

A Comparative Study of Vaginal Misoprostol and Cervical Catheter for Priming the Cervix in First Trimester Missed Abortions

Hayat T.¹

Address for Correspondence: Divisional Headquarters Hospital, Sargodha

Objective: To compare the effectiveness of cervical catheter and vaginal misoprostol as a cervical priming agent prior to surgical evacuation in first trimester missed abortions in terms of ease with which the conventional procedure of curettage was performed.

Design: Quasi-experimental study.

Setting: Divisional Headquarters Hospital, Sargodha from 1st June 2007 to 31st December 2008 in a period of one and a half year.

Methods: Seventy – four primigravidas having missed abortions of upto thirteen weeks were studied. They were offered intracervical catheter or vaginal misoprostol (400 mcg), 6 hours pre – operatively.

Main Outcome Measures: Cervical dilatation, amount of blood loss and time taken for evacuation along with side effects experienced.

Results: Cervical dilatation was significantly better in Foleys group as 50% of the patients had dilatation > 10mm as compared to 12% of misoprostol group. P value is 0.01 (significant). Blood loss was negligible in 80% of the Foleys group while 70% of the Misoprostol group had 75 to 100 ml of blood loss and 30% lost up to 200 ml. Time taken to complete the procedure ranged from 4 to 7 minutes. 50% of the Foleys group and 12% of the misoprostol group took 4 minutes. 35% and 37% of the tw0 groups took 5 minutes and 12 % 51% of both groups took 7 minutes consecutively.

Conclusion: Both are good priming agents. Cervical catheter is equally effective if not superior to vaginal misoprostol and has lesser side effects.

Key words: Misoprostol, Cervical Priming extra-amniotic catheter, missed abortions.

Introduction

Missed abortions before 13 weeks is quite a common entity especially in primigravidas. This also includes cases called missed miscarriage or early foetal demise (presence of a non-viable embryo / foetus) and blighted ovum (anembryonic pregnancy with absent embryonic echo).¹

Once the diagnosis of the foetal demise is confirmed, surgical evacuation has been the standard management for many years as expectant management is unacceptable to many women due to the time taken for complete expulsion of products of conception.²

Medical regimes using highly effective abortifacients (mifepristone in combination with prostaglandin analogue misoprostol) have been shown to be efficient and carry minimal risks but are not widely used.³

Surgical evacuation without prior cervical ripening is associated with risks of cervical injury, uterine perforation, excessive haemorrhage and incomplete uterine evacuation. Risk factor for cervical damage includes patient's age⁴ (more common in younger patients) more likely to be primigravidas.

Royal college of obstetricians and gynaecologists recommends that cervical preparation is beneficial prior to suction termination and should be routine when the woman is under 18 or at gestation of > 10 weeks.⁵

Similarly in conventional curettage a soft primed cervix makes the procedure easy and complications like perforation are prevented.⁶

The commonly used methods for cervical ripening include laminaria tents in the United States and the prostaglandin analogues in the United Kingdom. In U.K., the prostaglandin E₁ analogue gemeprost is most commonly used although the studies have shown that misoprostol is an effective alternative.⁷

Misoprostol can be administered orally or vaginally, the vaginal route has been shown to be more effective for termination of pregnancy in comparative studies.⁸ Pharmacokinetics of misoprostol suggests that it is more bioavailable when administered vaginally. Misoprostol acid peaks 1-2 hours after vaginal application, peak levels are sustained longer, so overall exposure to the drug is increased when it is used vaginally. Along with that it possibly has a direct effect on the cervix as well.

