COMPARATIVE STUDY OF "MIFEPRISTONE PLUS VAGINAL MISOPROSTOL" VERSUS "VAGINAL MISOPROSTOL ALONE" FOR SECOND TRIMESTER ABORTION

A Dissertation submitted to

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(BRANCH II)

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CHENNAI – 600 001.

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This is to certify that the dissertation entitled **"COMPARATIVE STUDY OF MIFEPRISTONE PLUS VAGINAL MISOPROSTOL VERSUS VAGINAL MISOPROSTOL ALONE IN SECOND TRIMESTER ABORTIONS"** is a bonafide work done by Dr. P.Anitha at R.S.R.M. Lying in Hospital, Stanley Medical College, Chennai . This dissertation is submitted to the Tamilnadu Dr.M.G.R. Medical University, Chennai, in partial fulfilment of University rules and regulations for award of M.S. Degree in Obstetrics and Gynaecology.

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DECLARATION

I, **Dr.P. ANITHA,** declare that I carried out this work on **"COMPARATIVE STUDY OF MIFEPRISTONE PLUS VAGINAL MISOPROSTOL VERSUS VAGINAL MISOPROSTOL ALONE IN SECOND TRIMESTER ABORTIONS"** has been prepared by me.

This is submitted to the Tamilnadu DR. M. G. R. Medical University, Chennai in partial fulfilment of the rules and regulation for the M. S. Obstetrics and Gynaecology. This has not been submitted previously by me for the award of any degree or diploma from any other University.

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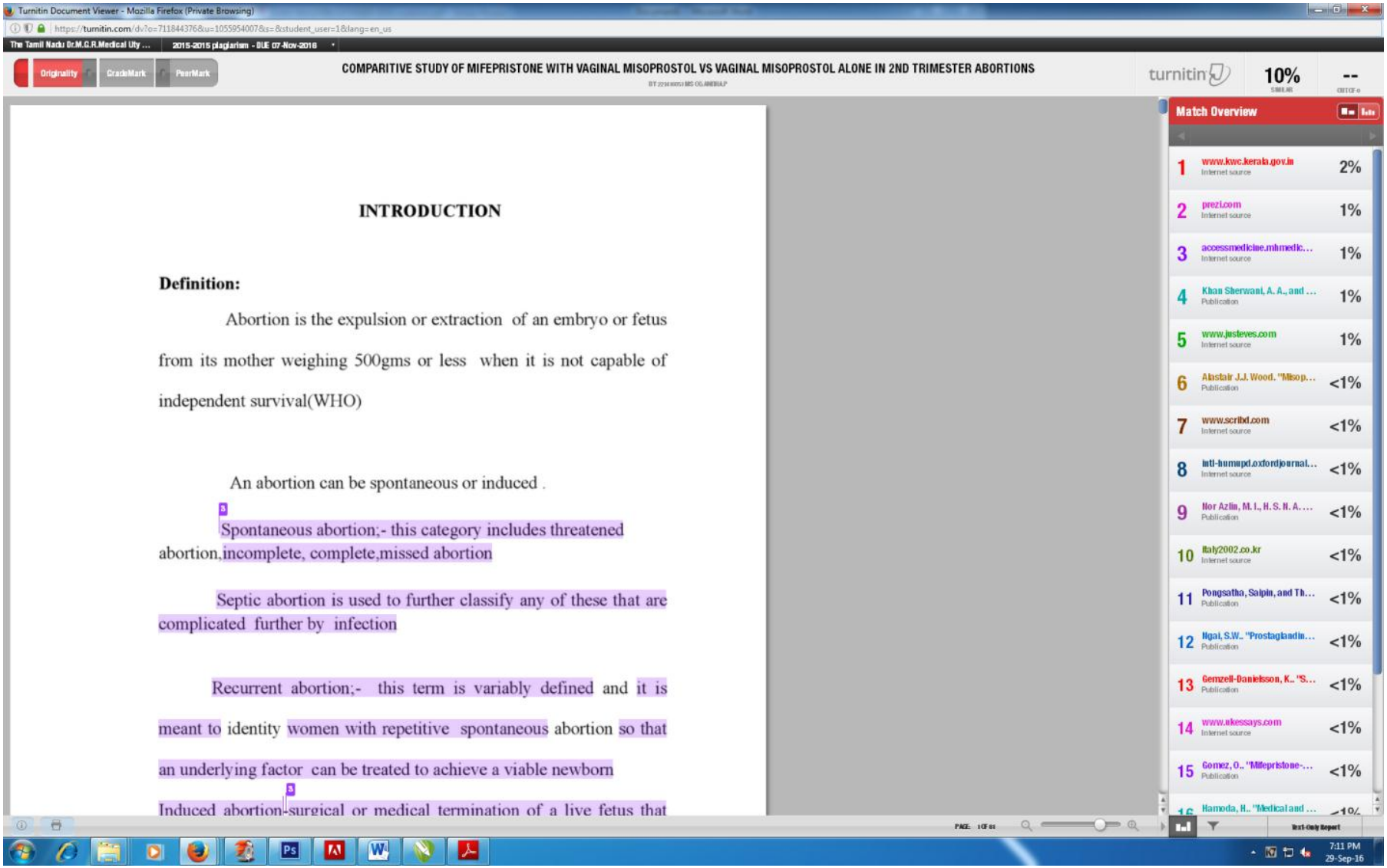
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INTRODUCTION
Definition:
Abortion is the expulsion or extraction of an embryo or fetus from its mother weighing 500gms or less when it is not capable of independent survival(WHO)
An abortion can be spontaneous or induced .
Spontaneous abortion;- this category includes threatened abortion,incomplete, complete,missed abortion
Septic abortion is used to further classify any of these that are complicated further by infection
Recurrent abortion;- this term is variably defined and it is meant to identity women with repetitive spontaneous abortion so that an underlying factor can be treated to achieve a viable newborn
Induced abortion-surgical or medical termination of a live fetus that
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INTRODUCTION

