International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Gupta NS et al. Int J Reprod Contracept Obstet Gynecol. 2018 Apr;7(4):1608-1612
www.ijrcog.org

pISSN 2320-1770 | eISSN 2320-1789

DOI: http://dx.doi.org/10.18203/2320-1770.ijrcog20181364

Original Research Article

An observational study of 100 cases of 25µg oral misoprostol for induction of labour in term pregnancy

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Received: 15 February 2018
Accepted: 09 March 2018

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ABSTRACT

Background: Labour induction is a clinical intervention that has the potential to confer major benefits to the mother and new born when continuation of pregnancy poses a risk/danger to the outcome of pregnancy. Misoprostol is an ideal agent for induction of labour, particularly in settings where the use of prostaglandin E_2 is not possible owing to lack of availability, facilities for storage, or financial constraints. It is stable at room temperature, relatively inexpensive and can be given via several routes (oral, vaginal, sublingual, and buccal).
Methods: It is an observational study of 100 cases conducted in the labour room of a Tertiary Care Government Hospital, Rajkot over a span from January 2016 to March 2017. After patient selection as per inclusion criteria and written informed consent after evaluating patients were enrolled in the study. Tablet misoprostol 25 microgram given orally every 4 hourly with maximum of 5 doses till the patient was in active stage of labour.
Results: Maximum patients delivered by a single dose of Tab. Misoprostol (35%), the mean induction delivery interval was 11.44 hours. Most of the women delivered by vaginal route (88%) without any maternal complications like PPH, cervical/vaginal tear and uterine rupture. Only 4 cases out of 100 of failed induction for which LSCS was taken. Eight babies were admitted in NICU for MSL and had good prognosis. The most common side effect of the drug was nausea (15%) followed by fever and vomiting. 69% patients did not have any adverse drug reaction.
Conclusions: Thus, induction of labour with oral misoprostol reduces the LSCS rates, lesser induction delivery interval and has good fetal outcome. The drug is well tolerated by the patients orally and has very few side effects.

Keywords: Labour induction, Low dose oral misoprostol, Postdatism, PROM

INTRODUCTION

Reproduction is our God's Gift. It provides the natural continuity in this world. So, the interest goes to how this gift "fetus" will be delivered with the safest, more rapid way with the minimum medical intervention.[1]

Induction implies stimulation of contractions before the spontaneous onset of labour, with or without ruptured membranes. When the cervix is closed, and uneffaced, labour induction will often commence with cervical ripening, a process that generally employs prostaglandins to soften and open the cervix. Labour induction is a clinical intervention that has the potential to confer major benefits to the mother and new born when continuation of pregnancy poses a risk or danger to the outcome of pregnancy.

Unpublished data from the WHO Global Survey on Maternal and Perinatal Health, which included 373 health-care facilities in 24 countries and nearly 300 000 deliveries, showed that 9.6% of the deliveries involved

labour induction. Overall, the survey found that facilities in African countries tended to have lower rates of induction of labour (lowest: 1.4% in Niger) compared with Asian and Latin American countries (highest: 35.5% in Sri Lanka).[2]

Misoprostol (a prostaglandin E_1 analogue) has several potential advantages: it is stable at room temperature, it is relatively inexpensive, and it can be given via several routes (oral, vaginal, sublingual, and buccal). These properties make misoprostol an ideal agent for induction of labour, particularly in settings where the use of prostaglandin E_2 is not possible owing to lack of availability, facilities for storage, or financial constraints.[3,4]

In 2007, the WHO Expert Committee on the Selection and Use of Essential Medicines included misoprostol 25µg tablets to its list and this inclusion will hopefully enable the national essential lists to include low-dose misoprostol for labour induction.[5] In this study Tab. Misoprostol 25µg is given orally 4 hourly upto 5 doses.

The main objective is to study the effectiveness and safety of 25µg oral misoprostol for induction of labour at term. To study the effectiveness by oral route in terms of induction-delivery interval, mode of delivery, maternal and fetal outcome. To study the side effects of misoprostol by oral route. To study the safety and efficacy with similar studies

METHODS

This is an observational study conducted on 100 cases in the labour room of Tertiary Care Government Hospital, Rajkot setting from Jan 2016 to March 2017. Tablet Misoprostol 25 microgram was used which was procured under JSSK scheme free of cost from the Government. Maximum of five doses were given every 4 hourly. Due Ethical Committee clearance is obtained before onset of study.

All eligible women fulfilling inclusion criteria with indication for labour induction and no contraindication for vaginal delivery were enrolled in the study. It was ensured that all the investigations were within normal limits and there was availability of emergency LSCS and neonatologist. Written and informed consent in vernacular language was obtained from the women who were willing to participate in the study.

