COMPARATIVE STUDY OF THE INDUCTION OF LABOUR WITH INTRAVAGINAL MISOPROSTOL AND INTRACERVICAL DINOPROSTONE GEL

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ABSTRACT

OBJECTIVES

To compare the efficacy of labour with Dinoprostone gel and Misoprostol with respect to induction delivery interval, type of delivery and cost effectiveness.

METHODS

100 patients admitted to labour ward of OBG Department of Katuri Medical College and Hospital with indications for induction of labour and unfavourable cervixes randomly assigned to receive either intravaginal Misoprostol or intracervical Dinoprostone gel between August 2012 and August 2013; 50 patients received 25 µg of intravaginal Misoprostol every 4 hours, maximum of 6 doses; 50 patients received 0.5 mg Dinoprostone gel intracervically every 6 hours, maximum of 3 doses as needed.

RESULTS

In Dinoprostone group, the mean induction delivery interval was 15.25±3.14 hrs. In the Misoprostol group, the mean induction delivery interval was 11.43±2.17 hrs; 72% required Oxytocin augmentation in the Dinoprostone group compared to 38% in Misoprostol group which is statistically significant (P<0.05); 78% of patients had vaginal delivery in Dinoprostone group and 90% of patients had vaginal delivery in Misoprostol group which is statistically significant (P<0.05). There was 10% incidence of NICU admission in both groups.

CONCLUSION

Misoprostol and Dinoprostone are safe and effective drugs for cervical ripening and labour induction. Misoprostol is more cost effective when compared to Dinoprostone. Misoprostol is stable at room temperature and does not need refrigeration.

KEYWORDS

Labour Induction, Misoprostol, Dinoprostone.


INTRODUCTION

Induction of labour is the non-spontaneous initiation of uterine contractions that result in progressive cervical effacement and dilatation with descent of the presenting part to achieve vaginal delivery when continuation of pregnancy presents a threat to the life or well-being of the mother or her unborn foetus. Labour induction near term is 10 to 20 percent of women. Medications that ripen cervix in a short period of time play an important role in modern obstetrics.

The method of administration that has been explored thoroughly is endocervical Dinoprostone or prostaglandin E2. Though this is widely used, it is expensive and required refrigeration for storage with warming before use.

It was only a matter of time before a comparably cheap, safe and effective vaginally administered Prostaglandin with limited side effects would be available and Misoprostol or PGE1 tablet fitted those criteria admirably.

MATERIAL AND METHODS

OBJECTIVES

To compare the efficacy of induction of labour with Dinoprostone gel and Misoprostol with respect to induction delivery interval, type of delivery cost effectiveness.

Source of Data

100 patients admitted to labour ward of OBG Dept. of Katuri Medical College and Hospital with an indication for induction of labour from Aug 2012 to Aug 2013.

Inclusion Criteria

- Singleton foetus with cephalic presentation.
- Over 37 weeks of gestation.
- Reactive foetal heart pattern.
- Unfavourable cervix Bishop Score <4.
- No contraindication to vaginal delivery.
Exclusion Criteria

- Previous LSCS or any uterine surgery.
- Mal presentation.
- Grand multiparity.
- Abnormal foetal heart rate pattern.
- Allergy to prostaglandins.

Method of Induction

- 50 patients with an indication for labour induction received with 25 µg of intravaginal Misoprostol and repeated for a maximum of 6 doses every 4 hours as needed.
- 50 patients with an indication for labour induction received with 0.5 mg of intracervical Dinoprostone gel and repeated for a maximum of 3 doses every 6 hours as needed.
- After informed consent had been obtained, the patients selected for the study were evaluated initially by modified Bishop’s Score and admission test for foetal wellbeing. Patients with a modified Bishop’s score ≤4 and a positive admission test were induced.
- After drug insertion, patients were monitored for signs of labour, maternal vital signs, foetal heart rate and progress of labour. The foetal heart rate was monitored by either intermittent auscultation or continuous foetal heart rate monitoring. A partogram was strictly maintained in all patients induced. Oxytocin was started depending on the modified Bishop’s score and in the absence of adequate uterine contractions after 6 hrs. of the last dose or for augmentation of labour in case of an arrest of dilatation. Oxytocin was started at the dose of 2 mu/min with increments of 2 mu/min every 30 minutes.
- Membranes were ruptured when the cervix was completely effaced with a cervical dilatation of more than 3 cms or at onset of active stage of labour.
- The data collection included indication for booked/unbooked case, maternal age, parity, gestational age on entry into the study, modified Bishop’s score at the time of induction, induction-delivery interval, oxytocin augmentation, type of delivery, Apgar score of the baby, maternal and neonatal complications.
- The results observed were subjected to statistical analysis by student’s ‘t’ test, Odd’s ratio and Chi-square test.

The Following Observations were made

<table>
<thead>
<tr>
<th>Drug</th>
<th>Mean Induction Delivery Interval (In hours)</th>
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</thead>
<tbody>
<tr>
<td>Dinoprostone</td>
<td>15.25 +/- 3.14</td>
</tr>
<tr>
<td>Misoprostol</td>
<td>11.15 +/- 2.17</td>
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</tbody>
</table>

Mean Induction Delivery Interval

P < 0.05 Significant

DISCUSSION

It was that majority of patients in Dinoprostone group were booked cases at our institution and in Misoprostol group were unbooked cases, who had no regular antenatal checkups at our institution or elsewhere.

