A PROSPECTIVE COMPARATIVE STUDY OF SUBLINGUAL VERSUS VAGINAL MISOPROSTOL IN SECOND TRIMESTER TERMINATION OF PREGNANCY

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CHENNAI.

DECLARATION

I **Dr. T.LAKSHMIDEVI** solemnly declare that the dissertation titled "**A PROSPECTIVE COMPARATIVE STUDY OF SUBLINGUAL VERSUS VAGINAL MISOPROSTOL IN SECOND TRIMESTER TERMINATION OF PREGNANCY**" has been prepared by me. I also declare that this bonafide work or a part of this work was not submitted by me or any other for any award, degree, diploma to any other University board either in India or abroad.

This is submitted to the Tamilnadu Dr.M.G.R. Medical University, Chennai in partial fulfillment of the rules and regulation for the award of M.D degree Branch – II (Obstetrics & Gynecology) to be held in March 2011.

Place: Madurai **Dr. T.LAKSHMI DEVI**
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BONAFIDE CERTIFICATE

This is to certify that the dissertation entitled "**A PROSPECTIVE COMPARATIVE STUDY OF SUBLINGUAL VERSUS VAGINAL MISOPROSTOL IN SECOND TRIMESTER TERMINATION OF PREGNANCY**" is a bonafide record work done by **Dr. T. LAKSHMI DEVI** under my direct supervision and guidance, submitted to the Tamilnadu Dr.M.G.R. Medical University in partial fulfillment of University regulation for M.D degree Branch– II Obstetrics & Gynecology.

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INTRODUCTION

INTRODUCTION

Abortion is universal, through history women have sought to terminate an unwanted pregnancy. Despite increased use of contraception, the need for abortion continues to be high. Prevention of unwanted pregnancy has been the top-priority concern with all health planning. A large number of abortions are performed worldwide. Approximately 1/3 to ½ of all at least one induced abortion performed under unsafe conditions. The safety and efficacy of the procedure used is therefore of global public health importance.

Approximately 35 million induced abortions that take place each year around the globe.

Despite the liberalization of abortion services since the early 1970s, access to safe abortion services remains limited for the vast majority of Indian women, particularly in rural areas. In India incidence of induced abortions is 6.7 million annually.

According to government data, only about one million of these are performed legally. The remaining abortions are performed by medical and non-medical practitioners. Levels of unsafe abortion are very high in India.

The Reproductive and Child Health Programme launched in 1997 and the National Population Policy, 2000 have also delineated a number of strategies to increase the access to safe abortion at the primary health care level.

Introduction of Medical Abortion in India is a landmark in women's health. Medical abortion is an approach to pregnancy termination which is non-invasive with minimal side-effects.

Way to reduce unsafe abortion and maternal mortality by:

- Providing basic training to providers of medical abortion on the regimen, correct prescription, side effects, post-abortion family planning, counselling and follow-up.
- Educating women and men about their reproductive health rights and family planning in general.
- Ensuring medical products meet the highest standards of quality and efficacy.

The mortality and morbidity rates are higher in second trimester termination of pregnancy than in the first trimester termination of pregnancy. There is a search for better, safer, quickest, cost effective, convenient and feasible method for termination in second trimester.

So in this study medical method of termination of second trimester pregnancy with two routes of administration of misoprostol is compared and taken for evaluation.

AIM OF THE STUDY

AIM OF THE STUDY

1. **To compare the outcome of sublingual versus vaginal administration of misoprostol for induction of second trimester abortion.**

2. **To evaluate the induction to abortion interval.**

3. **To Study and evaluate the failure rate, complications and side effects.**

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Our primary objective is to compare the efficacy and side effects of two different mode of administration of misoprostol (sublingual and vaginal) in second trimester termination of pregnancy.

Following are the studies conducted by various authors about the efficacy of misoprostol in second trimester termination of pregnancy.

1) BHATTACHARJEE N, SAHA SP, GHOSHROY SC, BHOWMIK S, BARUI G. A RANDOMIZED COMPARATIVE STUDY ON SUBLINGUAL VERSUS VAGINAL ADMINISTRATION OF MISOPROSTOL FOR TERMINATION OF PREGNANCY BETWEEN 13 TO 20 WEEKS. AUST N Z J OBSTET GYNAECOL 2008;48(2);165-71.

A randomized comparative trial where 300 women at 13-20 week gestation, requiring medical abortion, were randomly assigned to sublingual or vaginal route for misoprostol administration with a dose schedule of 400 µg three-hourly, up to a maximum five doses over 24 h. The same doses were repeated for another 24 h in non-responders. Primary outcome measure was complete abortion rate at 24 and 48h ; and

the secondary outcome measures were induction-abortion interval, failure rate, side effects and patients preference to the route.

No statistically significant differences in the complete abortion rates were observed at 24 h (64.03% vs 61.59%, P = 0.767) and at 48 h (79.14% vs 82.01% P = 0.651) when sublingual and vaginal groups were compared. Mean induction-abortion intervals in sublingual and vaginal groups were 14.1 hours and 14.5 hours, respectively (P = 0.066). Differences in the incidence of side-effects were also statistically insignificant when both groups were compared.

Both sublingual and vaginal administrations of misoprostol are equally effective in inducing medical abortion during second trimester but sublingual route was preferred by the patients.

2) SHIVANI AGARWAR, PUSHPA BHATIA KASTURBA HOSPITAL, DELHI (2008)

They compared the efficacy, side effects and acceptability of sublingual and vaginal misoprostol for second trimester medical abortion.

Sixty women at 12-20 weeks of gestation attending tertiary care and teaching hospital, were randomized to receive either sublingual or vaginal misoprotol 400 µg every 4 hours in a prospective randomized controlled manner. The course of misoprostol was repeated only if the woman did not abort in the next 24 hours.

There was no significant difference in the success rate at 24 hours (sublingual: 100%; vaginal: 93.4%). Five women in each group required D&C for completion. However, the success rate at 12 hours was significantly higher in the sublingual group (93%) compared with the vaginal group (38.4%). There was also a significant difference in the median induction-to-abortion interval. (Sublingual 7.5hrs & Vaginal 14.1 hours) Further, more women in the sublingual group preferred the route to which they were assigned when compared with vaginal group. The incidence of fever was less in the sublingual group though vomiting was significant.

3) HELENA VON HERTZEN1, GILDA PIAGGIO1, DANIEL WOJDYLA2, NGUYEN THI MY HUONG1 (AUGUST 2008)

To identify an effective misoprostol-only regimen for the termination of second trimester pregnancy, they compared sublingual and vaginal administration of multiple doses of misoprostol in a randomized, placebo-controlled equivalence trial.

Six hundred and eighty-one healthy pregnant women requesting medical abortion 13-20 weeks' gestation were randomly assigned. 400 μg of misoprostol administered either sublingually or vaginally every 3 h up to five doses, followed by sublingual administration of 400 μg misoprostol every 3 h up to five doses if abortion had not occurred at 24 h

after the start of treatment. Successful abortion within 48 h, was also considered as an outcome along with induction-to-abortion-interval, side effects and women's perceptions on these treatments.

At 24 h, the success (complete or incomplete abortion) rate was 85.9% in the vaginal administration group and 79.8% in the sublingual group (difference: 6.1%, 95% CI: 0.5t o 11.8). Thus, equivalence could not be concluded overall.

Equivalence between vaginal and sublingual administration could not be demonstrated overall. Vaginal administration showed a higher effectiveness than sublingual administration in terminating second trimester pregnancies, but this result was mainly driven by nulliparous women. Fever was more prevalent with vaginal administration. Registered with international Standard Randomized Controlled Trial number. ISRCTN 72965671

4) A.YASEMNIN KARAGEYIM KARSIDAG, ESRA E. BUYUKBAYRAK, BULENT KARS, RAMAZAN DANSUK, ORHAN UNAL, M.CEM TURAN. (2009)

To compare the efficacy of vaginal versus sublingual misoprostal for second-trimester pregnancy termination, and to evaluate the effect on the blood flow of the uterine and umbilical arteries. Forty-nine patients were randomized to receive either 200 µg of vaginal misoprostol every 6

hours or 200 µg of misoprostol sublingually every 6 hours. Doppler velocimetry studies were assessed immediately before and 60 minutes after the administration of the first dose.

The mean interval between induction and onset of active labor, induction and delivery, and the duration of oxytocin administration were significantly shorter in the sublingual misoprostol group. Both routes of administration increased the Doppler indices for the uterine arteries.

Sublingual administration of misoprostol of second-trimester medical abortion results in a higher success rate and does not affect umbilical blood flow.

5) CALISKAN E, DILBAZ S, DOGER E, OZEREN S, DILBAZ B, RANDOMIZED COMPARISON OF 3 MISOPROSTOL PROTOCOLS FOR ABORTION INDUCTION AT 13-20 WEEKS OF GESTATION. J REPROD MED 2005;50(3):173-80. ERRATUM IN: J REPROD MED 2005;50(9):732

Reported that administration of 100 µg of misoprostol sublingually every 2 hours was more effective for the induction of second-trimester abortion compared with 200 µg of misoprostol vaginally every 4 hours.

6) VIMALA N, DADHWAL V, MITTAL S. SUBLINGUAL MISOPROSTOL FOR SECOND-TRIMESTER ABORTION. INT J GYNECOL OBSTET 2004;84(1) 89-90.

Reported that success rate in using a single dose of 800 µg of misoprostol sublingually was 92% .

7) TANG OS, LAU WN, CHAN CC, HO PC, A PROSPECTIVE RANDOMIZED COMPARISON OF SUBLINGUAL AND VAGINAL MISOPROSTOL IN SECOND TRIMESTER TERMINATION OF PREGNANCY. BJOG 2004;111(9):1001-5.

Administered 400 µg of misoprostol every 3 hours for a maximum of 5 doses either sublingually or vaginally and repeated the regimen if patient did not abort within 24 hours. They concluded that the median induction to abortion interval was similar in 2 groups and the use of vaginal misoprostol had a higher success rate than that of sublingual misoprostol for the first 24 hours, but the abortion rate was similar in 48 hours.

8) NAGARIA TRIPTI, SOMAWAR SWATI, The Journal of Obstetrics and Gynaecology of India. (2007)

To assess the safety and efficacy, complete abortion rate, induction abortion interval (IAI) and side effect of misoprostol for voluntary termination of second trimester pregnancy.

Fifty selected women admitted for second trimester (13-22 weeks) abortion were administrated 800 µg misoprostol intravaginally followed by 300 µg sublingually every 3 hours upto a maximum of 3 doses or till abortion if occurred earlier.

Of the 50 women, 49 aborted with 24 hours of administration of vaginal misoprostal giving success rate of 98%. The complete abortion rate was 88%. Mean IAI was 9.36 + 3.50 hours and mean dose of misoprostol required 1485.63 + 219.25 µg. The mean blood loss was 60.2 + 2.01 ml. The main side effects were vomiting, diarrhea, and fever in 12% each.

Intravaginal misoprostol (800 µg) followed by sublingual (300 µg x 3 hourly) misoprostol is a safe, effective, cheap and acceptable method for the second trimester pregnancy termination.

9) DIABAZ S, et al Department of Obstetrics and Gynaecology, SSK Ankara Maternity ,Turkey.

