

Comparison of 800 Mcg Oral and Vaginal Misoprostol Prior to First Trimester Surgical Abortion: A Hospital Based Clinical Study



Medical Science

KEYWORDS : Misoprostol, Oral, Vaginal, Cervical dilatation, first trimester, surgical abortion

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ABSTRACT

Introduction: Abortion was made legal under specific circumstances only in 1971. Misoprostol has been found to be an effective drug with few side effects.

Aim: To compare the safety, efficacy, side effects and complications of oral and vaginal misoprostol for cervical priming prior to surgical abortion.

Design: Prospective randomised controlled study

Material and Methods: 800mcg misoprostol was used and evaluation was done at the end of 3 hour.

Result: A total of 675 patients met the eligibility criteria for first trimester surgical abortion but 95 patients were excluded from final analysis. Both the groups were well comparable. Mean cervical dilatation (CD) in oral group was 6.34±2.21 mm and in vaginal group it was 7.47±1.96 mm (unpaired t test value: 2.914, p value 0.004 (Highly significant) with 95% confidence interval). Failure rate was significantly higher (p value <0.05) in the oral group (23.64%) compare to vaginal group (6.56%). Side effect were higher in oral misoprostol group though nausea and vomiting were significantly higher in the oral misoprostol group (p value <0.005), remaining were higher but not significant (p value >0.05).

Conclusion: Misoprostol when used vaginally resulted in a better efficacy in terms of cervical dilatation as compared to the oral route for cervical priming prior to first trimester surgical abortion and also vaginally used misoprostol resulted in fewer side effects as compared to the oral route.

Introduction: The practice of abortion dates back to ancient times and today half of the world's current deaths due to unsafe abortions occur in Asia. Abortion was made legal under specific circumstances only in 1971. Interventions for abortion include pharmacological and non pharmacological methods which depend upon duration of pregnancy. Misoprostol is the drug that presents low cost, storage at room temperature, widespread availability and easily administrable by various routes. In 2000, the FDA approved medical abortion using 600 mg of oral mifepristone with 400 mcg of oral misoprostol 48 hours later for pregnancies up to 49 days of gestation. However, there is excellent evidence of efficacy up to 63 days of gestation using the regimens of 200 mg of mifepristone orally followed by home administration of either 800 mcg of buccal misoprostol in 24 to 36 hours or 800 mcg of vaginal misoprostol in 6 to 48 hours.

Cervical pre-dilation with misoprostol may be considered in all women having surgically induced abortions.^[1] Henery et al. concluded that vaginally applied misoprostol is as effective as gemeprost in cervical priming prior to first trimester vacuum aspiration. Misoprostol was associated with fewer side effects than gemeprost.^[2] Improved initial cervical dilation was demonstrated with 400 µg oral misoprostol when compared with 200 µg (mean difference 0.53 [95% CI 0.30, 0.77]) (Ngai 1999; Oppegard 2004). When the same doses were administered vaginally, similar results were found (mean difference 0.92 [95% CI 0.53, 1.31]), although significant heterogeneity is present between these data from two trials (Ngai 1999; Singh 1998). Dilatation was also greater with a 400 µg dose of sublingual misoprostol compared to 200 µg (mean difference 2.20 [1.61, 2.79]) (Vimala, Mittal 2004). With a 400 µg dose of sublingual misoprostol, the abortion procedure took less time (RR -1.22 [95% CI -1.72, -0.71]); however, women reported more pain (RR 2.50 [95% CI 1.31, 4.75]) than those who received a 200 µg dose.^[3-5] Nagi has shown that intravaginal misoprostol was effective for cervical priming before a surgically induced abortion.^[6]

Our aim to present this study is to compare the safety, efficacy, side effects and complications of oral and vaginal misoprostol for cervical priming prior to surgical abortion.

Material:

A Prospective randomised controlled study was designed in the Department of obstetrics and gynaecology, Pannadhahi Mahila Chikitsalaya, RNT Medical College, Udaipur from July, 2010 to December, 2012.

