostol and dinoprostone are safe in induction of labor after intrauterine fetal death (IUFD). Misoprostol is more effective in terms of reducing of induction delivery interval, requirement of lesser dose.

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#### Introduction:

According to WHO; fetal death is defined as “death prior to complete expulsion or extraction from its mother of a products of conception, irrespective of duration of pregnancy.” The care should be multi- fold higher in the case of a woman with an IUFD. Retention of dead fetus in utero has its own ill effects on physical, psychological and social aspects [1]. As in IUFD journey of labor pain will be fruitless. So, it is of utmost important to search for the method which can reduce hour of pain in labor of IUFD cases. Induction of labour in IUFD using pharmacological agents with known safety profile is recommended by most of the guidelines.

Prostaglandins are used for induction of labour in cases of IUFD; of which, misoprostol, a synthetic analogue of prostaglandins is widely used because of its low cost, stability at room temperature, long shelf life and ease of administration [2]. Side effects such as uterine over activity (hyper stimulation, hyper tonus and tachysystole) and systemic response (nausea, vomiting, diarrhoea and shivering) always remain issue of concerns. Dinoprostone (PGE2) gel is also widely used for induction of labour in IUFD but it is expensive. The present study was performed to find out the efficacy and safety of the misoprostol compared to dinoprostone gel, in an effort to find a better management of woman with IUFD.

#### MATERIALS AND METHODS

This prospective study included a consecutive series of 40 women with IUFD after 28 weeks of gestation attended to Department of Obstetrics and Gynaecology, Midnapore Medical College & Hospital, West Bengal, India, between March 2013 to Feb 2014. Inclusion criteria were women with IUFD with

- Gestational age 28-42weeks
- Modified Bishop's score  $\leq 5$
- Up to fourth gravida

Exclusion criteria were women with

- Severe asthma
- Cardiac diseases
- Previous LSCS or any scar on uterus
- Complete placenta previa
- Transverse fetal lie.

Gestational age was confirmed by a reliable LMP and for those who did not know their LMP, USG was used. The diagnosis of intrauterine fetal death (IUFD) was confirmed by USG. Written informed consent was taken from those who were willing to participate in the study. Eligible and consenting gravid women were randomly allotted to either tab. Misoprostol or dinoprostone gel for induction of labour. 20 cases were managed with 100µg of misoprostol inserted in posterior fornix every four hourly

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(maximum 600µg in 24 hours). Another 20 cases were managed with dinoprostone gel 0.5 mg intracervically every six hourly maximum 2 doses in 24 hours. If fetus not expelled, gap of 24h from the first dose was given and the course was repeated. If not expelled with repeat course also induction was categorized failed.

Subsequent to induction, uterine contractions, pulse, blood pressure, temperature and systemic symptoms were monitored hourly. Oxytocin was used for augmentation of labor in active labor if required. Cases having hyperthermia more than 100 degree Fahrenheit were treated with paracetamol. Analgesic used as per patient's requirement.

Statistical analyses of categorical variables were performed by Fisher exact test and the non paired Student t test to compare continuous variables. All P values were two-tailed, and P < 0.05 was considered statistically significant. Quickcalcs-GraphPad software was used for all analyses.

## RESULTS

Demographic and clinical characteristics of both groups were comparable with no significant difference found (Table-I). Efficacy was compared by two parameter such as induction to delivery interval and number of doses required. The induction to delivery interval reflects the time interval between first-dose to expulsion of the fetus. Both parameters were found significantly higher in dinoprostone gel group (Table- II).

**Table- I: Demographic and clinical characteristics**

	Misoprostol group (n= 20)	Dinoprostone gel group (n= 20)	P value
Age in years (mean ± SD)	21.05 ± 2.52 years	22.00 ± 2.18 years	0.2100
Parity (mean ± SD)	1.15 ± 0.99	1.00 ± 0.88	0.6206
POG in weeks (mean ± SD)	35.80 ± 1.74	35.53 ± 1.84	0.6351

POG: Period of gestation, SD: Standard deviation

**Table- II: Comparison of efficacy of both regimens**

	Misoprostol group (n= 20)	Dinoprostone gel group (n= 20)	P value
Induction to delivery interval (mean ± S.D) in hours	8.13 ± 1.62	14.32 ± 2.46	<0.0001
No. of dose required (mean ± SD)	1.78 ± 0.80	3.50 ± 1.12	<0.0001

**Table-III: Comparison of safety and tolerance of both regimen**

Study parameter	Misoprostol group (n= 20)	Dinoprostone gel group (n= 20)
Maternal side effects	3 (15%)	2 (10%)
Hospital stay (Days, mean±SD)	2.16±0.67	3.30±0.86
Post partum haemorrhage (PPH)	1(5%)	2(10%)
Oxytocin augmentation	4(20%)	6(30%)
Analgesia required	7(35%)	9(45%)

Nausea, vomiting, diarrhoea, pyrexia were considered as side effects. No cases of uterine tachysystole, hyperstimulation syndrome were recorded in any groups. Total hospital stay, PPH, oxytocin augmentation, analgesia requirement was found more in dinoprostone gel group. But maternal side effects were slightly more in misoprostol group (15% vs. 10%) (Table-III).

## DISCUSSION

This study has compared vaginal misoprostol (100 µg 4-hourly) with dinoprostone gel (0.5 mg 6-hourly) for induction of labor in late intrauterine fetal death. The findings have demonstrated that the use of misoprostol is associated with a shorter duration of labor, less dose requirement and less need for oxytocin augmentation. Hospital stay, PPH, analgesia requirement also found less in misoprostol group. But maternal side effects in terms of nausea, vomiting, diarrhoea, pyrexia noted slightly higher in misoprostol group (15% vs. 10%).

Various methods of induction of labour following IUFD have been tried and studied and most of the studies compared between combined method (mifepristone and misoprostol) and misoprostol only. No study undertaken to compare the role of dinoprostone gel vs. misoprostol in induction of labour in a case of IUFD. There are various randomized studies, which compared vaginal misoprostol with dinoprostone for induction of labor at term with living fetus. In those studies the incidence of vaginal delivery within 24 h of induction was found higher in the misoprostol group [3-7]. This is an agreement with our study. Pandis et al. [3] findings regarding maternal side effects, dose requirement, oxytocin augmentation, hospital stay, PPH, analgesia requirement was almost similar to our findings.

### CONCLUSION

In intrauterine fetal death case, misoprostol is an effective regimen to cut short the fruitless journey of labor pain. It is safe, tolerable and more efficacious than dinoprostone gel. However it was carried out over a very short period of time with a small group of pregnant population, it demands a larger and long term comprehensive, prospective comparative study.

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