They studied 250 women between 12 – 20 weeks of gestation. The women received 200 µg vaginally initially followed by 100 µg oral every 2 hours until expulsion of fetus. The main outcome was expulsion rate within 24 hours in 98% of cases. Mean Misoprostol dosage was 200 – 2100 mcg. Cox regression analysis revealed dead embryo don't affect the induction abortion time. But induction abortion time tends to be longer in the presence of live fetus and with gestational age of older weeks (>16 weeks) with live fetuses.

10) FARMINGTON USA

This study compared 2 different doses of Misoprostol in second trimester pregnancy in 40 women. An initial dose of 800 µg of vaginal Misoprostol and regimen of 400 mcg of oral Misoprostol every 8 hours is as effective as the same dose of vaginal Misoprostal, with no additional side effects.

11) RASHMI SHAH, ANITA PEDDAWAD, KAVITA TILWANI, BHAGYASHREE KANJE AND RUHI PEDNEKAR, REKHA DEVAR, J.J GROUP OF HOSPITALS. (2002 – 2004)

A Double Blind Randomized Comparison of Vaginal and sublingual Misoprostol regimens for Termination of Pregnancy in the Second Trimester (WHO Multicentre Study) of 13 – 20 weeks duration in 42 women was undertaken. The women are allocated randomly to receive the active drug i.e. 400 µg misoprostol administered either vaginally or sublingually every 3 hours up to five doses. Side effects are being recorded 3 hours during the stay at the hospital and outcome assessed 24 hours after the start of the treatment. According to this study both vaginal and sublingual regimens were equally effective in termination of pregnancy second trimester.

12) SHARMA Y, VIMALA N, DADHWAL V, MITTAL S.

A randomized comparison of sublingual and vaginal misoprostol for cervical priming before termination of early pregnancy.

ABORTION

Definition

Abortion is defined as the termination of pregnancy after implantation of the blastocyst in the endometrium but before fetus has attained viability (i.e.) before 20 weeks of gestation or weight less than 500 gms. (WHO).

Types of Abortions:

Abortions can be classified as either of the following:

- Spontaneous
- Induced

Abortion is legalised by MTP ACT 1971.

Medical termination of pregnancy means deliberate termination of pregnancy before the fetus becomes viable.

Second trimester termination of pregnancy means termination of pregnancy between 13 to 20 weeks of gestation.

Reproductive Health and Abortion Statistics in India:

Percent using Family Planning	-	49%
Population of women of reproductive age(15-49)	-	262,200,00
Number of Abortions, annually	-	6,700,000

Percent of maternal mortality caused by unsafe abortion – 89%

LEGAL STATUS OF ABORTION IN INDIA

According to the IPC Act 1860 induction of abortion was illegal in India. In 1964 a committee was set up to examine the old law. The committee submitted its report in 1966 recommending liberalization of abortion laws to bring down the morbidity and mortality resulting from illegal abortion. The MTP bill was enacted in 1971 and come into force in 1972 April 1st.

MTP Act

The MTP Act (Act No. 34 of 1971) has been defined in its opening lines as An Act to provide for the termination of certain pregnancies by registered medical practitioners and to matters connected therewith or incidental thereto.

Passed by Parliament on August 10, 1971, this is a Central Act that extends to the whole of India except the state of Sikkim.

Medical termination of pregnancy was liberalized in Indian with 2 main objectives. The first objective is to transfer a large number of criminal induced abortions with all their inevitable complication from the hands of untrained people to the safe hands of skilled and specialized obstetricians. The second objective is to aim at the target of population control which could not be achieved satisfactorily by the various contraceptive methods either due to the failure of individual method or

due to the non-adoption of any method by the general and uneducated people of our country.

With the advent of Medical termination of pregnancy the liberalization of abortion laws and necessity of family planning have led the increased demand for termination of pregnancy through out the world in general and in India in particular.

Consent

- If married - her written consent. Husband's consent not required.
- If unmarried and above 18years – her own written consent.
- If below 18years – written consent of her guardian.
- If mentally unstable – written consent of her guardian.
- A consent assures the clinician performing the abortion that she:
    - Has been informed of all her options.
    - Has been counseled about the procedure, its risks and how to care for herself after she chose abortion of her own free will.

Person or persons who can perform MTP: physicians qualified to do MTP are:

- Any qualified registered medical practitioner who has assisted in 25 MTPs.
- A house surgeon who has done six months post in Obstetrics and Gynaecology.

- A person who has a diploma/degree in Obstetrics and Gynaecology.
- 3 years of practice in Obstetrics and Gynaecology for those doctors registered before the 1971 Act was passed.
- 1 year of practice in Obstetrics and Gynaecology for those doctors registered on or after the commencement of the Act.
- Whenever the pregnancy exceeds 12 weeks but is below 20 weeks opinion of two registered practitioners is necessary.

A variety of Induced abortion services are available in India. They are

1. Government Hospitals and centres.
2. Municipal Hospitals and Maternity homes.
3. Recognized Non Governmental organizations.
4. Recognized Private Hospitals, Nursing Homes and Clinics.

INDICATIONS FOR LEGAL ABORTION:

- ✓ Medical
- ✓ Eugenic
- ✓ Humanitarian
- ✓ Social
- ✓ Contraceptive failure and
- ✓ As family planning procedure.

MEDICAL

Abortion is indicated in pregnant women who has a serious medical disease and continuation of pregnancy could endanger her life like:

1. Hypertensive disorders,
2. Renal disease with high blood urea,
3. Breast cancer
4. Cancer cervix
5. Psychotic illness
6. Diabetes mellitus with retinopathy

EUGENIC

When there is genetic transmission of mental disease like down syndrome, Neural tube anomalies like anencephaly and some cases of hereditary and metabolic diseases.

It is also indicated when the fetus is likely to be deformed due to the action of drugs or exposure to infections or radiation.

HUMANITARIAN

Pregnancy due to rape.

SOCIAL

According to WHO report, this forms the commonest indication in the present day medical practice. Pregnancy is terminated to promote not

only physical or mental health but also for social well being of the pregnant women and her family.

FAILURE OF CONTRACEPTIVE METHODS

According to Medical Termination of pregnancy Act, 1971, one can request a legal abortion in our country if she conceives due to failure of any contraceptive method.

FAMILY PLANNING PROCEDURES

Second trimester abortion is adopted as one of the family planning device.

INCIDENCE

About 85% of the induced abortions are in the first trimester and 15% in the second trimester. Ideally the first trimester termination is done, prognosis is better. Morbidity and mortality rates in mid trimester are 3-4 times higher than that of the first trimester terminating.

REASONS FOR DELAY IN SEEKING ABORTION

1. Lack of information on the availability of abortion facilities.
2. Ignorance and / or psychological denial of pregnancy.
3. Ambivalence regarding the desirability of abortion
4. Late identification of Medical disorders contraindicating the continuation of pregnancy.
5. Late discovery of fetal malformation.
6. Lack of financial resources to reach the hospitals.

METHODS FOR TERMINATION OF SECOND TRIMESTER PREGNANCY

MEDICAL METHODS

* Extra ovular instillation of drugs.
    a) Ethacridine lactate 0.1%
    b) Hypertonic saline
    c) Prostaglandins (PGE_2)

* Intra amniotic instillation of drugs.
    a) Hypertonic saline (20%)
    b) Urea
    c) Prostaglandins

* Extra ovular administration of drugs.
    a) Prostaglandins (Oral, vaginal, sublingual (PGE_1), parenteral ($PGF_{2}\alpha$)
    b) Oxytocics

* Extra ovular insertion of sterile catheter.

MEDICAL METHODS:

* **Ethacradine lactate:(** Emcredyl or Rivanol)
  - This drug is introduced through a sterile catheter through vagina into uterine cavity and placed in the extra amniotic sac.
  - This procedure is not painful, safe and cheap
  - Maximum of 150ml is instilled.
  - Uterine activity begins within 12 to 18hours
  - The mean induction abortion interval varies between 24 and 36 hours.
  - To hasten the process of abortion, it can be used along with prostaglandin or oxytocin.
* **Prostaglandin:**

  PGE_2:(cerviprime)
  - Prostaglandin in gel form is inserted into cervical canal.
  - Induces uterine contractions within few hours of insertion.
  - Oxytocin can be supplemented.
  - Abortion is usually achieved in less than 24hrs and the abortion is complete.

PGE_1: (MISOPROSTOL)

- Available in tablet form and given by oral / sublingual or can be inserted vaginally.
- 200mg of oral mifepristone (RU486) followed 36 to 48hrs later by 600µg misoprostal every 3 hourly with a maximum of 5 doses.

SURGICAL METHODS

a) Dilatation and evacuation

b) Aspirotomy

c) Hysterotomy

d) Hysterectomy (rare)

Aspirotomy:

- Procedure is similar to suction evacuation.
- To help in dilatation of cervix laminaria tents, prostaglandin may be used.

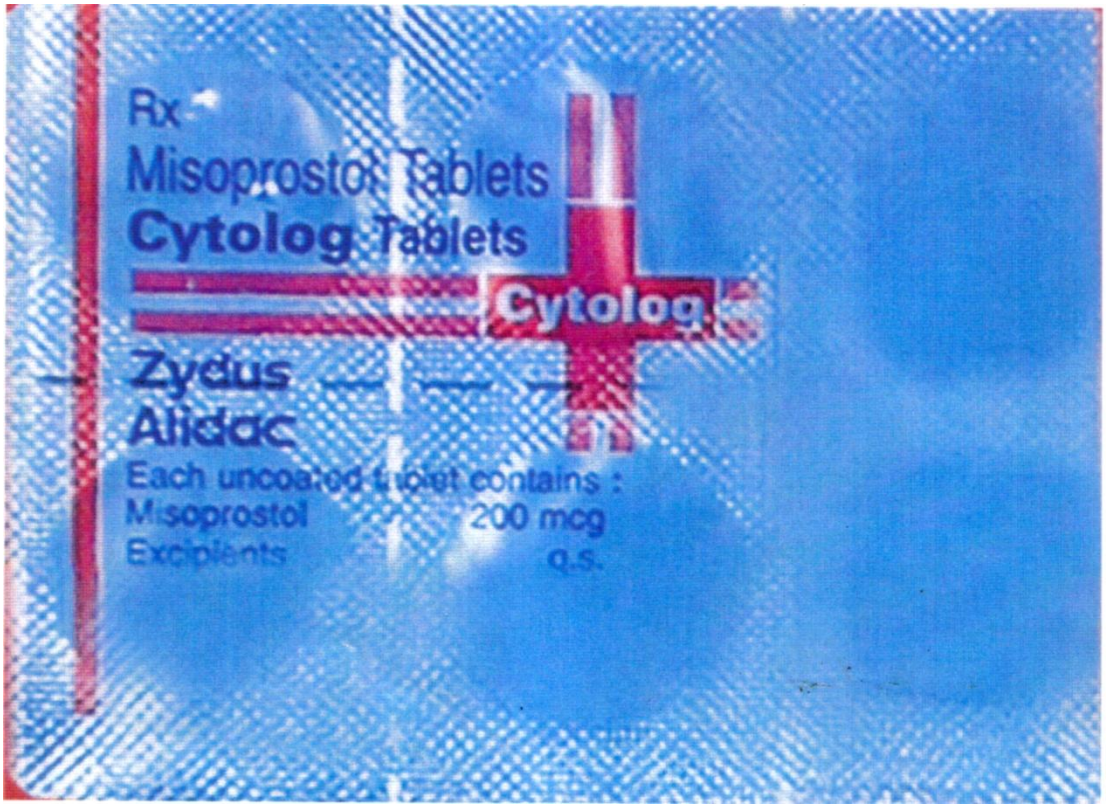
Hysterotomy:

- Operative procedure.
- Under Anesthesia abdomen is opened and the contents of the uterus is removed directly under vision.