Inclusion Criteria:

1. 7-12 weeks of gestation age.
2. Blighted ovum
3. Missed abortion

Exclusion Criteria:

1. >12 weeks of gestation
2. <7 weeks of gestation
3. Uterine fibroid and other anomaly
4. Severe Hypertention
5. Uterine infection or sepsis
6. Pelvic Inflammatory Disease(PID)
7. Cervicitis
8. Epilepsy
9. Molar pregnancy
10. Coagulopathy or taking oral anti-coagulants
11. Moderate or Severe anaemia i.e.Hb <7g%
12. CVS or CNS disorder
13. Allergy to misoprostol
14. Confirmed or Suspected ectopic pregnancy, undiagnosed adnexal mass
15. Intra Uterine Device(IUD) in place
16. Unstable haemodynamics and shock
17. Chronic adrenal insufficiency or on steroids
18. Inherited porphyria
19. Serious systemic disease(e.g. liver disease, significant cardiac disease, renal disorder)

Methodology:

Once the patient was eligible candidate for first trimester surgical abortions after going through inclusion and exclusion criteria, patients were randomly allocated either in oral or vaginal group. Simple random Sampling method was used for randomisation.

Oral group:

The patients allocated in this group were advised to take 800mcg of misoprostol with sip of water. They were followed up for 3 hrs which was the end point of our study for cervical dilatation. During this period they were also evaluated for the side effects and complications.

Vaginal group:

In patients allocated in this group we kept 800mcg of misoprostol in posterior fornix of vagina. They were followed up for 3 hrs which was the end point of our study for cervical dilatation.

During this period they were also evaluated for the side effects and complications.

The following side effects were evaluated

1. Nausea
2. Vomiting
3. Diarrhoea
4. Headache
5. Abdominal cramps
6. Shivering

The following complication were evaluated

1. Vaginal bleeding
2. Anaphylaxis

Outcome:

Successful: When cervical dilatation after 3 hrs of follow up of misoprostol administration either orally or vaginally was 6 mm or more irrespective of initial cervical status as measured by Hegar's dilator.

Unsuccessful/Failure: When cervical dilatation after 3hrs of follow up of misoprostol administration either orally or vaginally was less than 6mm irrespective of initial cervical status as measured by Hegar's dilator.

All desired information was submitted in pre set proforma and patients were evaluated for safety, efficacy, side effects and complications till 3hr after administration of 800mcg misoprostol. At any time patient had feature of side effect or complication as defined above was considered to be as present. All desired information about the finally selected cases were collected and entered in Microsoft Word Office EXCEL 2007. Data thus collected was classified and analysed with the help of Microsoft Word Office EXCEL 2007 and Primer Statistical Software. Proportions were analyzed using chi-square test. Level of Significance (LS) was decided with the help of Primer Statistical Software as per p value i.e. if p value was ≥ 0.05 then difference was not significant (NS), if p value was < 0.05 then difference was significant (S) and if p value was < 0.001 then difference was highly significant (HS).

Results & Discussion:

A total of 675 patients meet the eligibility criteria for first trimester surgical abortion but 95 patients were excluded from final analysis as 80 patients were absconded or were LAMA (Left Against Medical Advice) and 15 patients had spontaneous expulsion of fetus before 3hrs. So, total of 580 patients were incorporated for final statistical analysis after all stages of exclusion, as study population.

Among total study population i.e. 580 patients, 47.41% patients were in Oral group and remaining 52.58% were in Vaginal. Mean age of total study population was 24.82 ± 3.83 yr. In oral group it was 24.6 ± 3.76 yr and in vaginal group it was 25.03 ± 3.91 yr (unpaired t test value: 0.6054, p value 0.5461 (Not significant) with 95% confidence interval). Mean gestational age of total study population was 8.20 ± 1.51 wk. In oral group it was 8.22 ± 1.52 wk and in vaginal group it was 8.19 ± 1.50 wk (unpaired t test value: 0.07, p value 0.93 (Not significant) with 95% confidence interval).

Mean weight of total study population was 61.72 ± 11.05 kg. In oral group it was 60.82 ± 11.81 kg and in vaginal group it was 62.54 ± 10.37 kg (unpaired t test value: 0.83, p value 0.40 (Not significant) with 95% confidence interval). Mean height of total study population was 5.21 ± 0.29 ft. In oral group it was 5.21 ± 0.25 ft and in vaginal group it was 5.21 ± 0.32 ft (unpaired t test value: 0.02, p value 0.98 (Not significant) with 95% confidence interval). Both the groups were well comparable as per age, height, weight and gestational age (p value > 0.05 , not significant).

Number of patients in two group (Oral vs Vaginal) were not significantly different on the basis of Habitant (rural or urban), Caste (hindu or muslim), Per abdomen finding (10 wks, just palpable or not palpable uterus), Per Vaginal finding (Os closed or Os patulous), Booking (booked or unbooked) and Parity (P0/P1/P2/P3/P4) and group were well comparable.

