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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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 uterus 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 28-42 weeks
- Modified Bishop’s score ≤ 5
- Upto fourth gravida

Exclusion criteria were women with

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

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 100 μg of misoprostol inserted in posterior fornix every four hourly
(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

<table>
<thead>
<tr>
<th></th>
<th>Misoprostol group (n= 20)</th>
<th>Dinoprostone gel group (n= 20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years</td>
<td>21.05 ± 2.52 years</td>
<td>22.00 ± 2.18 years</td>
<td>0.2100</td>
</tr>
<tr>
<td>Parity</td>
<td>1.15 ± 0.99</td>
<td>1.00 ± 0.88</td>
<td>0.6206</td>
</tr>
<tr>
<td>POG in weeks</td>
<td>35.80 ± 1.74</td>
<td>35.53 ± 1.84</td>
<td>0.6351</td>
</tr>
</tbody>
</table>

POG: Period of gestation, SD: Standard deviation

Table-II: Comparison of efficacy of both regimens

<table>
<thead>
<tr>
<th></th>
<th>Misoprostol group (n= 20)</th>
<th>Dinoprostone gel group (n= 20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induction to delivery interval (mean ± SD) in hours</td>
<td>8.13 ± 1.62</td>
<td>14.32 ± 2.46</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>No. of dose required (mean ± SD)</td>
<td>1.78 ± 0.80</td>
<td>3.50 ± 1.12</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

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 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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References