It has been shown that the optimal interval for vaginal administration of misoprostol for cervical priming prior to surgical abortion is 3 hours or more.⁹ We gave a gap of 6 hours to get the best results. The dose of misoprostol used was 400 mcg, which is used in many studies.¹⁰

Inflated Foley's catheters have gained popularity as a mechanical device for ripening of the cervix in patients with

unfavourable cervix in term pregnancies.¹¹ It has been suggested that the use of an extra-amniotic catheter balloon has the advantages of simplicity, low cost, reversibility and lack of systemic or serious side effects. Better cervical preparation is achieved with the Foley's catheter in firm long, tubular cervixes as the cervical canal is taken up by the mechanical effect of the distended balloon and by the release of endogenous prostaglandins.¹² Many other studies have proved efficacy of the extra-amniotic. Foleys balloon in priming the cervix before induction of labour at term.¹³

This study was conducted to assess the effectiveness of Foleys balloon in preparing the cervix before surgical evacuation in 1st trimester missed abortions and it was compared with the effect of vaginal misoprostol. The results were compared in a period of 6 hours, in terms of the cervix to become soft, dilated and prepared for conventional procedure and the ease by which it was performed. The amount of blood loss was also considered. Most of the studies, performed to compare effectiveness of different cervical priming agents like vaginal mesoprostol and gemeprost are prior to vacuume aspiration and so suction curettage is considered to be the gold standard for evacuation.¹⁴ But we studied it in relation to conventional curettage as there are certain places in the periphery where specialized equipment for vacuum aspiration and skills are not available. This study is basically to find a device which can be helpful for practitioners working in less privileged areas.

Patients and Methods

This study was conducted in Divisional Headquarters Hospital, Sargodha which is a tertiary referral centre, drains a wide area of not only Sargodha division but also of the neighbouring divisions. It is a 500-bedded hospital. Its gynae wing is an 80-bedded separate hospital. It is now affiliated with Sargodha Medical College and has acquired the status of a teaching hospital.

Non probability purposive sampling technique was used and women who came to the out patients department with a diagnosis of missed abortion upto thirteen weeks in their first pregnancy on ultrasound, were included in the study. Bleeding, pain or any other symptoms or signs of threatened abortion were ruled out. Patients' general health was assessed. They were all young, healthy adult females and there were no contraindications to prostaglandins administration and no hemorrhagic disorders.

Baseline cervical consistency and dilatation was the same. They were all having nulliparous, closed cervix. On admission, they were explained about the priming of the cervix and the time, which they were likely to spend in the hospital before evacuation. They were offered cervical catheter and those who were apprehensive for it, were given an option of vaginal misoprostol.

40 patients were selected for cervical catheter in this way and 34 opted for misoprostol tablets vaginally. The tablet group was given 400 – mcg misoprostol, which is available in the market, by the name of cytotec tablets (200

mcg). Two tablets of cytotec (400 mcg) were placed simply high up in the posterior vaginal fornix while the patient was lying in the dorsal position six – hour preoperatively. (The tablets were not wet in water prior to insertion).

Those who were selected for extra-amniotic cervical catheter were called to labour room. Foleys catheter was passed into the cervix by either using the lithotomy position or in the dorsal position depending upon the accessibility of the cervix.

All these women were kept N.P.O. during the period after passing Foley's extra – amniotic catheter or taking vaginal misoprostal tablets. During the next six hours they were kept under observation. For assessment of side effects the women were asked to complete a questionnaire with the help of a junior doctor. At the end of six hours they were shifted to the operation theatre for evacuation where all patients were given minor general anesthesia, patients were placed in lithotomy position. All aseptic measures were taken. In those who had extra-amniotic Foleys, the balloon was pulled out as such, if could not, 5 cc water was removed from the balloon every time and pulling tried again till it was finally pulled out with some water in it or whatever.

Then after aseptic measures, Examination Under Anesthesia was performed and procedure of conventional curettage was started as per routine. The variables that were assessed were 1) No of Hegar dilator, which was passed easily, and the amount of dilatation, which was further, required for easy evacuation, 2) amount of blood loss and 3) The time taken for evacuation.

All the patients had an ultra sound confirmation of complete evacuation on the next day. They were given a 5 – day course of antibiotics and were discharged home.

Results

A total of 74 patients were included in the study all having missed miscarriage and anembryonic pregnancy between six and thirteen weeks. Maternal age range was 18-29 years mean age being 23 years. The assessment of gestational age was based on menstrual history and all ultrasound measurements (crown – rump length, gestational sac diameter) were within the 1st trimester. Gestational age of the study group ranged from 6 – 13 weeks, mean gestational age being – 64 days (9 weeks and 1 day).