Mean cervical dilatation (CD) of total study population was 6.94 ± 2.15 mm. In oral group it was 6.34 ± 2.21 mm and in vaginal group it was 7.47 ± 1.96 mm (unpaired t test value: 2.914, p value 0.004 (Highly significant) with 95% confidence interval) which means cervical dilatation was significantly better in those patients who had received misoprostol via vaginal route. Successful cervical dilatation (cut off value ≥ 6 mm) was also significantly better in patients who received misoprostol via vaginal route (p value 0.009, highly significant). 210 patients out of 275 in oral group and 285 patients out of 305 in vaginal group had successful cervical dilatation. Success rate was 76.36% (figure 1) in oral group and 93.44% (figure 2) in vaginal group respectively as shown in table 1. Failure rate was significantly higher (p value < 0.05) in the oral group (23.64%) compare to vaginal group (6.56%).

We also evaluated the effect of parity on cervical dilatation, though we did not find any significant difference but definitely with increase in parity, success rate of cervical dilatation increased. Success rate of cervical dilatation for primipara was 74.51% which approached to 100% for para three and para four.

Various side effects evaluated were nausea, vomiting, diarrhoea, shivering and headache. These were higher in oral misoprostol group though nausea and vomiting were significantly higher in the oral misoprostol group (p value < 0.005), remaining were higher but not significant (p value > 0.05). 97.30% (180) of patients those who experienced vomiting belonged to oral misoprostol group. Similarly 52.17% (60) of patients those who experienced diarrhoea belonged to oral misoprostol group.

No patient in either group had experienced anaphylaxis but one patient in oral group and three patients in vaginal misoprostol group had bleeding episode though the result were not significant (p value 0.361). We also observed, though did not find any clinical significant, that patients with blighted ovum had polymenorrhoea (> 45 days).

In accordance with preceding results, we observed that vaginal misoprostol is associated with higher success rate of cervical dilatation, lower side effects and comparable complication rates with good safety profile. Oral misoprostol has lower efficacy for cervical dilatation as well as higher side effects resulting in addition of morbidity.

Mean cervical dilatation of 7.47mm as in our study is well comparable to Nagi et al ^[7] (7.8 mm). Side effect profile was quite similar in both studies. Carbonell et al ^[8] also reported greater cervical dilatation and lower side effects with vaginally administered misoprostol. Cervical dilatation was 8.5 mm in his study and he concluded that vaginal route is the best route.

Later on K singh et al ^[9,10] also demonstrated the effective dose of vaginal misoprostol as well as optimal time for surgical evacuation after misoprostol administration.

Conclusion:

Misoprostol when used vaginally resulted in a better efficacy in terms of cervical dilatation as compared to the oral route for cervical priming prior to first trimester surgical abortion and also vaginally used misoprostol resulted in fewer side effects as compared to the oral route.

Table 1. Success rate of cervical dilatation in oral and vaginal group

Group/Cervical Dilatation	Unsuccessful	Successful
Oral	23.64%	76.36%
Vaginal	6.565	93.44%

REFERENCE

1. El-Refaei H, Calder L, Wheatley DN, Templeton A. Lancet. 1994 May 14;343(8907):1207-9. Erratum in: Lancet 1994 Jun 25;343(8913):1650. || 2. Henry AM, Haukkamaa M. Br J Obstet Gynaecol. 1999 Jun;106(6):540-3. || 3. Celentano C, Prefumo F, Di Andrea O, Presti F, Di Nisio Q, Rotmensch S. Acta Obstet Gynecol Scand. 2004 Aug;83(8):764-8. || 4. Allen RH, Goldberg AB; Board of Society of Family Planning. Contraception. 2007 Aug;76(2):139-56. Epub 2007 Jul 10. || 5. Singh K, Fong YF. Hum Reprod Update. 2000 Sep-Oct;6(5):442-8. Review. || 6. Vimala, Mittal 2004 {published data only} Vimala N, Mittal S, Dadhwal V. Sublingual misoprostol before first trimester abortion: a comparative study using two dose regimens. Indian Journal of Medical Sciences 2004; 58(2):54-61 || 7. SW Ngai, OS Tang, T Lao, PC Ho, HK Ma - Human Reproduction, 1995 - ESHRE || 8. JL Carbonell, A Velazco, Y Rodriguez... - European J. of ..., 2001 - informahealthcare.com || 9. K Singh, YF Fong, RNV Prasad, F Dong - Obstetrics & Gynecology, 1998 - Elsevier || 10. K Singh, YF Fong, RNV Prasad. Obstetrics & Gynecology, 1999 - journals.lww.com