Among the various methods, surgical methods compared to medical methods have the following disadvantages:

- Uterine hemorrhage
- Pelvic infection
- Cervical injury
- Uterine perforation
- Retained products
- Continuation of pregnancy especially in vacuum aspiration cases.
- Maternal morbidity and mortality may be increased.

T. Misoprostol



MISOPROSTOL PHARMACOLOGY

Misoprostol is a synthetic, $PGE_{1,}$ analogue (15-deoxy – 16-hydroxy – 16-methyl PGE_1), initially developed for the prevention and treatment of peptic ulcer is found to have uterotonic and cervical ripening effects as well. It is cheap, stable at room temperature and can be stored for a long time. The oral tablets are effective in different routes administration. Misoprostol in the required doses had only few (dose-dependent) side effects, and it is readily available in many countries.

Mechanism of Action

Misoprostol is actively absorbed, Primarily metabolized in liver and get converted into active plasma metabolite called Misoprostolic acid.

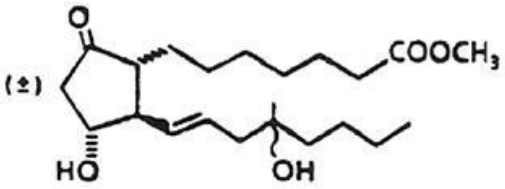
Misoprostol is a myometrial stimulant which binds to E-2 and E-3 prostanoid receptors and cause effective uterine contraction and ripening of cervix.

13) O.S.TANG, K.GEMZELL-DANIELSSON, P.C HO 2007

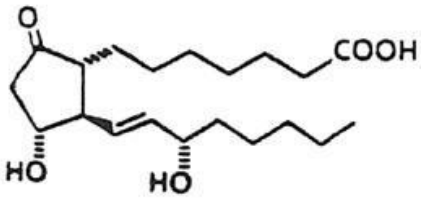
Misoprostol: Pharmacokinetic profiles, effects on the uterus and side-effects.

Misoprostol, a synthetic prostaglandin E1 analogue, is commonly used for medical abortion, cervical priming, the management of

The structure of misoprostol and naturally occurring prostaglandin (PGE1).



Misoprostol



PGE1

miscarriage, induction of labor and the management of postpartum hemorrhage.

Structure And Chemistry Of Misoprostol

Misoprostol differs structurally from natural prostaglandin E_1 by the presence of a methyl ester C-1, a methyl group at C-16 and a hydroxyl group at C-16 rather than at C-15. The methyl ester at C-1 increases the anti-secretary potency and duration of action of misoprostol, whilst the movement of the hydroxyl group from C-15 to C-16 and the addition o f a methyl group C-16 improves oral activity, increases the duration of action, and improves the safety profile of the drug.

Pharmacokinetic properties of the various routes of administration of misoprostol

Misoprostol tablets were used in following routes

1.Oral

2.Vaginal

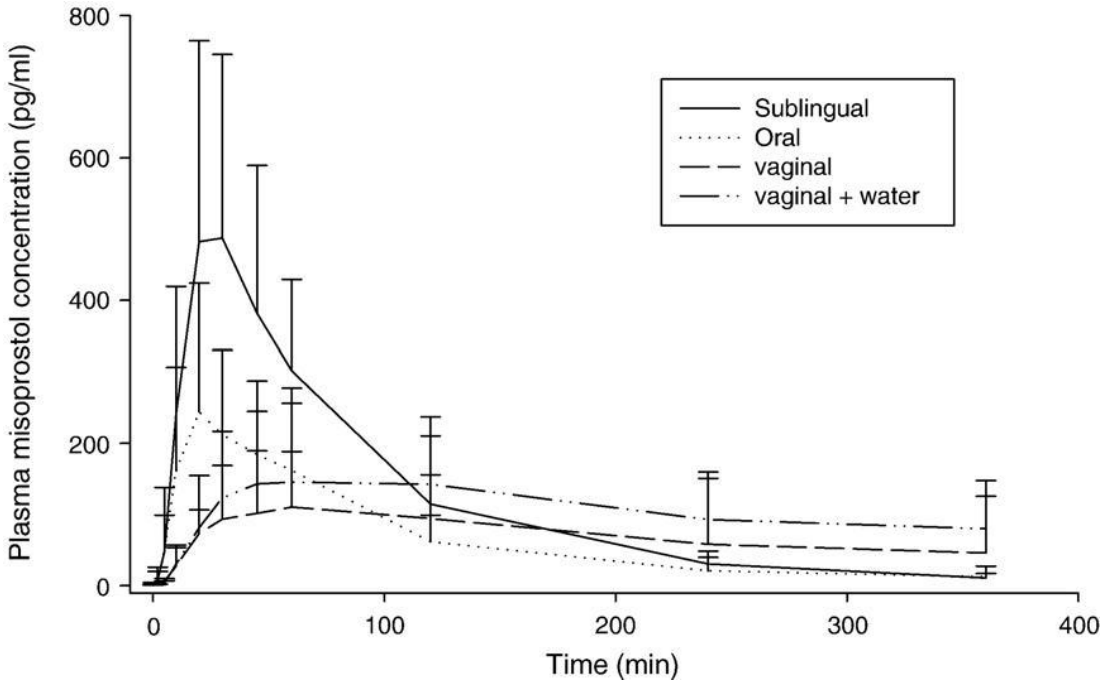
3.Sublingual

4.Buccal

5 Rectal.

Mean plasma concentrations of misoprostol acid over time (arrowbars = 1 SD).

[Tang. Pharmacokinetics of different routes of administration of misoprostol. Hum Reprod 2002. Reproduced by permission of Oxford University Press].



- **Oral route**

  After oral administration misoprostol is rapidly and almost completely absorbed from the gastrointestinal tract. However, the drug undergoes extensive and rapid first-pass metabolism (de-esterification) to form misoprostol acid. Following a single dose of 400 µg oral misoprostol , the plasma misoprostol level increases rapidly and peaks at about 30 minutes (Fig) declines rapidly by 120 minutes and remains low thereafter.

- **Vaginal route**

  The plasma concentration increases gradually after vaginal administration, reaching its maximum level after 70-80 minutes before slowly declining with detectable drug levels still present after 6 hours.

  Although the peak concentration after oral administration is higher than for vaginal administration, the 'area under the curve' is higher when given vaginally. The greater bioavailability of vaginal misoprostol may help to explain why it is more effective in medical abortion.

  It has been shown that the coefficient of variation of the AUC after vaginal administration is greater than that after oral administration. This means that the vaginal absorption of misoprostol is inconsistent.

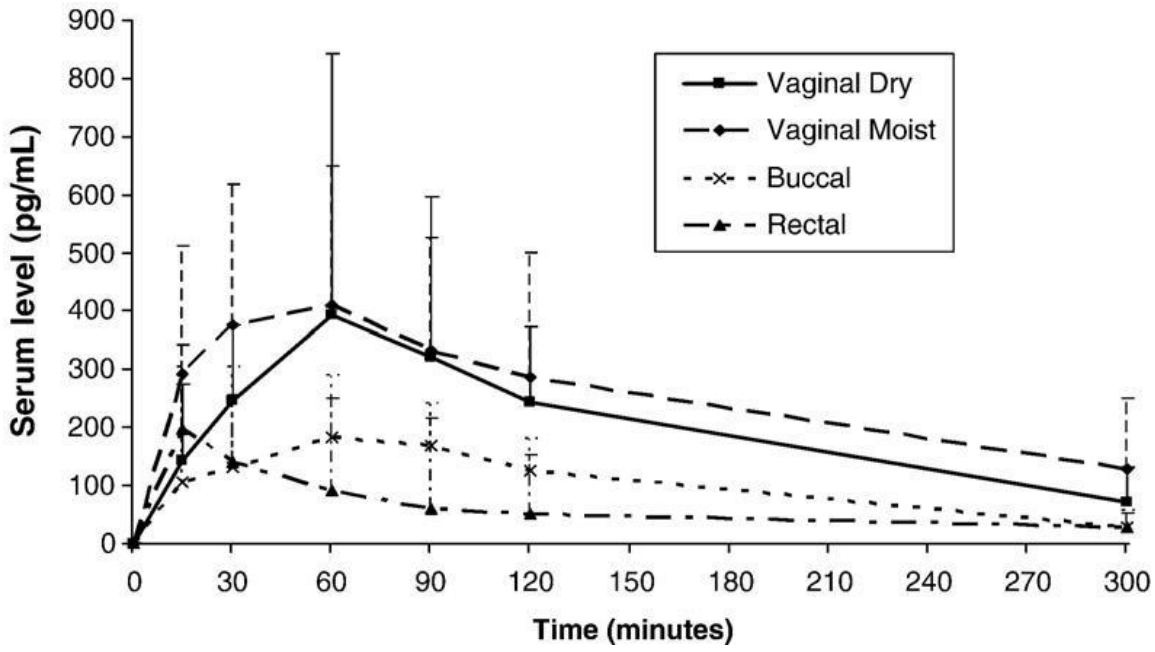
In clinical practice, remnants of tablets are sometimes seen many hours after vaginal administration, indicating that the absorption is variable and incomplete. This may be due to variation between women in the amount of pH of the vaginal discharge. Variation in the amount of bleeding during medical abortion may also affect the absorption of misoprostol through the vaginal mucosa. The addition of water to the misoprostol tablets is a common practice. However, this has been shown not to improve the bioavailability of vaginal misoprostol.

- **Sublingual route**

Misoprostol tablet is very soluble and can be dissolved in 20 minutes when it is put under the tongue. Sublingual misoprostol has the shortest time to peak concentration, the highest peak concentration and the greatest bioavailability when compared to other routes.

The peak concentration is achieved in about 30 minutes after sublingual and oral administration, whereas following vaginal administration, it takes 75 minutes. After 400 µg of misoprostol, a sublingual does achieves a higher peak concentration than that of oral and vaginal administration. This is due to rapid absorption through the sublingual mucosa as well as the avoidance of the first-pass

Mean serum levels of misoprostol acid in pg/mL for four epithelial routes of misoprostol administration over 5 hours. Error bars represent standard deviation. [Meckstroth. Misoprostol Absorption and Uterine Response. Obstet Gynecol 2006. Reproduced by permission of Lippincott Williams & Wilkins].



metabolism via the liver. The abundant blood supply under the tongue and the relatively neutral pH in the buccal cavity may be contributing factors. The rapid onset and high peak concentration means that of all the possible routes the systemic bioavailability, as measured by the AUC in the first 6 hours is greatest of sublingual administration.