Out of the 74 patients, 40 were agreed for extra-amniotic Foley's balloon and 34 were assigned for vaginal misoprostal.

Side effect experienced by patients are Shown in table – 1.

Lower abdominal pain and backache started almost immediately after insertion of the Foleys balloon in 23 women (n = 40 i.e, 56.5%). 10 (25%) women had the same symptoms within 1-2 hours after insertion. 7 women (n=34) started backache earlier but lower abdominal pain started about 3 – 4 hours later.

In 12 patients (Foleys group n = 40), bleeding started on insertion of Foleys balloon, which remained for 5 – 10

Table 1: Side Effects Experienced.

| Symptoms | Foley GP n (%) | Misoprostal n (%) | P – Value |
|----------------|----------------|-------------------|-----------|
| N | 40 | 34 | |
| Abdominal Pain | 23 (57.5) | 20 (58.8) | 0.910 |
| Backache | 23 (57.5) | 20 (58.5) | 0.910 |
| Tiredness | 0 (0.0) | 10 (29.4) | ----- |
| Bleeding | 10 (25.0) | 14 (41.1) | 0.140 |
| Headache | 0 (0.0) | 4 (11.7) | ----- |

minutes at a slow pace and stopped on its own.

The misoprostol group suffered from symptoms of abdominal pain (60%), tiredness (56%) and bleeding (40%). Only 4 women (12%) complained of headache. Symptoms of bleeding and pain started about 2 hours after insertion of the misoprostol vaginally.

Analgesia was required in 5 women (n = 40, Foleys Group) due to abdominal pain and backache (13%) while it was in 4 women in vaginal misoprostol group (n = 34, 9%).

Analgesia was given in the form of a sedative analgesic injection in both groups, which proved adequate. Bleeding was not significant in any of the case and blood transfusion was not required.

The Variable which were recoded in the theater are given is table 2.

Table 2a: Dilation of the cervix.

| Cervical Dilation in mm | Foley GP n (%) | Misoprostal n (%) | P-Value |
|-------------------------|----------------|-------------------|---------|
| N | 40 | 34 | |
| ≥ 6 | 5 (12.5) | 18 (35.0) | 0.004 |
| ≥ 8 | 15 (37.5) | 12 (35.2) | 0.837 |
| ≥ 10 | 20 (12.5) | 4 (11.7) | 0.005 |

Table 2b: Blood loss during the procedure.

| Blood Loss in mm | Foley GP n (%) | Misoprostal n (%) | P – Value |
|------------------|----------------|-------------------|-----------|
| N | 40 | 34 | |
| 75 | 8 (20.0) | 12 (35.2) | 0.142 |
| 100 | 0 (0.0) | 12 (35.2) | ----- |
| 200 | 0 (0.0) | 10 (29.4) | ----- |

In the Foleys group (n = 40), 20 patients had dilatation of the Cervix to such an extent that ovum forceps of 15 mm width could be passed easily. Gestational sac was easily removed with 2 – 3 passages of the ovum forceps followed by gentle curettage. Time taken for complete evacuation was about 4 minutes.

Table 2c: Time taken to complete the procedure.

| Time Taken in Min | Foley GP n (%) | Misoprostal n (%) | P-Value |
|-------------------|----------------|-------------------|---------|
| N | 40 | 34 | |
| 4 | 20 (50.0) | 4 (11.7) | 0.005 |
| 5 | 15 (37.5) | 12 (35.2) | 0.837 |
| 7 | 5 (12.5) | 18 (53.0) | 0.002 |

In rest of the patients (n = 40), 15 had a cervix, which could admit hegar 9 dilator easily, and the smaller ovum forceps of 10 mm width could only be passed. The products of conception required 4 – 6 passages of the smaller ovum forceps and time taken for the whole procedure was about 5 minutes. 5 patients in foley’s group (n = 40) had a cervix, which needed further dilatation under general anesthesia, and in these cases the procedure took an additional 2 minutes to complete that makes 7 minutes.

