THE JOURNAL OF OBSTETRICS AND GYNECOLOGY OF INDIA

The Journal of Obstetrics and Gynecology of India (September–October 2011) 61(5):531–533
DOI 10.1007/s13224-011-0082-z

ORIGINAL ARTICLE

Sublingual Misoprostol for Cervical Priming in Surgical First Trimester Pregnancy Termination

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Received: 25 June 2009 / Accepted: 27 July 2011 / Published online: 29 October 2011

Abstract
Objectives To determine the efficacy of 400 mcg sublingual misoprost as an adjunct to suction evacuation in first trimester pregnancy termination.
Method(s) During the study period of January2006–June 2007, two hundred twenty-one pregnant women wanting first trimester pregnancy termination were randomised into two groups. In the study group of one hundred twenty-one women, sublingual misoprostol was used 3 h prior to suction evacuation. In the control group of hundred women, direct suction evacuation was used. In cervical dilatation achieved by misoprostol, time required for suction evacuation, blood loss, pain perceived by patient and complications that occurred in the two groups were compared by STATA 9 stastistical software.
Result(s) In the study group, mean cervical dilatation was up to 5.61 with Hegar dilator and in control group, it was 5.03. ($P = 0.004$). Average time required for suction evacuation was 7.28 min in study group and 8.73 min in control group ($P < 0.0001$). Blood loss was less in study group as compared to those in the controls. In study group, only 10.74% women perceived pain compared to twenty percent women in control group.
Conclusion(s) Use of sublingual misoprost prior to first trimester pregnancy termination by suction evacuation ripens the cervix so there is less need for cervical dilatation, pain perceived by patient is less, the time required for suction evacuation is less and there is reduction in blood loss. Sublingual misoprostol is effective and safe for cervical ripening and dilatation before suction evacuation.

Keywords Misoprostol · First trimester pregnancy termination · Suction evacuation

Introduction

Surgical methods of abortion in the first trimester abortion carry several risks like haemorrhage, uterine perforation, incomplete abortion and cervical injury [1]. The risk is increased when difficulty is encountered during cervical dilatation especially in nulliparous patients. A reduction in the incidence of these complications would prevent both short term and long term morbidity. Misoprostol is an effective cervical dilator prior to suction evacuation, having advantages of being stable at room temperature, inexpensive and easy accessibility. Oral, vaginal & sublingual route has been described in the literature. Oral misoprostol 400 mcg should be given 12 h prior to suction evacuation and vaginal prostaglandins should be administered 2–4 h

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before surgery and some women did not like it. Sub lingual route avoids first pass effect through the liver in oral route and it is most vascular area of the buccal cavity [2]. 400 mcg sublingual misoprostol can be given 3 h prior to surgery giving good results. This route is not accessed in literature before surgical evacuation for cervical priming, so this study has been done with an aim to evaluate the safety and efficacy of sublingual misoprostol for cervical priming before surgical evacuation.

Methods

The 221 women who underwent voluntary termination of first trimester pregnancy (MTP) were recruited for the study. Of these one hundred twenty-one women formed the study (group-I). They were given 400 mcg of sublingual misoprostol. Hundred women were in control group, (group-II) in whom suction evacuation was done without misoprostol (Jan 2006–June 2007).

Inclusion criteria were gravidity up to four with gestation of 5–12 weeks irrespective of maternal age or socio-economic status.

Exclusion criteria were gestational age greater than 12 weeks, gravidity five or more, cardiorespiratory disorders and haemoglobin, <8.0 g/dl.

Gestational age was estimated by last menstrual period and confirmed by pelvic examination and sonography.

A detailed history was taken, basic investigations were done and written informed voluntary consent was taken. In study group, two tablets of misoprostol (400 mcg) were given sublingually 3 h prior to suction evacuation. In control group, suction evacuation was done without giving misoprostol. The women were counselled about possibility of pain in lower abdomen, nausea, vomiting, diarrhoea, fever and vaginal bleeding. All were subjected to dilatation and suction evacuation. The degree of cervical dilatation in both groups was measured by noting the largest Hegar dilator that could be passed through internal os without resistance hundred ml of saline was used to flush the suction tube after completion of vacuum aspiration. Blood loss was calculated by subtracting hundred ml from volume of conceptus in the suction apparatus. Time spent for the operation from the initiation of cervical dilatation to the end of suction evacuation was considered as time taken for the procedure. Side effects & complications were recorded. Statistical analysis was done using STATA 9 statistical software. Differences in continuous variables were analysed with student-t test. Differences in discontinuous variables were analysed by Fisher, s exact test. P value of < 0.05 was considered as significant.

Results

The basic variables, age of the women, gestational age and parity were similar in both groups (Table 1). The requirement of cervical dilatation, amount of blood loss, time taken to complete the procedure, side effects and complications that occurred are given in Table 2.