Although vaginal absorption has been shown to be slower and the peak concentration lower than that for the other routes, the serum level of misoprostol is sustained at the low level for a longer period of time. Therefore, the effect of misoprostol may linger for more than 6 hours after a single dose, though the threshold serum level for clinical action is unknown.

- **Buccal route**

Buccal administration, the drug is placed between the teeth and the check and allowed to be absorbed through the buccal mucosa.

The shape of the buccal route absorption curve is very similar to that for vaginal absorption but the serum drug levels attained are lower throughout the 6 hours study period.

After buccal administration the Tmax is 75 minutes which is similar to that after vaginal administration, but the AUC of buccal administration is just half that of the vaginal administration.

- **Rectal route**

The rectal route of administration has been studied recently for the management of postpartum hemorrhage. This route of administration is less commonly used for the other applications. The shape of the absorption curve after rectal administration is similar to that of vaginal administration but its AUC is only 1/3 that of vaginal administration. The mean Tmax after rectal administration is 40-65 minutes.

Sublingual misoprostol, which has the shortest Tmax, is perhaps useful for clinical applications that require a fast onset of clinical action, such as postpartum hemorrhage or cervical priming. Vaginal misopostol on the other hand, which has a high bioavailability and sustained serum level, is useful for indications that require longer time for the manifestation of its clinical effects, like medical abortion.

Route	Onset of action	Duration of action
Oral	8 min	2 hours
Sublingual	11 min	3 hours
Vaginal	20 min	4 hours
Rectal	100 min	4 hours

EFFECTS

- **Uterus**

  After a single dose of oral misoprostol there is an increase in uterine tonus. To produce regular contraction, however, a sustained plasma level of misoprostol is required and this required repeated oral dose.

  The mean time to increase in tonus is 8 and 11 min for oral and sublingual administration respectively compared with 20 mins for vaginal administration. The mean time to maximum tonus is also significantly shorter for oral and sublingual misoprostol compared to vaginal administration. One to two hours after the administration of misoprostol, the tonus begins to decrease. In the case oral misoprostol, this is the end of the activity. For vaginal and sublingual treatment, however, the tonus is slowly replaced by regular uterine contractions. These regular uterine contractions are sustained for a longer period after vaginal administration than after sublingual treatment, with decreased activity occurring only after 4 hours (compared to 3 hours with sublingual).

- **Cervix**

  Misoprostol has been used extensively for its cervical softening effect before induction of labour and surgical evacuation of the

uterus. It is more likely to be due to the direct effect of misoprostol on the cervix. The exact mechanism leading to physiological cervical ripening is not known. The biochemical events that have been implicated in cervical ripening are decrease in total collagen content and increase in collagen solubility, and an increase in collagenolytic activity. Action of misoprostol appeared to be mainly on the connective tissue stroma with evidence of disintegration and dissolution of collagen.

- **Gastrointestinal effects:**

Misoprostol has gastric antisecretory effects and mucosal protective effect. Misoprostol is effective in preventing NSAIDS induced gastric ulcer.

Side effects:

Misoprostol is a safe and well-tolerated drug. Pre-clinical toxicological studies indicate a safety margin of at least 500 – 1000 fold between lethal doses in animals and therapeutic doses in humans. No clinically significant adverse hematological, endocrine, biochemical, immunological, respiratory, ophthalmic, platelet or cardiovascular effects have been found with misoprostol.

- Gastro – intestinal side effects like diarrhea, abdominal pain, nausea, flatulence, dyspepsia, headache, vomiting and constipation.
- Shivering
- Hyperthermia
- Dizziness
- Pelvic Pain
- Severe genital bleeding
- Pain due to uterine contraction
- Uterine rupture

Over dosage can cause sedation, tremor, convulsion, dyspneoa, abdominal pain, diarrhea, fever, palpitation or bradycardia. Symptoms should be treated with supportive therapy.

Contraindications to the use of misoprostol

- Cardiac disease
- Renal disease
- Hypertension
- Bronchial asthma
- Previous caesarean scar
- Hepatic failure

14) ARONSSON et al.

The increase in uterine tonus is more rapid and more pronounced following oral and sublingual treatment than after vaginal treatment.

MATERIALS AND METHODS

MATERIALS AND METHODS

This study was carried out in the Family welfare unit of Department of obstetrics & gynaecology, Government Rajaji Hospital, Madurai during the period of March 2010 to November 2010.

The purpose of this study is to compare the efficacy of sublingual and vaginal routes of misoprostol administration for medical abortion in the second trimester.

Study population:

100 women requesting pregnancy termination at 12- 20 weeks of gestational age were randomly selected for the study. This includes from all age groups, parity and socioeconomic status.

Exclusion criteria

Patients with following are excluded

- Bronchial asthma
- Hemorrhagic Disorders
- Cardiac diseases
- Renal disease
- Jaundice
- Scarred uterus

They were grouped into two

50 patients - Group A : Sublingual misoprostol
50 patients - Group B : Vaginal misoprostol

Informed Consent:

Written consent of the patients were taken and if patient was a minor, her parent's consent was obtained. Patient was given prophylactic antibiotics.

Preparation of patients:

- ➲ On admission, complete history was taken. General examination and systemic examination were carried out.
- ➲ Abdominal examination and bimanual pelvic examination was done. By speculum examination any torn, cicatrized cervix ruled out.
- ➲ Patient was instructed about the method and side effect of the drug.

Investigations:

- ❖ Urine - Albumin
  Sugar
  Deposits
- ❖ Haemoglobin
- ❖ Blood grouping & Rh typing
- ❖ Bleeding time
- ❖ Clotting time
- ❖ Blood urea, sugar, serum creatinine
- ❖ Ultrasonogram

METHODOLOGY

Group A:

400 μg of misoprostol (2x200μg tablets) was given sublingually, and repeated every 4 hours until abortion or to a maximum of 6 doses.

Patients in this group were asked not to eat or drink for 20 minutes following administration of the drug.

Group B:

Under aseptic precaution, patient in dorsal position, with speculum the posterior lip of cervix was visualized and 400μg of misoprostol soaked in normal saline was kept in the posterior fornix and the patient was instructed to stay in bed for 30 minutes. Dose was repeated every 4hours until abortion or to a maximum of 6 doses.

In each case, the following parameters were recorded

- Time of application of tablets
- Monitoring of pulse, blood pressure and temperature (hourly)
- Progress of abortion assessed
- Interval between induction and onset of active labour (hours)
- Interval between induction and abortion in hours
- Duration of oxytocin acceleration in hours.

- Patients were carefully monitored for development of symptoms

  - Nausea
  - Vomiting
  - Fever
  - Diarrhoea

If the patients did not get aborted within 24 hours, it was taken as failed induction. They were treated with second course of misoprostol or hysterotomy.

After expulsion of product of conception, check curettage was routinely done for all cases.

Haemoglobin was rechecked after 48 hours.

Follow up:

Patient was advised to come for the follow up at the end of one month and at the end of 3 months to enquire about the menstrual regularity and general status.

STATISTICAL TOOLS

The information collected regarding all the selected cases were recorded in a Master Chart. Data analysis was done with the help of computer using **Epidemiological Information Package (EPI 2008)** developed by Centre for Disease Control, Atlanta.

Using this software range, frequencies, percentages, means, standard deviations, chi square and 'p' values were calculated. Kruskul Wallis chi-square test was used to test the significance of difference between quantitative variables. A 'p' value less than 0.05 is taken to denote significant relationship.

ANALYSIS OF STUDY

ANALYSIS OF STUDY

100 cases:

* Group A – SUBLINGUAL MISOPROSTOL – 50 CASES
* Group B – VAGINAL MISOPROSTOL – 50 CASES.

Analysis was done in the following aspects.

- Distribution of age
- Socio economic status
- Parity distribution
- Gestational age
- Induction abortion interval
- Induction outcome
- Induction outcome and age
- Induction outcome and parity
- Side effects
- Change in Hemoglobin value

RESULTS

AGE DISTRIBUTION

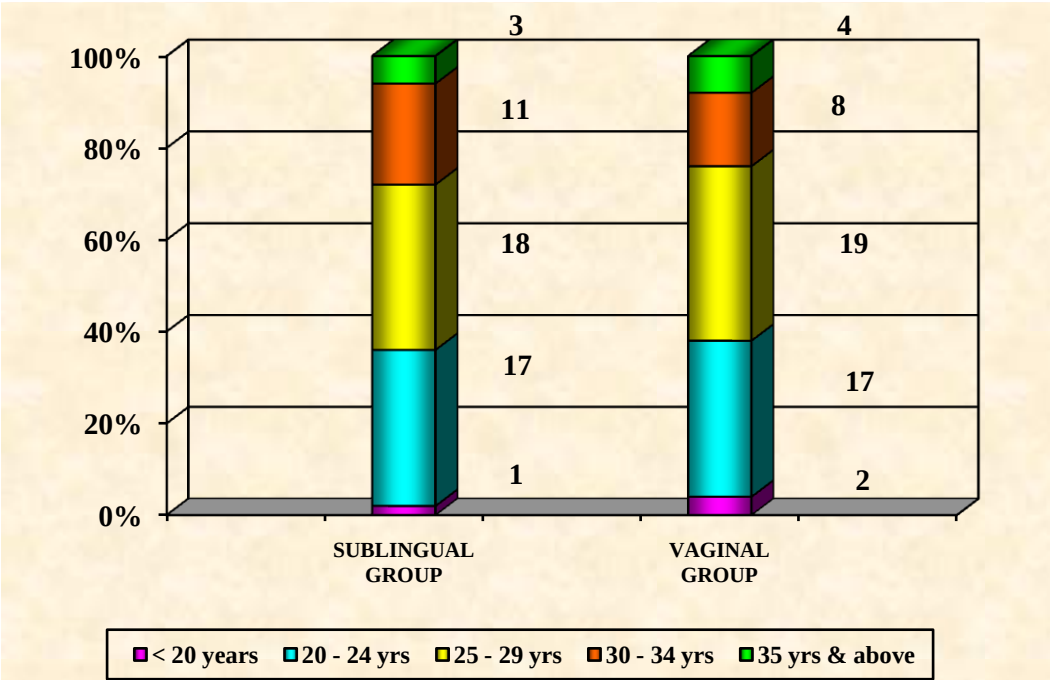


Table 1: Age distribution

Age in years	No of Cases in			
	Sublingual Group A		Vaginal Group B	
	No	%	No	%
Less than 20 years	1	2	2	4
20 - 24 years	17	34	17	34
25 – 29 years	18	36	19	38
30 – 34 years	11	22	8	16
35 years & above	3	6	4	8
Total	**50**	**100**	**50**	**100**
Range	18 – 37 years		19 – 35 years	
Mean	26.7 years		26.4 years	
S.D	4.5 years		4.4 years	
'P'	0.727 Not Significant			

Comparing the age distribution in both the groups, majority of the patients were between 20-29 years of age 70% (35/50) in Group A and 72% (36/50) in Group B. Teenage group contributes to minority of the population 2% (1/50) in Group A and 4% (2/50) in Group B.

There is no statistically significant difference in mean age in both groups.

