https://doi.org/10.22502/jlmc.v1i1.14

Original Research Article

Comparative Evaluation of 25µg and 50µg of travaginal Misoprostol for Induction of Labor

Buddhi Kumar Shrestha,[a,c] Sushila Jain,[a,c] Roshi Maskey,[b,c] Hasena Banu[b,c]

ABSTRACT:

Introduction: To compare the efficacy and safety of 25g vs. 50g of intravaginal (Posterior fornix) misoprostol for induction of labor in 100 patient from Jan 2012 to Dec 2012 at Lumbini Medical College. **Methods**: One hundred pregnant lady requiring induction were randomly assigned to receive either 25 g (group A=50) or 50 g (group B=50) of intra vaginal misoprostol every 4 hrs till adequate contractions were achieved or maximum dose of 150 g was used. **Results**: The onset of contraction was earlier in group B in 34 cases as compared to group A, where only 25 cases had earlier contraction (P> 0.05). 38 cases (76%) in Group B and 35 cases (70%) in Group A delivered vaginally. Induction to delivery interval was shorter(<12hrs) in group B in 15 cases and in 10 cases in group A. Mean dose of Misoprostol (94micrograms) for successful induction in group B was high compared to Group A (75.5 microgram). Requirement for oxytocin infusion was higher in group A, 26% vs. 15%. Abnormal contractility pattern was seen in B group 24% cases compared to 14% cases in Group A. APGAR score < 7 at 1 min was seen in 26% neonates in Group B and in only 10% neonates in Group A. Ruptured uterus did not occur in any group. Conclusion: 50 g dose of misoprostol is more efficacious than 25 g dose as seen in our study. However it appears to be less safe both for mother and baby due to the high incidence of tachysystole, hyperstimulation and intrauterine passage of meconium.

Keywords: fornix • induction • intravaginal • labor • misoprostol

INTRODUCTION:

Misoprostol is a new agent for labour Induction. It was found that it had excellent cervical ripening and is uterotonic agent. Though not USFDA (United States Federation for Drug Adminstration) approved it is being increasingly used in medical Abortion, Cervical Repining before surgical abortion. However FDA recognizes that in certain circumstances off label use of approved products are appropriate, rational, and accepted medical practice.1Advandtage of misoprostol over other inducing agents include stability at room temperature, low cost, variety of routes and can be used in different dose. This study was planned to compare the efficacy and safety of 25g vs 50g intravaginally misoprostol for induction labour.

a - Lecturer
b - Medical Officer
c - Department of Obstetrics and Gynecology
Lumbini Medical College Teaching Hospital, Palpa, Nepal

Corresponding Author:
Dr. Buddhi Kumar Shrestha
e-mail: drbkshrestha@jlmc.edu.np

How to cite this article:
Shrestha BK, Jain S, Maskey R, Banu Hasena. Comparative evaluation of 25µg and 50µg of intravaginal misoprostol for induction of labor. Journal of Lumbini Medical College. 2013;1(1):46-7. doi:10.22502/jlmc.v1i1.14.

METHODS:

The study was carried out on pregnant lady (37 weeks or more of Gestation) requiring induction of labour for any medical or obstetrical indication. The study duration was of 1 year and it was approved by the ethical committee of the hospital (Lumbini Medical College).Women with singleton pregnancy at 37 or more weeks of gestation were included after informed consent. Pregnant lady with favorable cervix (Bishop score > 6), any contraindication to vaginal birth, previous c/s. and PROM (premature rupture of membrane) were excluded from the study. The study included 100 cases pregnant females, out of which 50 cases received 25 g (group A) or 50 cases received 50 g (group B) misoprostol intravaginaly in posterior vaginal fornix. The drug was repeated every 4hrs till regular adequate uterine contractions were achieved or maximum up to 150 g of dose of the drug was used up. Female with inadequate contractions or no uterine contractions despite of 150 g dose were augmented using oxytocin. Various indication for induction were, postdated pregnancy 78%, oligohydromnios 12%, hypertension 10%.

RESULTS:

The Induction to delivery interval was shorter in Group B as shown in Table 1.There was no difference between the both group with respect to mode of delivery (vaginal) 35 cases (70%) in group A and 38 cases (76%) in

group B. The onset of contraction was earlier in group B in 34 cases as compared to group A, where only 25 cases had earlier contraction (P> 0.05). 38 cases (76%) in Group B and 35 cases (70%) in Group A delivered vaginally. Induction to delivery interval was shorter (<12hrs) in group B in 15 cases and in 10 cases in group A. Mean dose of Misoprostol (94 µg) for successful induction in group B was high compared to Group A (75.5 µg). Misoprostol related side effect, especially gastrointestinal side effect (nausea, vomitting, diarrhea, fever, headache) were common with group B as compare to group A (30%vs 25%), which is not statically significant. Failed induction in group A was seen in 7 cases and in 2 cases in group B. Requirement for oxytocin infusion was higher in group A, 26% vs. 15% . Abnormal contractility pattern was seen in B group 24% cases compared to 14% cases in Group A, both statically not significant, as shown in Table 2. APGAR score < 7 at 1 min was seen in 26% neonates in Group B and in only 10% neonates in Group A as shown in Table 3. Of all the patient who underwent Caesarian Section, various indication for LSCS(lower segment Caesarian Section) was irregular FHS(Fetal Heart Sound), Meconium Stained liquor, failed induction. Common Indication for LSCS was fetal distress,10 cases in group B and 8 cases in group A.