Definition:-

Abortion is the expulsion or extraction of an embryo or fetus from its mother weighing 500gms or less when it is not capable of independent survival. (WHO)

An abortion can be spontaneous or induced.

Spontaneous abortion;- this category includes threatened abortion, incomplete, complete, missed abortion.

Septic abortion is used to further classify any of these that are complicated further by infection.

Recurrent abortion:- this term is variably defined and it is meant to identity women with repetitive spontaneous abortion so that an underlying factor can be treated to achieve a viable new born

Induced abortion-surgical or medical termination of a live fetus that has not reached the period of viability.

About 10-20% of pregnancies end in miscarriage, 10% are induced. Before 16th week most of the miscarriages occur and about 80% occur before 12th week of gestation.

According to the American college of obstetrics and gynaecology (2011); the most effective way to reduce abortions is to prevent unwanted and unintended pregnancies.

Second trimester termination of pregnancy can be done either by medical or surgical method.

Use of the prostaglandin and mifepristone had made second trimester termination of pregnancy effective and safe.

The prostaglandin analogue –misoprostol was introduced in 1970, it was given by Vaginal / Oral/ Buccal /sublingual routes.

Antiprogestin- mifepristone was introduced in 1980-Shortened the induction-abortion interval, dosage of misoprostol required has been reduced though the cost is high.

The present study is compare the abortifacient efficacy of mifepristone with vaginal misoprostol and using misoprostol alone in the mid trimester abortion.

MTP ACT

Medical termination of pregnancy (MTP) was passed in the Indian parliament in 1971 and it was implented from April 1972. The implented rule and regulations were again revised in 1975 for approval of places and to make services more available and to eliminate time Consuming procedures.

Indications for termination of pregnancy:-

MTP can be performed based on four grounds:-

1. MEDICAL

2. EUGENIC

3. HUMANITARIAN

4. SOCIAL

MEDICAL GROUNDS:-

Medical grounds when the continuation of pregnancy is likely :-

- When the continuation of pregnancy would involve serious risk of life or grave injury to the physical and mental health of the patient.

- The indications are limited and scarcely justifiable now days expect in the following cases:- cardiac diseases (Grade 3 an 4)with history of decompensation in the previous pregnancy or in between the pregnancies.