SOCIO ECONOMIC STATUS

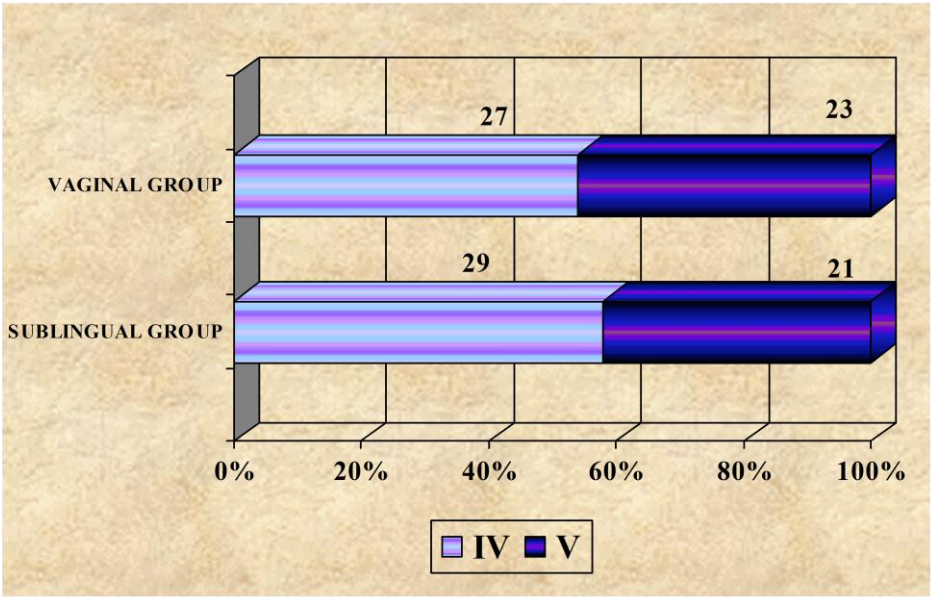


Table 2: Socio Economic Status

Socio Economic Status	Sublingual Group A		Vaginal Group B	
	No	**%**	**No**	**%**
I	Nil	Nil	Nil	Nil
II	Nil	Nil	Nil	Nil
III	Nil	Nil	Nil	Nil
IV	29	58	27	54
V	21	42	23	46
Total	**50**	**100**	**50**	**100**
'P'	0.8403 Not Significant			

There is no statistically significant difference between the socioeconomic status of two groups. All the cases belong to the lower strata of the society.

PARITY

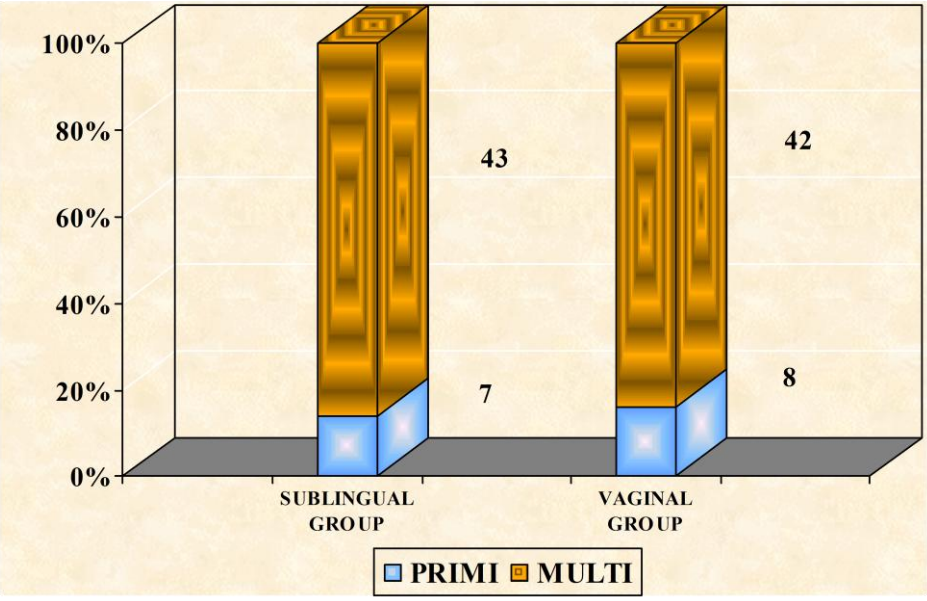

100%
80%
60%
40%
20%
0%
43
7
42
8
SUBLINGUAL GROUP
VAGINAL GROUP
PRIMI
MULTI

Table 3: Parity

Parity	Sublingual Group A		Vaginal Group B	
	No	**%**	**No**	**%**
Primi	7	14	8	16
Multi	43	86	42	84
'P'	0.7805 Not Significant			

The difference in the Parity of the two groups of patients is not statistically significant.

Most of the patients were multigravida 86% (43/50) in Group A and 84% (42/50) in Group B.

GESTATIONAL AGE

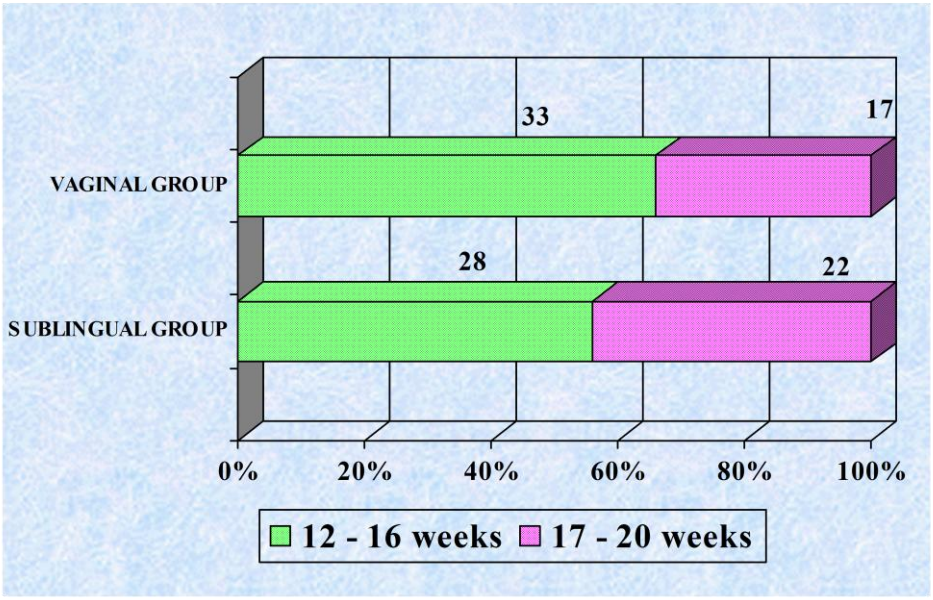


Table 4: Gestational Age in weeks

Gestational Age (in weeks)	**Sublingual Group A**		**Vaginal Group B**	
	No	**%**	**No**	**%**
12- 16 weeks	28	56	33	66
17- 20 weeks	22	44	17	34
Total	**50**	**100**	**50**	**100**
Range	13 – 20 weeks		13 – 20 weeks	
Mean	16.4 weeks		16.2 weeks	
S.D	2.4 weeks		2.6 weeks	
'P'	0.5029 Not Significant			

The mean Gestational age of both groups is not significantly different. (P value is 0.5029)

INDUCTION ABORTION INTERVAL

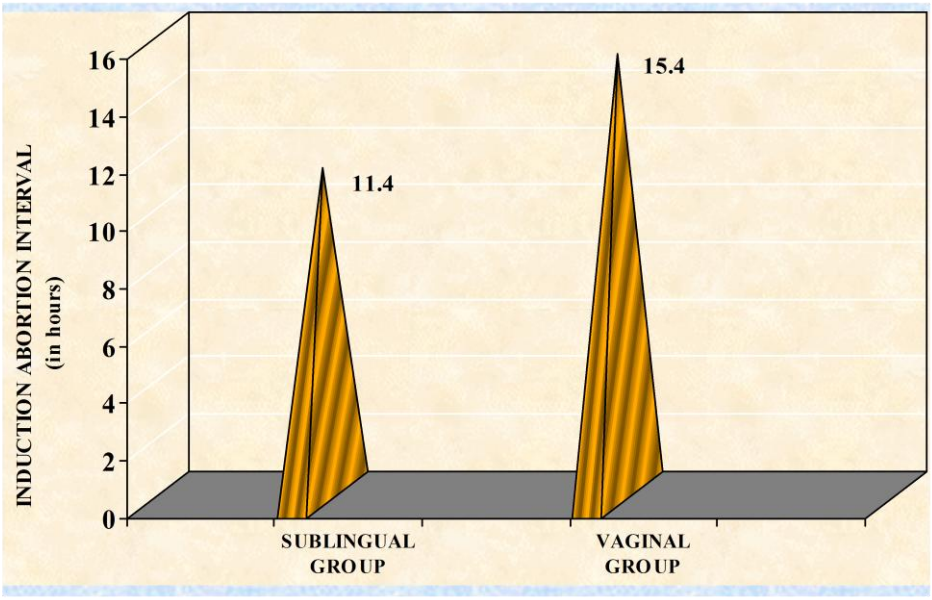


Table 5: Induction abortion interval (in hours)

Induction abortion interval (in hours)	Sublingual Group A		Vaginal Group B	
	No	**%**	**No**	**%**
Up to 6 hours	4	8	1	2
6.1 - 12 hours	27	54	12	24
12.1 - 18 hours	10	20	16	32
18.1 - 24 hours	6	12	16	32
Failed Induction	3	6	5	10
Total	**50**	**100**	**50**	**100**
Range Mean S.D	5.5 – 24 hours 11.4 hours 4.9 hours		5.16 – 23 hours 15.4 hours 5.0 hours	
'P'	0.0001 Significant			

The mean induction abortion Interval in Group A is 11.4 $\pm$ 4.9hours and that of Group B is 15.4 $\pm$ 5 hours.

The induction abortion interval is shorter in sublingual misoprostal Group A than Vaginal misoprolstal Group B and the difference is statistically significant.
(p=0.0001)

INDUCTION OUTCOME

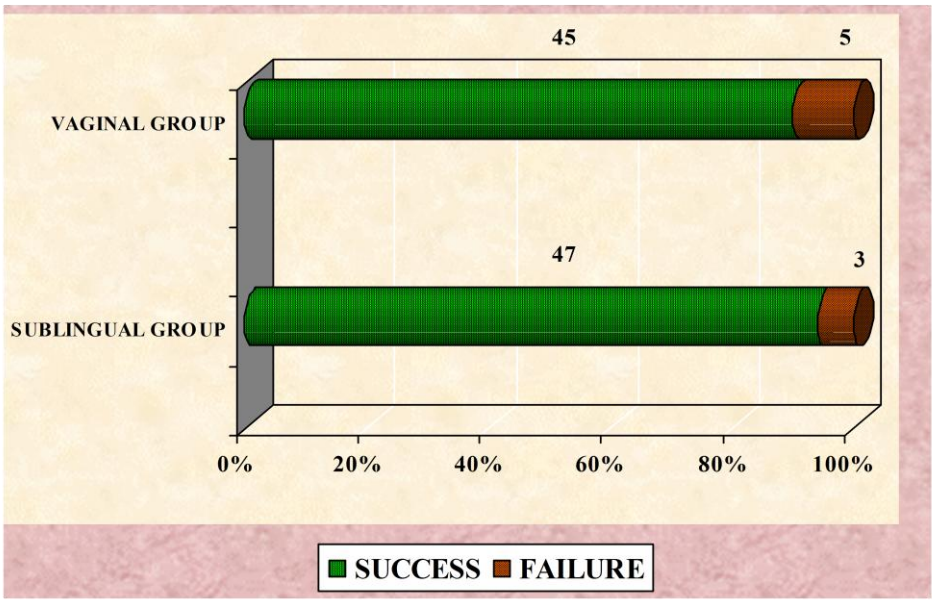


Table 6: Induction Outcome

Induction outcome	Sublingual Group A		Vaginal Group B	
	No	**%**	**No**	**%**
Success	47	94	45	90
Failure	3	6	5	10
'P'	0.3575 Not Significant			

Success rate is slightly high in Group A 94% (47/50) than Group B 90% (45/50) but it is not statistically significant (P = 0.3575).