In vaginal misoprostol group, 12 patients (n = 34). 35% could pass H-9 easily and the procedure was completed with small ovum forceps of 10 mm width with little further dilatation. Time taken was 5 minutes. Blood loss about 75 – 100 ml.

In rest of the 22 patients (n = 34) 64% the cervix was dilated up to H – 8. Further dilation provoked bleeding and the procedure was completed using small ovum forceps of 10 mm width. Time taken was 6 – 7 minutes and blood loss was 100 – 200 ml.

Recovery from anesthesia was smooth in all the cases. They were shifted to the ward where routine postoperative monitoring was done. A special watch was kept on vaginal bleeding which remained non-significant in all the cases and non of the women in either group required any further management in the hospital for incomplete abortion or medical complications related to abortion.

Statistical Analysis

The data was entered and analyzed using STATA. 8.2 Mean # S.D is given for quantitative variable. Frequencies and percentages are given for qualitative variables. Pearson Chi-Square and Fisher exact test were applied to observe associations between qualitative variables. A P – value of > 0.05 is considered to be as statistically significant.

Discussion

Studies have shown that misoprostal is an effective cervical priming agent before surgical evacuation. Oral and vaginal misoprostol has been shown to be at least as effective as gemeprost as cervical priming agent prior to vacuum aspiration.¹⁵

Our study compared the results of effective cervical priming caused by the vaginal misoprostol to that of a Foleys balloon passed into the cervix and pressing over the internal os by its mechanical effect. Study time was six hours al-

though misoprostol has been suggested to be administered by vaginal route 4 hours prior to abortion.¹⁶ This extra – time of 2 hours was basically to allow some more time to the Foleys balloon to be effective. Foleys catheter improves the cervical state probably by causing release of enzymes from the cervical tissue and uterine decidual cells, which act on the phospholipids to form arachidonic acid and prostaglandins. This view is supported by the demonstration of elevated levels of 13, 14 – dehydro. 15 – keto prostaglandins (a metabolite of prostaglandin – F) when the cervix is disturbed as during a cervical encirclement.¹⁷

Our results showed that Foley's catheter was even better in causing dilatation of the cervix as it caused 10 mm dilatation in 50%, 20 out of 40 of the cases and allowed easy passage of a larger ovum forceps, quick and sure removal of the Products of the Conception and negligible amount of blood loss. 42% (15 out of 40) had a dilatation up to 8 mm in Foleys group while 35% of misoprostol group had the same results. Although the time taken for complete evacuation ranged between 4 – 7 minutes, which is only a minor difference. Our results in total time and ease to perform the procedure in both groups are comparable to other studies conducted with vaginal misoprostal⁽¹⁸⁾. Studies have been conducted on the positive role of Foleys catheter in induction of labour at term but no systematic review is available in the literature on its role in first trimester abortions although it is being used for the same purpose in many centers.

In terms of other parameters of the study i.e. the amount of blood loss and time taken for evacuation, Foleys catheter proved equally effective if not superior to vaginal misoprostol as can be seen in table 2. However, initial insertion of the Foleys catheter in the cervix may cause some discomfort to the patients, which might not be acceptable to some women.

Bleeding before evacuation is seen in 40% of misoprostol group and 25% of Foleys group, which in both groups was not serious.

Other side effects like abdominal pain and backache are almost the same in both groups (Table 1).

Tiredness in 56% of the cases of misoprostol group and almost none in Foleys group.

Headache is non significant in the both groups.

As the cervix is properly prepared and primed by both agents, the evacuation of the uterus is smooth and uneventful, blood loss is minimal. Antibiotic cover is routine and so chances of sepsis are minimized whether the procedure is conventional or suction curettage. This is confirmed in our study where no case of incomplete abortion is recorded on ultrasound follow up and no other serious complication like excessive bleeding or sepsis is noticed. This study also proves that cervical priming should be routine before surgical evacuation in case of missed abortion in whatever available way.