This indirectly reflects the socio-economic status. A single dose of Dinoprostone costs Rs. 230, thus was used most commonly in patients who were booked. A single dose of Misoprostol costs Rs. 8/- used in patients who were unbooked. Thus, concluding that Misoprostol is more cost effective than compared to Dinoprostone.

The other patient’s characteristics like gravidity, gestational age and Bishop’s score prior to induction had no major differences in both groups.

Response to Drug

Vaginal Deliveries

The rate of vaginal deliveries was 78% in the Dinoprostone and 90% in the Misoprostol group.
Dinoprostone is comparable to the studies of Trufatter et al.

Trufatter et al. (1985)

Yonekura et al. (1985)

Nager et al. (1987)

Bernstein et al. (1987) states that the induction delivery interval of misoprostol every 4th, hourly with an induction delivery interval of 11.15±2.1 hrs, which is comparable to the studies of Bugallo et al. (1995) and Sanchez Ramos et al. (1993). who used 50 µg misoprostol 12th hourly to a maximum of 200 µg with an induction delivery interval of 10.4 hrs and Sanchez Ramos et al. (1993) who used 50 µg misoprostol 4th hourly to a maximum of 600 µg with an induction delivery interval of 11±7.3 hrs.

Induction to Vaginal Delivery Interval

Authors and Year | DINOPROSTONE (Dose) | MISOPROSTOL (Dose) |
--- | --- | --- |
Varaklis et al. (1995) | 22.4±10.9 (0.5 mg 6 hrs.) | 16.0±7.7 (25 µg 2 hrs.) |
Wing Da et al. (1995) | 23.5±14.5 (0.5 mg 6 hrs.) | 15.1±8.0 (50 µg 3 hrs.) |
Herabuyta et al. (1997) | 21.3±13.9 (1.5 mg) | 19.1±10.6 (100 µg) |
Ozgur et al. (1997) | 8.2±5.9 (0.5 mg) | 7.6±1.9 (100 µg) |
Blanchette et al. (1999) | 31.3±13.0 | 19.8±10.4 |
Kolderup et al. (1999) | 28.5±2.0 (0.5 mg 6 hrs.) | 19.5 (50 µg 4 hrs.) |
Present study | 15.25±3.14 (0.5 mg 8 hrs.) | 11.15±2.17 (25 µg 4 hrs.) |

Various authors in their studies have compared the efficacy of misoprostol and dinoprostone in relation to induction-delivery interval.

Failed Induction

Failed inductions were those cases, which did not fulfil the criteria for the definition of induction of labour. Thus all caesarean deliveries were considered 'failed induction,' irrespective of the cause of the same.

Caesarean delivery rates in the present study are 22% in the dinoprostone group and 10% in the misoprostol group. The various indications were foetal distress, failure to progress due to deep transverse arrest or secondary arrest of dilatation. In the dinoprostone group secondary arrest of dilatation formed the major indication for caesarean delivery and in the misoprostol group foetal distress formed the major indication.
Indication for caesarean delivery. In the Misoprostol group, it was found the presence of thick meconium stained liquor in all cases.

Maternal Side Effects
The maternal side effects observed were tachysystole, hyperstimulation, vomiting, diarrhoea, fever and PPH.

In the Dinoprostone group the major side effects were vomiting: 8% and PPH of which traumatic were 12% and 6% atonic. The major side effects observed in the Misoprostol group was tachysystole 6% and hyperstimulation 4%. A concern with Misoprostol induction has been excessive uterine activity namely tachysystole and hyperstimulation, 3 cases of hyperstimulation were seen with foetal distress for which caesarean delivery had to be done. Other side effects in the Misoprostol group were fever, vomiting and diarrhoea which were minimal. Misoprostol had 3 patients with traumatic PPH; all were cervical tears and did not require any blood transfusion.

Neonatal Outcome
The mean birth weight and mean Appgar scores in both groups did not show any major difference. The incidence of NICU admission was 10% in both groups. The indications for NICU admission were meconium aspiration syndrome, birth asphyxia and hyperbilirubinaemia. There was an increased incidence of meconium aspiration syndrome and birth asphyxia in the Misoprostol group and was associated with uterine hyperstimulation.

CONCLUSION
Misoprostol and Dinoprostone are safe and effective for cervical ripening and labour induction. Misoprostol is cost-effective when compared to Dinoprostone. Misoprostol is stable at room temperature and does not need refrigeration, whereas Dinoprostone requires refrigeration. Induction delivery interval, requirement of Oxytocin augmentation is less in Misoprostol group when compared to Dinoprostone. Vaginal delivery rate is high in Misoprostol group when compared to Dinoprostone.

One disadvantage with Misoprostol is uterine tachysystole and hyperstimulation with further foetal distress. Therefore, further work is needed to determine the ideal dosing to prevent such complications.

In conclusion we believe that Misoprostol is apparently safe, efficient and a cost-effective induction agent which may become the drug of choice for induction of labour in the coming years.

REFERENCES