INDUCTION OUTCOME & AGE

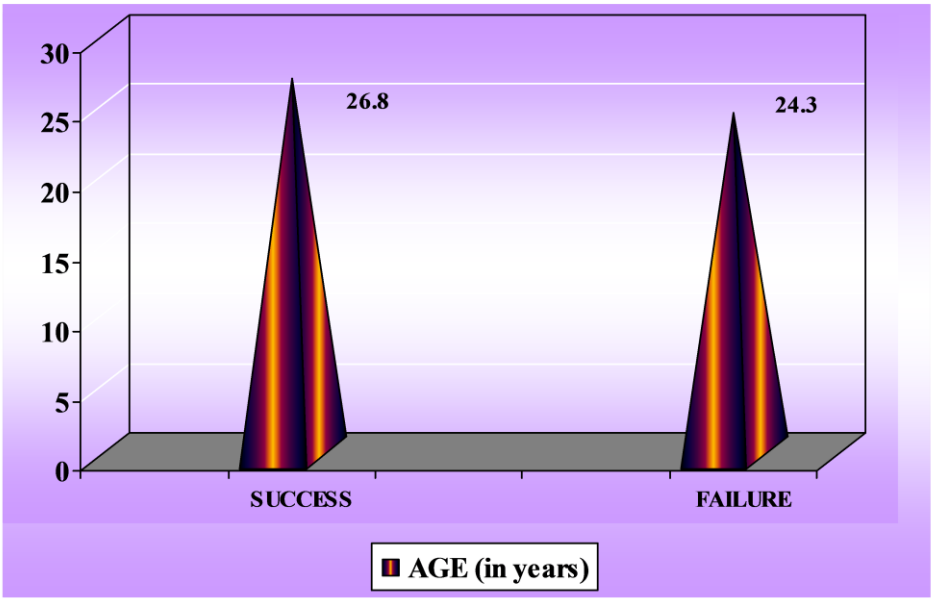


Table 7: Induction Outcome and age

Induction outcome	Age in Years		
	Range	**Mean**	**S.D**
Success	18 – 37 years	26.8	4.6
Failure	20 – 28 years	24.3	2.5
'P'	0.1215 Not Significant		

There is no statistical significance of age in relation to induction outcome.

INDUCTION OUTCOME & PARITY

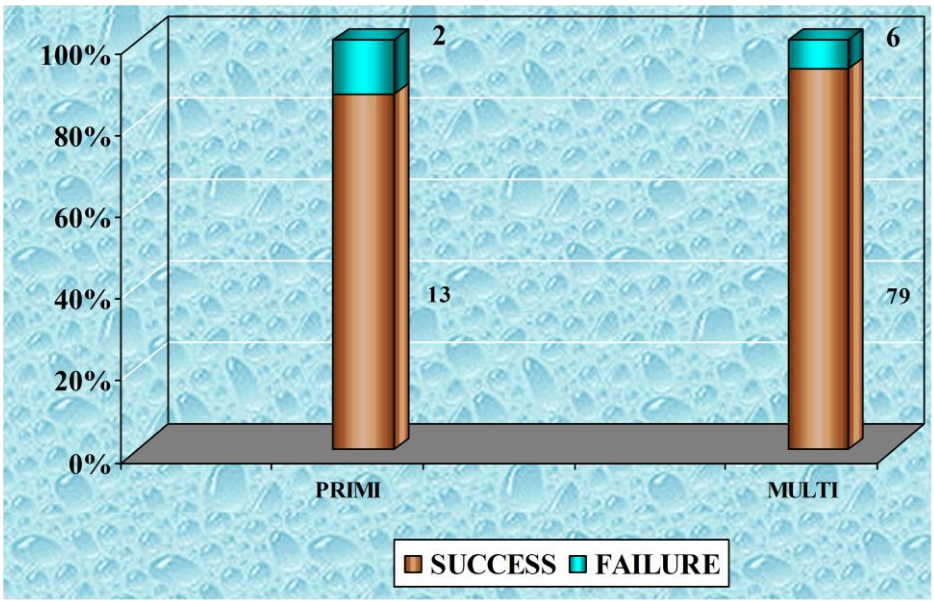


Table 8: Induction Outcome and Parity

Parity	Induction outcome			
	Success		Failure	
	No	%	No	%
Primi (15)	13	86.7	2	13.3
Multi (85)	79	92.9	6	7.1
'P'	0.3435 Not Significant			

There is no statistical significance of parity in relation to induction outcome.

SIDE EFFECTS

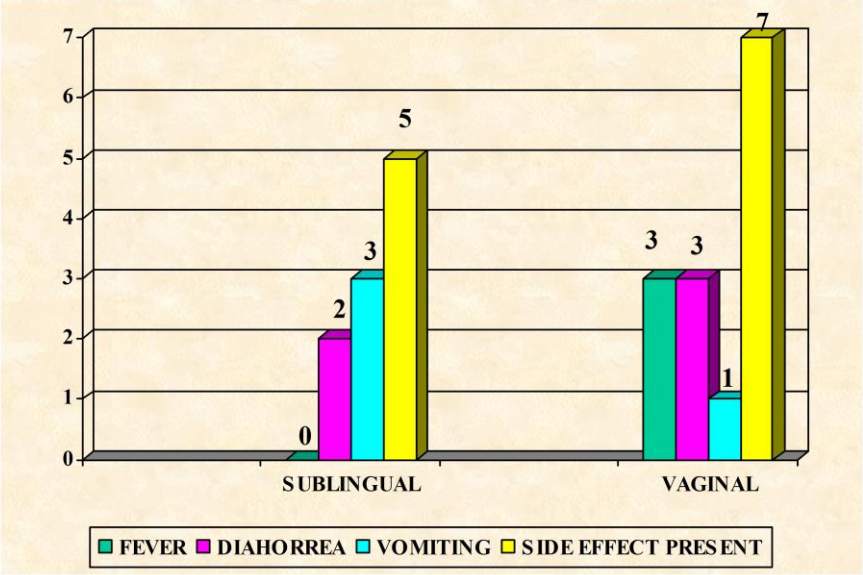


Table 9: Side Effects

Side Effects	Sublingual Group A		Vaginal Group B	
	No	**%**	**No**	**%**
Fever	-	-	3	6
Diarrhea	2	4	3	6
Vomiting	3	6	1	2
Total with Complication	5	10	7	14
Total without Complication	45	90	43	86
'P'	0.7583 Not Significant			

Side effects are present in 10% (5/50) in Group A and 14% (7/50) in Group B.

There is no statistically significant difference in side effects between two groups.

Hb. AT INDUCTION & AFTER EXPULSION

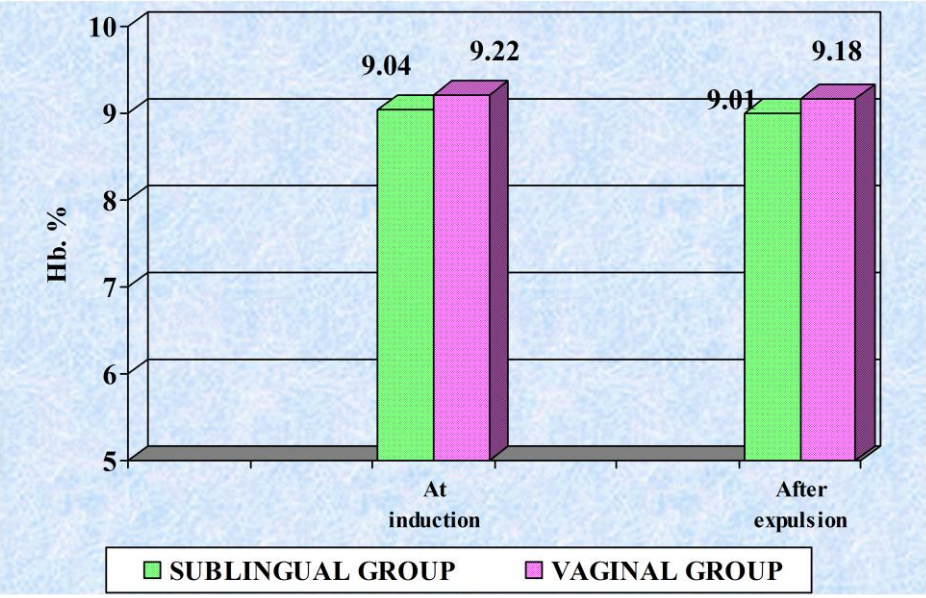


Table 10: Changes in Hemoglobin (gm%) at Induction and after expulsion

Hemoglobin gm%	Sublingual Group A		Vaginal Group B	
	Mean	**SD**	**Mean**	**SD**
At Induction	9.04	0.46	9.22	0.45
After expulsion	9.01	0.45	9.18	0.44
Change in Hb%	0.03	0.1	0.04	0.1

P Value 0.3423 (Not. Significant)

The change in Hemoglobin value in both groups before and after expulsion is not statistically significant.

DISCUSSION

DISCUSSION

There are variety of medical and surgical techniques for termination of pregnancy. Second trimester abortion constitutes 15% of all induced abortion. During the last decade, medical methods for second trimester abortion have become safe and more considerable. Uterine evacuation by medical methods reduces the morbidity associated with surgical intervention.

Cervical ripening and uterotonic effects of prostaglandin (PGE_1 analogue - MISOPROSTOL) is effectively utilized in this study for non invasive expulsion of products of conception.

Here this study was conducted in Department of Obstetrics and Gynaecology, Government Rajaji Hospital, Madurai to assess the efficacy, side effects and acceptability of sublingual and vaginal misoprostal in second trimester termination of pregnancy.

In this study 50 patients were given 400 µg sublingual misoprostol. Another 50 patients were given 400 µg vaginal misoprostol.

1. AGE:-

In our present study majority of the patients in both groups are between 20 – 29 years of age. The mean age is (26.7 $\pm$ 4.5) in sublingual group and (26.4 $\pm$ 4.4) in vaginal group, and is not a statistically significant difference.

This results is similar to that of the study by *KOUDAG et al.,(2009)*

2. SOCIO-ECONOMIC STATUS:-

All the patient in the present study belong to low socio-economic status (Grade IV and Grave V). There is no statistically significant difference in Socio-economic status between sublingual and vaginal group.