Conclusion

Efficacy of misoprostol is proved by a No. of studies in the literature as a cervical ripening agent prior to surgical evacuation but we recommend that Foleys catheter in this context is equally effective and it has the advantages of simplicity, low cost and no systemic or serious side effects.

References

1. Royal College of Obstetricians and Gynaecologists. The Management of Early Pregnancy Loss. Guideline No. 25. London. RCOG Press, 2000.
2. Justovic D, Ross JA, Nicolaidis KH. Expectant Management of Miscarriage. *Br. J. obstet Gynaecol* 1998; 105: 670-671.
3. El Refaey. H, Hinstaw K, Henshaw R., Smith N., Templeton – A, Medical Management of missed abortion and anembryonic pregnancy. *BMJ* 1992; 305: 1399.
4. Schulz KF, Grimes DA, Cates JRW, Measures to Prevent Cervical injury during suction curettage abortion. *Lancet* 1983; 1 (8335) 1182-1185.
5. RCOG clinical effectiveness support unit. The care of women requesting induced abortion. London RCOG Press, 2000.
6. Grimes D. A schulz K.F, cates Jr W.J “Prevention of uterine perforation during curettage abortion”. *JAMA* 1984; 251 (16): 2108-2111.
7. Ashok PW, Flett GM, Templeton A, Mifeprostion Versus Vaginal Administered Misoprostol for cervical priming before 1st trimester termination of pregnancy a randomized controlled study. *Am J. obstet gynaecol*, 2000; 183 (4): 998-1002.
8. Danielsson GK, Marisons L, Rodriguez A, Spur BW, Wong PYK, Bygdeman M. Comparison between oral and vaginal administration of misoprostol on uterine contractility. *Obstet Gynaecol* 1999; 93: 275-280.
9. Ziemann M, Fong S.K., Benowitz NL, Bankster D, Darney P.D. Absorption Kinetics of Misoprostol with oral or vaginal administration *obstet gynaecol*. 1997; 90: 88-92.
10. Premila W. Ashok, Haithan Hamoda, Fatima Nathani, Gillian M.M. Flett, Allan Templeton. Randomized controlled study comparing oral and vaginal misoprostol for cervical priming prior to surgical termination of pregnancy. *BJOG*: December 2003; Vol. 110: pp. 1057-1061.
11. James C, Peedicayil A, Seshodri L. Use of Foleys Catheter as a cervical ripening agent prior to induction of labour. *Int J. Gynaecol Obstet* 1994; 47: 229-232.
12. Tasneem K. Hayat, Induction of Labour in Unripe Cervix: An experience with 153 patients *J.C.P.S.P.*, Vol. 7 (5): 205-208.
13. Obey J.Y, Adewolf IF, The unfavourable cervix: Improving the Bishop Score with the Foley Catheter *West Afr. J. Med* 1994; 13: 209-212.
14. Nigai SW. Jeung KC, Lao. T, Ho Pc Oral Misoprostol versus Vaginal Gemeprost for cervical dilatation prior

- to vacuum expiration in women in the 6th to 12th week of gestation. *Contraception* 1995; 51 (6): 347-350.
15. Lawrie. A, Penny. G. Templeton. A. A randomized comparison of oral and vaginal misoprostol for cervical priming before suction termination of pregnancy, *Br. J. Obstet Gynaecol.* 1996; 103 (11): 1777-1119.
 16. Carbonell, JL, Velazco A, Rodriguez Y. Oral versus vaginal misoprostal for cervical priming in first – trimester abortion: a randomized trial. *Eur J Contracept Reprod Health Care* 2001; 6 (3): 134-140.
 17. Bibby JG, Brunt J, Mitchell, MD, Anderson AB, Turnbull, AC, The effect of cervical encerclage on plasma concentrations during early human pregnancy. *Br J obstet gynaecol*, 1979; 86: 19-22.
 18. Fong Y.F, Singh .K, Prasad R.N. A comparative study using 2 doses regimens (200 mcg and 400 mcg) of vaginal misoprostol for pre operative cervical dilatation in first trimester nulliparae. *Br. J. obstet. Gynaecol* 1998; 105 (4): 413-417.