    - Chronic glomerulonephritis

    - Malignant hypertension

    - Intractable hyperemesis

    - Cervical or breast malignancy

    - Diabetes mellitus with retinopathy

    - Epilepsy or psychiatric illness with advice of the psychiatrist

EUGENIC GROUNDS:-

This is done under the provision of substantial risk of the child being born with serious physical and mental abnormalities so as to be handicapped in life.

The indication is rare :-

- Structural (Anencephaly)

- chromosomal (Downs syndrome)

- genetic (haemophilia) abnormalities of the fetus

- When the fetus is likely to be deformed due to the action of teratogenic drugs (warfarin) or radiation exposure(>10rad) in early pregnancy.

-Rubella viral infection affecting in the first trimester is an indication for termination.

HUMANITARIAN GROUNDS

Humanitarian grounds when pregnancy is caused by rape or incest.

SOCIAL GROUNDS:-

Social grounds when

- Pregnancy caused by as a result of contraceptive failure

VALID LEGAL CONSENT:-

Pregnancy can be terminated in a minor girl (below the age of 18 yrs) and lunatics cannot be terminated without written consent of the parents or legal guardian (INDIAN LUNATIC ACT 1912)

Pregnancy can be terminated on the written consent of the woman, husband consent is not required.

THE PLACE WHERE MTP CAN BE PERFORMED:-

The act stipulates that no MTP can be performed at any place other than.

1. At hospital established or maintained by Government.
2. A place recognized and approved by the government, under this act.

RECOMMENDATIONS:-

In the revised rules, a registered medical practitioner is qualified to perform an MTP:-

- One has assisted in atleast 25MTP in an authorized center and having a certificate
- 6months house training in obstetrics and gynaecology
- Diploma or degree holders in obstetrics and gynaecology
- Pregnancy can be terminated upto 20 weeks. When the pregnancy exceeds 12 weeks, opinion of two medical practitioners is required

COMPLICATIONS OF MTP:-

- There is no universally safe and effective method which is applicable in all cases. However the complications are less 5% if termination is done before 8 weeks by MVA or suction evacuation.

- The complications are about five times more in mid- trimester abortions. But the use of Prostaglandins has made mid trimester abortions effective and same.

- The complications are either related to the methods employed or the abortion process.

MORTALITY:-

- Below 8wks of gestation-0.5%

- 9-12 weeks of gestation -1.6%

- 11-12 weeks of gestation- 3.3%

- Risk is found to be increased every 50% at every week of gestation

Immediate complications:-

- Injury to the cervix (cervical lacerations).
- Uterine perforation during D&E.
- Haemorrhage and shock due to trauma, incomplete abortion, atonic uterus, or rarely coagulation failure.
- Thromobosis or embolism.
- Postabortal triad of pain, bleeding and low grade fever due to retained clots or products. Antibiotics should be continued, may need repeat evacuation.

Related to the methods employed;

Prostaglandins:- intractable vomiting, diarrhoea, fever, uterine pain, cervicouterine injury.

Oxytocin:-

Water intoxication, convulsions which occur rarely

REMOTE:-

Gynaecological complications:-

- menstrual disturbances,
- chronic pelvic pain,
- infertility due to cournal block,
- scar endometriosis (1%),
- uterine synechiae leading to secondary amenorrhoea

Obstetrical complications:-

- recurrent midtrimester abortion due to cervical incompetence,
- ectopic pregnancy which is increased to threefold, preterm labour,
- dysmaturity,
- increased perinatal loss,
- rupture uterus during pregnancy and labour,
- Rh isoimmunisation,
- Asherman syndrome,
- continuation of pregnancy

AIM OF THE STUDY

- To compare the abortifacient effect of mifepristone with vaginal misoprostol and misoprostol alone in second trimester termination of pregnancy.
- Induction-abortion interval, success rate, outcome were compared.
- To compare side-effects and complications.
- To compare the cost effectiveness.

REVIEW OF LITERATURE

Termination of pregnancy in second trimester constitute 10-15% of all induced abortions second trimester abortions can be done by both medical and surgical methods.