3. PARITY:-

In the present study most of the patients are multigravida 86% (43/50) in sublingual group and 84%(42/50) vaginal group.

The difference in the parity of the two groups is not statistically significant. (p value is 0.7805).

4. GESTATIONAL AGE IN WEEKS:-

The Range of Mean gestational age of both sublingual and vaginal group is 13 weeks to 20 weeks.

There is no statistically significant (p=0.5029) difference in both group with regard to gestational age.

In the present study there is no statistically significant difference in maternal age, parity and gestational weeks, which is similar to the study conducted by *A.YASEMNIN KARAGEYIM KARSIDAG et al., (2009)*

5. INDUCTION ABORTION INTERVAL:-

In the present study the mean interval between start of induction and vaginal delivery is shorter in the sublingual group 11.4 hours than vaginal group 15.4 hours and this difference is statistically significant. (p=0.0001). In (27/50) 54% of Sublingual group Induction Abortion Interval is 6.1 to 12 hours.

This result is compatible with the study conducted by a *A.YASEMIN, ESRA, BALINT RAMZAN(2009)* on vaginal versus sublingual misoprostol for second-trimester pregnancy termination and effect on Doppler measurements. In their study mean induction abortion interval in sublingual group 12.8 hours and vaginal group is 22 hours and was statistically significant.

6. INDUCTION OUTCOME:-

In the present study the success rate is 94% (47/50)in sublingual group and 90% (45/50) in vaginal group. There is no statistically significant difference in success rate between sublingual and vaginal group. Thus both sublingual and vaginal misoprostol is equally effective in inducing second trimester abortion.

This results is similar to study conducted by *BHATTACHARJEE : SHYAMA PRASA SAHA : SAMEI CHANDRA GHOSTRY (2008)* Their study concluded as both sublingual and vaginal administration of misoprostol are equally effective in inducing medical abortion during second trimester.

The study by *CALISKAN et al*(2005) Showed sublingual administration of misoprostol for second trimester abortion results in a higher success rate than vaginal misoprostol.

Tang et al study (BJOG:2004) showed vaginal misoprostol had a higher success rate than that of sublingual misoprostol for first 24 hours but the abortion rate was similar in 48 hours.

Failure rate is 6% (3/50) in sublingual group and 10% (5/50) in vaginal group. Those patients who were not aborted after 24 hours were reassured and further treated with one of the following measures.

Methods	**No. of Patients**	
	Sublingual	**Vaginal**
Second Course of Misoprostol	2	2
Bougie insertion	-	2
Hysterotomy	1	1
Total cases	**3**	**5**

7. INDUCTION OUTCOME AND AGE:-

There is no statistical significance of age in relation to Induction outcome.

8. INDUCTION OUTCOME AND PARITY:-

The success rate is 86.7% in Primi and 92.9% in Multigravida.

There is no statistical significance of parity in relation to Induction outcome (P=0.3435)

HELENA VON HERTZEN1 et al., (2008) their study suggested that equivalence could not be made between sublingual and vaginal group in inducing second trimester abortion. Vaginal administration showed a

higher effectiveness than sublingual administration in termination second trimester pregnancies but this result was driven mainly by NULLIPAROUS Women.

9. SIDE EFFECTS:-

- Diarrhea occurred in 2 patients of sublingual group and 3 patients of vaginal group.
- Fever occurred in 3 patients of vaginal group.
- Vomiting occurred in 3 patient of sublingual group and 1 patient of vaginal group.

Thus side effects occurred in less number of patients (12/100 patient)

There is no statistically significant difference in side effect between two groups.

A.YASEMIN KARAGYIN KARSIDAG et al.,(2009) in this study there is no statistically significant difference between sublingual an vaginal group. In this study the side effects were nausea, vomiting, diarrhea and fever.

BHATTACHARJEE NABENDU et al., (2008) in this study the difference in the incidence of side effects were statistically in significant between two groups.

The result of the present study is similar to the above studies.

TANG OS, LAU WN, CHAN CC, HO PC et al., (2004), ARONSSON A et al., (2004),

In the above three study Sublingual Misoprostol was associated with a higher incidence of adverse effects especially diarrhea, fever and chills.

10. CHANGE IN HEMOGLOBIN VALUE (GM%):-

The mean hemoglobin at induction is 9.04 gm in sublingual group and 9.22 gm in vaginal group.

The mean Hemoglobin after expulsion is 9.01 in sublingual group and 9.18 in vaginal group.

The change in Hemoglobin value before and after expulsion is not statistically significant between sublingual and vaginal group.

SUMMARY

SUMMARY

This study 'A' Prospective comparative study of sublingual versus vaginal misoprostol in second trimester termination of pregnancy is conducted in Department of Obstetrics and Gynaecology in Madurai Medical College, Madurai. The result of the analysis of the study is summed up as follows:

Group A- Sublingual misoprostol – 50 patients

Group B- Vaginal misoprostol – 50 patients

- 70% of the patients were between 20- 29 years of age in sublingual and 72% in vaginal group.
- All patients belong to lower socio-economic status.
- 86% of the patients were multigravida in sublingual group and 84% in vaginal group.
- Mean gestational age is (16.4 $\pm$ 2.4 weeks) in sublingual group and (16.2 $\pm$ 2.6 weeks) in vaginal group.
- There is no statistically significant difference in age, socio economic status parity and gestational age in weeks between sublingual and vaginal misoprostol groups.
- Induction to Abortion interval is shorter in sublingual group (11.4 $\pm$ 4.9 hours) than vaginal group (15.4 $\pm$ 5 hours) and is statistically significant.
- There is no statistically significant difference in success rate between sublingual and vaginal group .

- There is no statistical significance of age in relation to Induction outcome. (p = 0.1215)
- There is no statistical significance of parity in relation to Induction outcome.(p = 0.3435)
- Side effects occurred in less number of patients. 10% in sublingual group and 14% in vaginal group.
- The change in Hemoglobin value before and after expulsion is not statistically significant between sublingual and vaginal group.

CONCLUSION

CONCLUSION

- Misoprostol is equally effective in both sublingual and vaginal route in inducing second trimester abortion.

- Expulsion is more rapid with sublingual misoprostol than vaginal misoprostol.

- Misoprostol is a safe drug with minimal side effects.

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PROFORMA

A PROSPECTIVE COMPARATIVE STUDY OF SUBLINGUAL VERSUS VAGINAL MISOPROSTOL IN SECOND TRIMESTER TERMINATION OF PREGNANCY

Serial No:	**Name Code:**	**Hospital No.:**
Date of Admission:	**Date of Expulsion:**	**Date of Discharge:**

NAME: **AGE:** **OBSTETRIC CODE:**

LMP: **GESTAIONAL AGE IN WEEKS:**

SOCIO ECONOMIC CLASS :

INCLUSION CRITERIA - Second Trimester (12 - 20wks) medical abortion (Requested termination / congenital anomalies)

EXCLUSION CRITERIA

- Bronchial asthma
- Hemorrhagic disorders
- Cardiac disease
- Renal disorder
- Jaundice
- Scarred uterus
- Known allergy to prostaglandin

GENERAL EXAMINATION **SYSTEMIC EXAMINATION**

PR BP CVS
TEMP: RS

INVESTIGATIONS: Hb% Blood Sugar: CT : USG:

Urea: BT :

Sr Creatinine:

OBSTETRIC EXAMINATION:

P/A Uterus Size FH

S/E P/V Cervix

Group A: Sublingual misoprostol 400 μg every 4 hrs

Group B: Vaginal misoprostol 400 μg every 4 hrs

Time of Administration of First dose of Misoprostol:

Time of onset of Uterine contraction:

	Group A (Sublingual)	**Group B (Vaginal)**
No. of Misoprostol Doses		
Interval between induction and onset of active labour (hrs)		
Interval between induction and abortion in (hrs)		
Duration of Oxytocin acceleration (hrs)		

Time of expulsion :

Outcome : 1) Success (expulsion of products of conception within 24hrs of misoprostol administration)

2) Failed induction

Side effects :

	Group A	**Group B**
Vomiting / Nausea		
Tachycardia		
Diarrhea		
Fever		
Headache		
Post partum hemorrhage		

Hb % after expulsion :

MASTER CHART

GROUP - A SUBLINGUAL										
S.NO	**NAME**	**AGE**	**IP.NO**	**S.C**	**OBST. CODE**	**GEST. AGE IN WKS**	**HB IN GM% AT INDUCTION**	**INDUCTION ABORTION INTERVAL**	**COMPLI-CATION**	**HB IN GM% AFTER EXPULSION**
1	DHANAM	24	002215	IV	G2P1L1	14 WKS	9.8 GMS	5 HRS 30 MIN		9.8 GMS
2	DEVI	30	002270	IV	G4P3L3	14 WKS	8.8 GMS	10 HRS30 MIN		8.8 GMS
3	PANDIAMMAL	28	002726	V	G4P3L3	13 WKS	9 GMS	9HRS		9 GMS
4	SELVI	30	002778	IV	G3P2L2	18 WKS	8.8 GMS	5 HRS 30 MIN		8.8 GMS
5	RAJESHWARI	27	030273	V	G5P3L3A1	20 WKS	8.6 GMS	8HRS 25MIN		8.6 GMS
6	PALKANI	30	002973	IV	G4P3L3	16 WKS	9 GMS	18HRS 30 MIN	VOMITING	8.8 GMS
7	MURUGESHWARI	22	003337	V	G2P1L1	18 WKS	8.2 GMS	9 HRS		8.2 GMS
8	RAJI	23	036789	IV	G3P2L2	18 WKS	8.4 GMS	24HRS		8.4 GMS
9	SIVANAMMAL	32	043214	V	G2P1L1	20 WKS	8.2 GMS	10HRS		8.2 GMS
10	SIVAGAMI	27	036786	IV	G5P4L4	18 WKS	9.4 GMS	9 HRS		9GMS
11	MUNIAMMAL	25	036788	IV	PRIMI	14-16 WKS	8.4 GMS	FAILED INDUCTION	VOMITING	8.4 GMS
12	MEKALA	26	003893	V	G3P2L2	14 WKS	9.4 GMS	6 HRS		9.4 GMS
13	KALAVATHY	37	040788	IV	G3P2L2	19 WKS	8.8 GMS	8HRS 30 MIN		8.8 GMS
14	MUTHUPANDI	34	041525	IV	G3P2L2	16 WKS	9 GMS	12HRS		9 GMS
15	KALAVATHY	27	041527	IV	G3P2L2	18 WKS	9.4 GMS	20 HRS45MIN	DIARREA	9.4 GMS
16	KALEESHWARI	26	041623	IV	G2P1L1	16 WKS	9.8GMS	17HRS 30 MIN		9.4GMS
17	PUSHPAVALLI	25	004609	V	G3P2L2	14-15 WKS	8.6 GMS	7HRS 30 MIN		8.6 GMS
18	RADHA	28	004728	V	G3P2L2	14 WKS	8.8 GMS	8HRS		8.8 GMS
19	VALLI	20	050213	IV	PRIMI	17 WKS	8.8 GMS	FAILED INDUCTION		8.8 GMS
20	BHUVANESHWARI	21	004838	IV	G3P2L2	13 WKS	9.2 GMS	7HRS		9.2 GMS
21	REENA	27	051354	V	G2P1L1	14 WKS	8.6 GMS	14 HRS 30 MIN		8.6 GMS
22	PUSHPAVALLI	22	053549	IV	PRIMI	20 WKS	9 GMS	18HRS		9 GMS
23	GOWTHAMY	20	005380	IV	G2P1L1	14 WKS	9.2 GMS	7 HRS30 MIN		9.2 GMS
24	PAVUNTHAI	32	05564	V	G3P2L2	14 WKS	8.8 GMS	7 HRS30 MIN		8.8 GMS
25	RAMUTHAI	27	005566	IV	G4P3L3	18 WKS	9 GMS	7 HRS30 MIN		9 GMS

