



## COMPARATIVE STUDY ON EFFECTIVENESS AND ACCEPTABILITY OF SUBLINGUAL AND VAGINAL MISOPROSTOL FOR CERVICAL PRIMING IN I TRIMESTER MTP

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### ABSTRACT

100 women were divided into two groups of 50 each. Group A patients were given 400µg of sublingual misoprostol 3 hours prior to MVA. In group B, 400 µg of misoprostol was placed in the posterior fornix 3 hours prior to MVA. Primary outcome was degree of dilatation achieved. Secondary outcomes were duration of procedure, intra operative blood loss, side effects and pain score. The mean cervical dilatation in the sublingual group was 9 mm. The mean cervical dilatation in the vaginal group was 7.8 mm. The mean cervical dilatation was higher in the sublingual group. The mean duration of procedure in the sublingual group was 7.76 min. The mean duration of procedure in the vaginal group was 10.44 min. The duration of procedure was lower in the sublingual group compared to vaginal group. The mean intraoperative blood loss in the sublingual group was 16.66 ml compared to 19.3 ml in the vaginal group. The intra operative blood loss was less in the sublingual group. The pain score in the sublingual group was 1.94 compared to 2.88 in the vaginal group. The pain score was less in the sublingual group compared to vaginal group. The side effects like nausea, vomiting, fever, diarrhea and shivering, was 1.52 in the sublingual group. In the vaginal group it was 0.84. The incidence of side effects was more in the sublingual group. The vaginal bleeding in the sublingual group was 1.34 and in the vaginal group was 0.84 which is higher in the sublingual group. The sublingual group had significant cervical dilatation, less time duration of procedure and lower pain score. Intra operative blood loss was less in sublingual group. Side effects like abdominal pain, nausea, vomiting, shivering was more in the sublingual group. The sublingual group route is convenient to use, avoids vaginal application and comfortable to the patients..

**Key words:** I Trimester Mtp ,Cervical Priming , Misoprostol, Sublingual, Vaginal.

### INTRODUCTION

Medical termination of pregnancy is one of the most commonly performed operations. WHO estimates that around 50 million pregnancies are terminated each year in the world and around 100-200 thousand women die each year due to complications of abortion. Vacuum aspiration is being performed for terminating pregnancies up to 12 weeks. Dilatation of cervix is a critical step in vacuum aspiration. Cervical priming can be achieved by mechanical or pharmacological methods. Mechanical methods include dilators and laminaria tents. Pharmacological agents include mifepristone and

prostaglandins E1, E2 and F2α. Misoprostol (prostaglandin E1) is cheap, easily available, stable at room temperature, no drug interactions, effective and can be used through different routes. The sublingual administration has shorter time to peak concentration than oral and vaginal administration. It has highest peak concentration, no first pass metabolism in the liver and greater bioavailability. To compare the effectiveness and acceptability of sublingual and vaginal misoprostol for cervical priming in I Trimester MTP.

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## MATERIALS AND METHODS

The present study was conducted in the department of Obstetrics and Gynecology, PES Institute of Medical Sciences & Research, Kuppam in women opting for I Trimester MTP. Counselling and details about the method of study were explained to the participants. Informed and written consent was obtained from the participants. Thorough preoperative evaluation was done which includes detailed history, physical examination and routine investigations. Inclusion Criteria were age above 18 years, having single intrauterine pregnancy not exceeding 12 weeks as per dates and USG and patients giving informed consent. Exclusion criteria were patients with Hb% < 8gms, patients with active infection and patients not giving consent.

The patients and attendants were explained about the procedure and informed consent was obtained. Base line investigations were carried out. The patients were divided into two groups of 50 each. Group A patients were given 400µg of sublingual misoprostol 3 hours prior to MVA. In group B, 400 µg of misoprostol was placed in the posterior fornix 3 hours prior to MVA. After 3 hours manual vacuum aspiration was done under aseptic precautions. In apprehensive patients paracervical block was given. The cervix was held with a non traumatic vassellum and plastic karmans cannula of increasing size was inserted into the cervix. The correct size of the cannula passed through the cervical os with no resistance was chosen and introduced into the uterus. A hand operated double valve vacuum created syringe (50ml) was attached to the cannula. The cannula was given rotatory to and fro movements and aspiration of the products of conception was done. The products of conception were filtered and the amount of blood loss was measured. The patients were discharged on the next day if all parameters were normal and no complications observed. The two groups were assessed for efficacy on the basis of various parameters like degree of dilatation achieved, duration of procedure, intra operative blood loss, side effects and pain score.