The mean base line cervical dilatation was 5.61 and 5.03 mm in study and control group, respectively (P value 004 statistically significant). The mean time taken to perform suction evacuation was 7.28 and 8.73 min in the study and control group, respectively ($P < 0.0001$ statistically significant). Blood loss > 75 ml occurred in twenty-eight women (23.14%) in the study group and in 34 women (34%) in control group.

Blood loss < 75 ml occurred in ninety-three women (76.86%) in the study group and in sixty-six women (66%) in control group (P value = 0.050 borderline significant).

Thirteen women in study group (10.74%) complained of pain in lower abdomen while in control group twenty women (20%) had pain (P value 0.04 significant).

In study group versus control group, incidence of vomiting, (14.88 vs. 8%), diarrhoea (8.26 vs. 2.0%), and vaginal bleeding (7.44 vs. 2%) was more in study group.

Uterine perforation occurred in four women (4%) in the control group and in six women (4.96%) in study group. They were managed conservatively, none of them required laparotomy. Two women (2%) in control group and four women (3.3%) in the study group had incomplete abortion.

Discussion

Sublingual misoprostol is effective as a cervical ripening agent and uterotonic agent. It was observed that the misoprostol tablet can be dissolved under the tongue in 15–20 min and therefore, it may have a faster onset of action and absorption rates may be more reliable [3]. It also has the advantage of avoiding fluid intake before operation and this is especially important if the vacuum aspiration is done under general anaesthesia.

Table 1 Base line characteristics

Characteristic	Study group ($n = 121$)	Control group ($n = 100$)	P value	Remarks
Mean age (years)	24.77 ± 7.18	24.69 ± 4.17	0.91[a]	NS
Parity	1.66 ± .99	1.78 ± 1.40	0.38[a]	NS
Gestational age	7.06 ± 1.40	7 ± 1.7	0.77[a]	NS

NS Not significant

[a] Student's test

Table 2 Comparison of effects & complication

Parameters evaluated	Study group ($n = 121$)	Control group ($n = 121$)	P value	Remarks
Cervical dilatation (mm)	5.6 ± 1.45	5.03 ± 1.45	0.004[a]	Significant
Time taken to complete the procedure (min)	7.28 + 1.52	8.73 + 1.54	0.001[a]	Significant
Blood loss < 75 ml	93 (76.86)	66 (66%)	0.05[b]	Borderline Significant
Blood loss > 75 ml	28 (23.14%)	34 (34%)	0.05[b]	Borderline Significant
No. of women having abdominal pain	13 (10.74%)	20 (20%)	0.04[b]	Significant
Vomiting	18 (14.88%)	8 (8%)	0.08[b]	NS
Uterine perforation	6 (4.96%)	4 (4.00%)	0.49[b]	NS
Diarrhoea	10 (8.26%)	2 (2.00%)	0.03[b]	Significant
Incomplete abortion	4 (3.31%)	2 (2.00%)	0.43[b]	NS
Vaginal bleeding	9 (7.44%)	2 (2.00%)	0.05[b]	Borderline significant

NS Not significant

[b] Fisher's test

[a] Student's test

A pharmacokinetic study has shown that after a single dose of sublingual misoprostol peak concentration is achieved in a shorter time than vaginal misoprostol. The peak concentration and bioavailability were also higher with sublingual misoprostol [4].

Use of oral and vaginal misoprostrol for cervical priming is well described in the literature but sublingual route is not explored so in the present study, the endeavour was to compare cervical dilatation, amount of blood loss, time required to complete the procedure with sublingual route.

In Jaju Purushotam et al. studies, with 400 mcg vaginal misoprostol, the mean cervical dilatation was 8.37 and 3.5 mm in study group and control group ($P < 0.01$) [5]. Pandey et al. studied 400 mcg of oral misoprostol for preoperative cervical dilatation they found cervical dilatation of 9.42 versus 2.2 mm in study versus control group ($P = 0.02$) [6]. Our study showed that mean cervical dilatation was 5.61 mm in study group compared to 5.03 mm in control group (P 0.004 statistically significant). Our results are comparable with these reports. Time taken to complete the procedure was also less in study group as compared to that in control group ($P < 0.0001$ statistically significant).

Intra operative blood loss was also less in study group as compared to that in control group ($P = 0.50$ borderline significant).

Few side effects of drugs i.e., vomiting, diarrhoea, and vaginal bleeding were seen in study group. These required symptomatic management only.

In this study, there were fewer patients perceiving abdominal pain in study group (P 0.042 statistically significant).

The incidence of perforation & incomplete abortion in the two groups was not statically different ($P = 49$, 0.43 respectively).

Conclusion

WHO warrants that services for voluntary termination of pregnancy should be an integral part of maternity and family health services. Use of sublingual misoprostol, prior to vacuum aspiration in first trimester of pregnancy causes adequate cervical dilatation, minimises blood loss and reduces time required to complete the procedure and complications of surgical evacuation are reduced.

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