26	RATHIDEVI	32	005586	V	G3P2L2	14 WKS	9 GMS	7 HRS30 MIN		8.6 GMS
27	BASURA BEGAM	23	005685	V	G2P1L1	18 WKS	9.2 GMS	15HRS		9.2 GMS
28	LEELA	25	005712	IV	G4P3L3	14 WKS	9 GMS	12 HRS 30 MIN		9 GMS
29	SUMATHY	29	005718	IV	G3P2L2	15 WKS	8.6 GMS	8 HRS 45 MIN		8.6 GMS
30	BACKIALAKSHMI	25	005800	V	G4P3L3	18 WKS	9 GMS	13 HRS45 MIN		9 GMS
31	KALAIVANI	30	05847	IV	G4P2L2A1	18 WKS	8.8 GMS	20 HRS 30 MIN		8.8 GMS
32	SAKILA BANU	34	005901	V	G4P3L3	18 WKS	9 GMS	22 HRS 30 MIN	DIARREA	9 GMS
33	NATHIYA	24	006000	IV	G3P2L2	13 WKS	9.6 GMS	9 HRS 15 MIN		9.6 GMS
34	MUTHUMARI	28	006261	V	G3P2L2	16 WKS	9.2 GMS	7HRS		9.2 GMS
35	MAHALAKSHMI	22	006266	IV	G2P1L1	20 WKS	10.4 GMS	FAILED INDUCTION	VOMITING	10.4 GMS
36	GEKCHI PRIYADHARSHINI	29	006363	IV	G3P2L2	16 WKS	9.2 GMS	9HRS 30 MIN		9.2 GMS
37	VIJAYALAKSHMI	33	006379	V	G3P1L1A1	14 WKS	9 GMS	21HRS		9 GMS
38	PREETHI	18	006615	IV	PRIMI	16 WKS	9.4 GMS	11 HRS 30 MIN		9.4 GMS
39	ROSI	29	007575	V	G3P2L2	20 WKS	8.8 GMS	11 HRS 30 MIN		8.8 GMS
40	KAVITHA	30	069826	IV	G4P2L2A1	14 WKS	9.2 GMS	7HRS		9.2 GMS
41	MANJULA DEVI	23	008729	IV	PRIMI	18 WKS	8.2GMS	13HRS45 MIN		8.2GMS
42	SANGEETHA	21	008107	V	PRIMI	20 WKS	9 GMS	10HRS45 MIN		9 GMS
43	VALLI	21	008126	IV	G2P2L2A1	16 WKS	9 GMS	13 HRS		9 GMS
44	REVATHY	28	008027	V	G4P3L3	16 WKS	8.8 GMS	9 HRS30MIN		8.8 GMS
45	MURUGA PRIYA	22	008243	V	PRIMI	14 WKS	10 GMS	7HRS15MIN		10 GMS
46	NAGALAKSHMI	23	008391	IV	G3P2L2	20 WKS	9.4 GMS	12HRS15MIN		9.4 GMS
47	JEYA	36	008679	V	G3P2L2	14 WKS	9.2 GMS	6HRS30 MIN		9.2 GMS
48	AMUTHA	35	008960	IV	G2P1L1	20 WKS	8.6 GMS	13 HRS20 MIN		8.6 GMS
49	SUDHA	23	009368	V	G2P1L1	14 WKS	9.8GMS	11 HRS30 MIN		9.8GMS
50	MALARKODI	24	009439	IV	G3P2L2	20 WKS	9.4 GMS	6HRS		9.4 GMS

GROUP - B VAGINAL										
S.NO	NAME	AGE	IP.NO	S.C	OBST. CODE	GEST. AGE IN WKS	HB IN GM% AT INDUCTION	INDUCTION ABORTION INTERVAL	COMPLI-CATION	HB IN GM% AFTER EXPULTION
1	MAHALAKSHMI	35	001318	IV	G3P2L2	20 WKS	9.4 GMS	17 HRS 15 MIN		9.4 GMS
2	VIJAYARANI	32	001629	V	G4G3L3	14 WKS	9.8GMS	16 HRS		9.6GMS
3	GOWRI	35	001689	IV	G4P3L3	14 WKS	10 GMS	15HRS		10 GMS
4	KAMATCHI	32	001691	V	G4P3L3	16 WKS	10GMS	23 HRS		10 GMS
5	MEENA	28	018928	IV	G3P2L2	18 WKS	9.2 GMS	19 HRS 30 MIN		9.2 GMS
6	LAKSHMI	29	020601	V	G2P1L1	18 WKS	8.6 GMS	23HRS		8.6 GMS
7	VASIAMMAL	28	000885	IV	G1P3L3	14 WKS	9.2 GMS	9 HRS45 MIN		9.2 GMS
8	LOHESHWARI	30	002727	IV	G3P3L2	14 WKS	9.4 GMS	9HRS45 MIN		9.4 GMS
9	LAKSHMI	23	002818	V	G2P1L1	14 WKS	9.2 GMS	14HRS		9.2 GMS
10	ANGALESHWARI	28	002865	IV	G2P1L1	14 WKS	8.8 GMS	18HRS 30 MIN		8.8 GMS
11	VELLAIYAMMAL	30	003008	IV	G4P3L3	14 WKS	9.2 GMS	8 HRS30 MIN		9.2 GMS
12	PONIRUL	24	033133	V	G3P2L2	20 WKS	9.2 GMS	FAILED INDUCTION		9.2 GMS
13	RAJALAKSHMI	21	003138	IV	G3P2L2	16 WKS	9 GMS	22 HRS 30 MIN	FEVER	9 GMS
14	NANSARA PARVEEN	19	035823	IV	PRIMI	13 WKS	9 GMS	13 HRS30 MIN		9 GMS
15	SHANTHI	22	037128	IV	G2P1L1	16 WKS	9.8 GMS	15HRS		9.8 GMS
16	VELLAIYAMMAL	31	003000	V	G4P3L3	13 WKS	-	14 HRS 30 MIN		-
17	MAHESHWARI	28	003542	V	G3P2L2	19 WKS	8.8 GMS	FAILED INDUCTION	FEVER	8.4GMS
18	SUDHA	24	038428	IV	G2P1L1	16 WKS	9.4 GMS	18 HRS30 MIN		9.4 GMS
19	NAGALAKSHMI	23	041353	IV	G3P2L2	16 WKS	9.2 GMS	FAILED INDUCTION	DIARREA	9.2 GMS
20	REVATHY	26	004151	V	G4P3L3	14 WKS	9 GMS	7 HRS 45MIN		9 GMS
21	POTHUMPONNU	22	036877	IV	G3P2L2	13 WKS	9 GMS	22HRS		9 GMS
22	SHANTHI	20	004366	IV	G3P2L2	13 WKS	10 GMS	9 HRS		10 GMS
23	JEYAPANDIAMMAL	28	004484	V	G3P2L2	14 WKS	9 GMS	8 HRS		9 GMS
24	SAHILA BANU	28	004795	IV	PRIMI	14 WKS	9 GMS	20 HRS	VOMITING	9 GMS
25	NITHYA	27	004645	V	G3P2L2	13 WKS	8.6 GMS	9 HRS 30 MIN		8.6 GMS
26	KASIPRIYA	20	050772	V	PRIMI	20 WKS	9.4 GMS	9 HRS45 MIN		9.2 GMS

27	RAJAMANI	21	051441	IV	PRIMI	20 WKS	9.8 GMS	14HRS15 MIN		9.8 GMS
28	CHINNAPAPU	35	052953	V	G2P1L1	14 WKS	9.8 GMS	10 HRS20 MIN		9.8 GMS
29	MUTHUMARY	20	005384	IV	G2P1L1	20 WKS	8.8 GMS	13 HRS		8.8 GMS
30	MALAR	23	054870	V	G3P2L2	20 WKS	10 GMS	10HRS15 MIN		9.6 GMS
31	SUMATHY RANI	26	005426	IV	PRIMI	19 WKS	8.6 GMS	22 HRS 30 MIN	DIARREA	8.6 GMS
32	BACKIYAM	23	005321	V	G3P2L2	15-16 WKS	8.4 GMS	21 HRS15 MIN		GMS
33	VASANTHI	28	055127	IV	G2P1L1	20 WKS	9.2 GMS	17 HRS 30 MIN		9 GMS
34	BASARIYA BEGAM	22	005685	V	G2P1P1	16 WKS	8.8 GMS	21 HRS 20 MIN	FEVER	8.8 GMS
35	MASILAKSHMI	21	060408	IV	PRIMI	20 WKS	9 GMS	14 HRS		9 GMS
36	JEYARANI	32	006047	V	G3P2L2	20WKS	9.4 GMS	19 HRS30 MIN		9.4 GMS
37	MATHI	25	006248	IV	G4P3L3	14 WKS	8.8 GMS	5 HRS 10 MIN		8.8 GMS
38	PANDIAMMAL	29	063055	V	PRIMI	14 WKS	10 GMS	9 HRS 15 MIN		9.6 GMS
39	KALA	26	006682	IV	G3P2L2	16 WKS	9.2 GMS	FAILED INDUCTION		9.2 GMS
40	ALAGURANI	26	007961	V	G2P1L1	16 WKS	10.2 GMS	FAILED INDUCTION		10.2 GMS
41	KAVITHA	30	069826	V	G4P2A1	14 WKS	9 GMS	12 HRS		9 GMS
42	LAKSHMI	30	008439	IV	G2P1L1	20 WKS	9.4 GMS	18 HRS 30 MIN		9.4 GMS
43	PANCHAVARNAM	23	008925	IV	G3P2L2	13 WKS	9.8 GMS	14 HRS45 MIN		9.8 GMS
44	MEENAKSHI	35	008098	V	G3P2L2	16 WKS	9 GMS	15 HRS		9 GMS
45	MUTHULAKSHMI	25	009638	IV	G4P3L3	20 WKS	9 GMS	10 HRS 30 MIN		9 GMS
46	VASUKI	28	009577	V	G3P2L2	18 WKS	8.8 GMS	17 HRS		8.8 GMS
47	CHITHAYI	26	008210	V	G3P2L2	14 WKS	8.8 GMS	19HRS45 MIN	DIARREA	8.6 GMS
48	KAMATCHI	24	008879	IV	G3P2L2	13 WKS	9.2 GMS	18 HRS		9.2 GMS
49	THOTTESHWARI	28	009383	V	G3P2L2	16 WKS	8.8 GMS	13 HRS15 MIN		8.8 GMS
50	NADHIYA	19	007892	IV	PRIMI	20 WKS	9 GMS	22 HRS		9 GMS