Patient's vitals were recorded, per abdomen and per vaginum examination was done and bishop score calculated. If needed USG for confirmation of presentation and amniotic fluid index, expected fetal weight was done as per individual case requirement. Depending on the eligibility criteria, patients were randomly selected for the study to receive Tablet Misoprostol per oral. The findings were documented on the proforma. Intermittent intrapartum fetal monitoring was performed by auscultating fetal heart every 30 minutes. Two units of blood kept ready in the blood bank.

The dose of 25µg was repeated every 4 hourly to a maximum of five doses. The further dosing was interrupted as per the need of emergency intervention for maternal or fetal indication.

Per vaginal examination was repeated 4 hourly and patients were monitored for: uterine contractions, hyperstimulation, nausea, vomiting, fever, diarrhea, vaginal bleeding or other untoward side effects. Progress of labour was monitored and partograph was maintained in all patients in active labour. Labour was augmented with oxytocin in patients with arrest of cervical dilatation due to poor contraction and 4 hours after last dose of misoprostol and were recorded.

Inclusion criteria

- Nulliparous and Multiparous (2^{nd}, 3^{rd} gravida) with low risk
- Singleton pregnancy, cephalic presentation, between 37 and 42 weeks gestation
- Obstetrics or medical indication for induction of labour such as postdate pregnancy, PROM and mild oligohydramnios with reactive NST and uncompromised fetoplacental circulation.
- Bishops score of ≤6

Exclusion criteria

- Preterm pregnancy
- Multiple pregnancy
- Pregnancy with scarred uterus (Previous CS, hysterotomy, myomectomy)
- PPROM
- Hypertensive disorders of pregnancy
- Medical disorders of pregnancy such as anemia, diabetes mellitus, liver, cardiac or renal disorder
- Amniotic fluid index of <5 with nonreassuring fetal heart rate
- Patients with absolute contraindications to prostaglandins such as asthma, glaucoma. hypersensitivity to prostaglandin
- Malpresentation, IUFD, Congenitally malformed fetus
- Patients refusing to enroll for the study

Outcome measured in terms of number of doses, induction-delivery time interval, maternal and fetal outcome, mode of delivery and adverse effects of the drug.

RESULTS

In this table, 97% of the cases were in age group between 20 and 30 years. Two percentage above 30 years and 1% below 20 years of age (Table 1).

Table 1: Age distribution of cases.

Age (in years)	Total no. of cases (N=100)
Below 20	1
20-30	97
More than 30 years	2

Table 2 shows, 66% patients were primigravida, 24% were second gravida and third gravida patients were 10%.

Table 2: Gravidity.

Gravida	Total no. of cases (N=100)
Primi	66
G2	24
G3	10

Table 3: Indication of induction.

Indication	Total no. of cases (N=100)
Postdatism	58
PROM	42

Table 3 shows that the most common cause of induction of labour was postdatism (58%) followed by PROM (42%).

Table 4: Bishop score.

Bishop score	Total no. of cases
1-3	3
4-6	97

The average bishop score in this study was 5.21.

Table 5: Number of doses.

Number of doses	Total no. of cases (N=100)
1	35
2	25
3	17
4	11
5	12

Table 5 shows that in the present study, 35% cases were induced in single dose of Tab. Misoprostol of 25 micrograms, 25% cases were induced with 2 doses, 17% with 3 doses, 11% with 4 doses and 12% required 5 doses. Average number of doses required for induction of labour was 2.4.

Table 6: Mode of delivery.

Mode of delivery	Total no. of cases (N=100)
Vaginal	86
Forceps	2
Caesarean section	12

Table 6 shows that, 86% were delivered vaginally, 12% were delivered by caesarean section and in 2% forceps was used. Out of 12 caesarean sections, 4 were taken in case of failed induction, 6 were taken in case of fetal distress out of which 2 were due to non-progression of labour in second stage, 4 were due to meconium stained liquor 1 was taken in case of cord prolapse with fetal distress and 1 was taken in case of deep transverse arrest.

Table 7: Induction- delivery interval.

Induction-delivery interval	Total no. of cases (N=100)
≤24 hours	95
>24 hours	5

Table 7 shows that, 95% cases were delivered within 24 hours of induction of labour. Mean induction delivery interval of this study was 11.44 hours.

Table 8: Augmentation with oxytocin.

Oxytocin	Total no. of cases (N=100)
Yes	77
No	23

In present study, 77% cases required augmentation of labour with oxytocin.

Table 9: Meconium stained liquor and NICU admission.

MSL	Total no. of cases	NICU admission
Yes	15	8
No	85	92

In the present study, 15% cases had meconium stained liquor, out of which only 8 babies were referred to NICU and had good prognosis. One baby expired on 2nd day of life.

Table 10: Adverse drug reactions.

Adverse drug reactions	Total no. of cases (N=100)
Fever	12
Nausea	15
Vomiting	4
Diarrhea	0
Hyperstimulation	0

Table 10 shows that, in the present study 12% patients had low grade fever, 15% had nausea and 4% had vomiting. 69% patients did not have any adverse effect of misoprostol. There were no maternal complications in the form of postpartum hemorrhage, cervical/vaginal tear and uterine rupture.