Table 1*: Induction to delivery interval*

SNo	Induction to delivery interval (hrs)	Group A (n = 35	Group B (n = 38)
1	<12	10	15
2	12-24	15	16
3	>24	10	7

Table 2*: Abnormal contractility pattern*

SNo	Indication	Group A, n = 50	Group B, n = 50
1	Tachysystole	4(8%)	6(12%)
2	Hypertonus	2(4%)	3(6%)
3	Hyper Stumulation	1(2%)	3(6%)
Total		**7(14%)**	**12(24%)**

Table 3*: Fetal outcome analysis*

SNo	Outcome	Group A, n=50	Group B, n=50
1	APGAR <7 in 1 min	5 (10%)	13 (26%)
2	APGAR >7	30 (60%)	25 (50%)
3	Resuscitation	7 (14%)	9 (18%)
4	Meconium	6 (12%)	9 (18%)
5	Admission	7 (14%)	10 (20%)

DISCUSSION:

Misoprostol the PGE1 and analogue appears to be safe and effective but only the optimal dose needs to be determined. In our study induction delivery interval was shorter in group B as compared to group A. Lisa et al, their study on 399 pregnant females reported shorter induction delivery interval in female who recieved 50 g of misoprostol (826 min vs. 970 min, p>0.02), Few cases in both group required oxytocin augmentation as in our study.[1,2] A Cochrane review by Hofmeyr also revealed that low doses of Misoprostol required more oxytocin augmentation as in our study (26%Vs 15%, P>0.05).[3] However, the cases with failed induction were more common in low dose misoprostol, these finding was consistent with one of the study of meydanliet et al.[4] Their study also reported that the proportion of women delivering vaginally with one dose of vaginal misoprostol was significantly greater in 50 g group (0/49 vs. 41/47;p>0.001) which was not studied in our cases. In a comparative study reported by Has et al showed the rate of Cesarian Section due to fetal distress was higher with higher dose (28.6 vs. 10.3% p>0.05).[5] This was comparable to our study (group B 20 % vs group A 16%). We observed that the incidence of normal contraclity pattern (tachysystole, hyperstumulation) was higher in 50 g (24% vs 14%, p>0.05%) was comparable with study by Sanchez-Ramos et al.[6] Minor side effects were common with higher dose but uterine Rupture did not occur in both groups in our study. However, there are so many studies that have reported serious complication with the use of misoprostol. A systematic review by Wsagner, 16 medico legal cases agreed with these findings, with uterine rupture in 7 cases and hypoxic encephalopathy in 14 cases.[7] Thomas et al reported rupture uterus in a primigravida patient after the use of 100 g of misoprostol (25 g given 4hrly).[8] Neonatal outcome was also adversely affected in females who received higher dose. Babies with low Apgar score, requiring admission were significantly higher in 50 g group. This was in concurrence with the observations made by Has et al.[5] Contrary to this Sanchez-Ramos et al in their meta-analysis of five randomize clinical trials reported comparable neonatal outcomes with the two doses.[6]

CONCLUSION:

Misoprostol is a effective agent for labour induction. Complication remain a matter of concern. These can be minimized by judicious selection of misoprostol dose. 25g misoprostol appears to be safer than 50 g misoprostol due to high incidence of tachysystole, hyperstumulation and meconium in 50 g misoprostol. Although this requires stastical correlation in larger series.

REFERENCES:

1. Off-label drug use and FDA review of supplemental drug applications: hearing before the Subcommittee on Human Resources and Intergovernmental Relations of the Committee on Government Reform and Oversight, House of Representatives. 104th Congress, 2nd Session, September12. Washington: U.S. GP.O 1996;53-94.
2. Farah LA, Sanchez-Ramos L, Rosa C, Del Valle GO, Gaudier FL, Delke I, et al. Randomized trial of two doses of the prostaglandin E1 analog misoprostol for labor induction. Am J Obstet Gynecol. 1997;177:364–71.
3. Hofmeyr GJ, Gulmezoglu AM. Vaginal misoprostol forcervical ripening and induction of labor. CochraneDatabase Syst Rev 2003;(1): CD000941.
4. Meydanli MM, Caliskan E, Burak F, Narin MA, Atmaca R. Labor induction post-term with 25 micrograms vs 50 micrograms of intravaginal misoprostol. Int J Gynaecol Obstet 2003;81:249-55.
5. Has R, Batukan C, Ermis H et al. Comparison of 25 and50 microgram vaginally administered misoprostol for preinduction of cervical ripening and labor induction.Gynecol Obstet Invest 2002;53:16-21.
6. Sanchez-Ramos L, Kaunitz AM, Delke J. Labour induction with 25 g versus 50 g intravaginal misoprostol : asystematic review. Obstet Gynecol.2002;99(1):145-51.
7. Wagner M. Adverse events following misoprostol induction of labor. Midwifery Today Int Midwife. 2004;71:9-12.
8. 8. Thomas A, Jophy R, Maskhar A . Uterine rupture in primigravida with misoprostol used for induction of labor. BJOJ . 2003;110:217-8.