Cervical dilatation was measured with maximum size of plastic cannula passed through the cervical os without any resistance. Intraoperative blood loss measured after sieving away the products of conception. Intra operative pain score based on nominal scale of 0-10, 0-3 mild, 4-6 moderate, 7-10 severe. Before surgical evacuation the patients were asked about side effects like abdominal pain: graded from 0-3, 0- No pain, 1- mild pain, 2- moderate pain that did not require analgesic, 3 severe pain that required analgesic. Nausea vomiting, shivering and vaginal bleeding, ranging from 0-3, 0- no bleeding, 1- minimal spotting, 2- bleeding like menstrual flow, 3- severe bleeding.

## RESULTS

The mean age in the sublingual group was 36.84 and in the vaginal group was 27.8. There was no significant difference with respect to age. The mean BMI in the sublingual group was 20.94 and in the vaginal group the mean BMI was 21.44. There was no significant difference with respect to BMI. For the sublingual group the mean gestational age was 8.14. In vaginal group. The mean gestational age was 8.06. There was no significant difference with respect to gestational age. For the sublingual group the mean Hb% was 9.97. In vaginal group the mean Hb% was 9.98. There was no significant difference with respect to the Hb% level. The mean cervical dilatation in the sublingual group was 9 mm. The mean cervical dilatation in the vaginal group was 7.8 mm. The mean cervical dilatation was in the higher in the sublingual group. The mean duration of procedure in the sublingual group was 7.76 min. The mean duration of procedure in the vaginal group was 10.44 min. The duration of procedure was lower as the sublingual group compared to vaginal group. The mean intraoperative blood loss in the sublingual group was 16.66 ml compared to 19.3 ml in the vaginal group. The intraoperative blood loss was less in the sublingual group. The pain score in the sublingual group was 1.94 compared to 2.88 in the vaginal group. The pain score was less in the sublingual group compared to vaginal group. The side effects like nausea, vomiting, fever, diarrhea and shivering, was 1.52 in the sublingual group. In the vaginal group it was 0.84. The incidence of side effects was more in the sublingual group. The vaginal bleeding in the sublingual group was 1.34 and in the vaginal group was 0.84 which is higher in the sublingual group.

## DISCUSSION

First trimester abortion by surgical methods has been widely used in modern obstetrics. Vacuum aspiration is a commonly used method for first trimester abortion and is one of the most common surgical procedures performed worldwide. Cervical dilatation is the most critical step in vacuum aspiration as most cervical and uterine injuries are due to forceful dilatation of cervix. Adequate dilatation decreases pain and duration of surgery and increases operative ease. Previously, laminaria tent, gemeprost and PGE2 gel have been used for cervical ripening. These days misoprostol, a synthetic PGE1 analog, has become popular for its effectiveness and for its other advantages like less cervical injuries, minimal intraoperative blood loss, reduced requirement of general anesthetics and availability in different dosage forms. It can be given by oral, intravaginal, sublingual or intrarectal route. The present study observed that the cervical dilatation achieved with misoprostol was favourable among the sublingual group compared to the vaginal group. The observed difference can be attributed to the different absorption kinetics and subsequent more systemic bioavailability with the

sublingual routes. The duration of procedure was less in the sublingual group. This can be explained on the basis of the more cervical ripening and dilatation achieved in this group. The mean intraoperative blood loss was found to be slightly less in sublingual group as compared to vaginal group. In the present study, subjects in sublingual group experienced more preoperative side effects as compared to vaginal group, the most common being the pain. Other side effects like bleeding, nausea and shivering were also seen slightly more frequently in sublingual group. This increased frequency of side effects may be explained by the higher bioavailability of sublingual misoprostol. None

of the subjects in the present study experienced fever, diarrhea or vomiting.

## CONCLUSION

There was no significant difference between the sublingual and vaginal group with respect to age, parity, gestational age and BMI. The sublingual group had significant cervical dilatation, less time duration of surgery and lower pain score. Intra operative blood loss was less in sublingual group. Side effects like abdominal pain, nausea vomiting and shivering was more in sublingual group. The sublingual group route is convenient to use, avoids vaginal application and comfortable to the patients.

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