Analysis of data done by statistical methods like standard deviation (SD), Chi square, Chi square with Yate's correction, Pearson's co-relation test, Spearman co-relation test and Mann Whitney U-test.

DISCUSSION

The purpose of the study is to find out the effectiveness of Tab. Misoprostol by oral route in terms of induction-delivery interval, mode of delivery, maternal and fetal outcome and side effects of the drug.

In this study median age is 22.5 years. In the study carried out by Marilyn Morris et al on "Safety and effectiveness of oral misoprostol for induction of labour in a resource-limited setting: a dose escalation study" at New Guinea, median age of pregnant women was 27 years.[6] A similar study carried out by Shazia Syed et al have taken 250 pregnant women in age group of 18 to 24 years, among which 47% (118) were primigravida. The mean age with standard deviation of the study population was 24.08±3.25 years with the range of 18 to 31 years in study of Aftabun Nahar et al.[7]

The most common indication for induction of labour in the present study was postdatism (58%) and PROM was 42%. In study of Marilyn Morris et al, majority of women underwent induction of labour for post-dates (56%; 117/209).[6] Forty-five (22%) had pre-labour rupture of membranes (PLROM), 28 (13%) had pre-eclampsia and 10 (5%) had suspected fetal compromise including intrauterine growth restriction. In study of Shazia Syed et al postdated women were 52%, PROM was 18.8% and PIH were 16.4%.[8] Alfirevic Z et al after reviewing 76 randomized control trials says that reasons for induction include being overdue, pre-labour rupture of membranes and high blood pressure.[9]

In this study mean Bishop score was 5.21.[11] Mean Bishop's Score was 6.2±1.76 with a minimum value of 3 and maximum value 10 in study of Aftabun Nahar et al.[7] Marilyn Morris et al demonstrated that median bishop score among successfully induced was three and among whom who had failed induction was also three.[6]

In this study out of 100 patients 35 required only one dose, 25 required 2 doses and 17 patients required 3 doses, 11 required 4 and 12 patients required 5 doses. In study by Nahar et al, it is showed that out of 60 patients 31(51.7%) patients needed only 1 dose of misoprostol and 24(40%) patients needed 2 doses and only 5(8.3%) patients needed 3 doses of Misoprostol.[7]

In the present study, 88% cases had vaginal delivery out of which 2 were instrumental (forceps) delivery and 12% cases underwent LSCS out of which only 4% LSCS was taken in case of failed induction. Marilyn et al showed that ninety percent of women (188/209) had a successful vaginal delivery compared to 10% (21/209) who failed IOL and underwent caesarean section. Of those with a successful vaginal delivery, 74% delivered within 24 hours.[4] In Varsha et al, a majority (96%, n=241) of mothers went into labour but 4% had failed induction.[10]

In this study mean induction delivery interval was 11.44 hours. In study of Nahar et al, mean induction delivery interval was of 11.1±4.4 hrs.[9] In study of Marilyn et al, mean induction delivery interval in patients with postdatism was 9 hours and patients with PROM was 6.4 hours.[6] In the study Shazia et al, The mean induction-delivery interval was 11±2.7 hours.[8] In Varsha et al, mean induction to delivery interval was 14.16±3.45 hours.[10]

In the present study, 8 babies were admitted in the NICU and had good prognosis. Marilyn et al showed that the majority of babies (99%; 206/209) survived with a good outcome on discharge.[6] Varsha et al, 6.5% of patients had meconium-stained amniotic fluid, 3% of babies were admitted of which 33.33% were admitted for meconium aspiration syndrome and had good prognosis. Take-home baby rate was 100%.[10]

In this study the most common side effect noted was nausea (15%) followed by fever (12%) and vomiting (4%). In Varsha et al, nausea n = 20 (10%), vomiting n = 11 (5.5%), fever n =4(2 %), diarrhoea n = 9 (4.5%), uterine hyperactivity: tachysystole n = 6 (3%) hypertonus n = 2 (1%) uterine hyperstimulation syndrome n =0.[10]

CONCLUSION

It can be concluded that Tab. Misoprostol 25µg orally for induction of labour is safe, effective, reduces the caesarean section rates, lesser induction delivery interval and has good maternal and fetal outcome.

This study suggests that repeated small doses of misoprostol ripened the cervix and overcame the cervical barrier, resulting in a high rate of vaginal delivery and can be easily implemented in resource-limited settings. In addition to being cheap and stable at ambient temperatures, the simplicity and popularity of oral misoprostol is likely to improve induction of labour rates in developing countries, which will in turn reduce the unacceptably high maternal and perinatal mortality rates in these settings.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Gupta NS, Prajapati SS. An observational study of 100 cases of 25µg oral misoprostol for induction of labour in term pregnancy. Int J Reprod Contracept Obstet Gynecol 2018;7:1608-12.