The mortality and morbidity in second trimester termination of pregnancy is increased to 3-5times than in the first trimester abortions.

Second trimester abortion management have undergone tremendous change with advent of prostaglandin analogues. Medical methods are safer comparatively, noninvasive, have no anaesthesia complications and have advent over surgical methods. In medical abortion, success rate is 95%, morbidity is low and it has been easy accessible.

Medical abortion is improved with reduction in the risk of complication and side effects by using PG analogues and by using mifepristone prior to prostaglandins.

DRUGS USED IN TERMINATION OF SECOND TRIMESTER PREGNANCY

CARBOPROST;-

Carboprost tromethamine-250micrograms IM given every 3 hours for a maximum 10 doses can be used. The success rate is about 90% in 36 hours. It is contraindicated in cases with bronchial asthma. This PG analogues are not used nowadays.

SULPROSTONE(PGE2)

Sulprostone was used for second trimester pregnancy termination previously and it not used now as it causes myocardial infarction and coronary vasospam

Gemeprost (PGE1) analogue :-

Gemeprot can be used in the second trimester termination of pregnancy as vaginal pessary .1mg of vaginal pessary every 3-6hoursfor five dodes in 24 hours has got about 90%. The mean induction-abortion interval was 14-16 hrs.

PROSTAGLADINS:-

Cervical ripening induced by prostaglandins by :-

- directly acting on the cervix

- by myometrial activity stimulation

A significant role is played by prostaglandin analogues in regulation uterine contractility as the receptors present throughout pregnancy.

Prostaglandins Oxygenated metabolites of C20 carboxylic acid and in the most of the biological tissues they are naturally found .They are modulators of cell function and through G- protein receptors

The term prostaglandin was coined by VON EULER in 1935 after isolating a substance from accessory glands of male genital tract.

CHEMISTRY:-

Prostaglandins are the biologically active derivatives of 20 carbon atom polyunsaturated essential fatty acids that are released from cell membrane phospholipids. They are major lipid derived phospholipids. Prostaglandins are considered to be the derivatives of prostanic acid. It has a five membered ring and two side chains projecting in opposite directions at right angle to the plane of the ring.

There are many series of prostaglandins designated as (A, B, C, D, E, F, G, H, I). Each series has members with the subscript 1, 2, 3 indicating the number of double bonds in the side chains.

Prostaglandins E2, PGF2α and 15—methyl PGF2α are potent uterine stimulants, especially in the later part of the pregnancy and cause ripening of the cervix.

Prostaglandins are derived from arachidonic acid present in the membrane phosolipids. The cyclooxygenase (COX) Pathway generates Prostaglandins with ring structure.

Natural prostaglandins are unstable compounds that lack specificity and are tolerated poorly , these disadvantages are evaded by the synthetic prostaglandins like misoprostol.

MISOPROSTOL:-

Misoprostol is a longer acting synthetic PGE1 analogue (15-hydroxy – 16 hydroxy – 16 methyl PGE1 – which has been initially developed for prevention and treatment of peptic ulcer . 100mcg and 200 mcg of misiprostol is manufactured and it can be used as orally, vaginally, rectally.

Pharmacology:-

Misoprostol is quickly absorbed and deesterised to its active pharmacological form misoprostol acid. When administrated orally, peak level in plasma is attained in 30 minutes and it rapidly declines with a half life of 20 minutes.

It is metabolised primarily in the liver, and is excreted in urine. Dose of the drug needs to be adjusted in liver disease. In renal disease and in dialysis patients , dose needed not to be adjusted. Cytochrome P-450 enzyme system is not affected by misoprostol.

Misoprostol binds toEP2/EP3 receptor and thus it is found to be an efficient uterotonic agent.

Misoprostol when administrated vaginally have more advantage in reducing gastrointestinal side–effects and on reproductive tract, profound effect is exerted and plasma concentration peak is reached in one to two hours and it declines slowly.

Oral misoprostol given has less systemic bio availability when compared to vaginal misoprostol.

Intrauterine pressure is increased by 8 and 25 minutes and maximum is reached by 25 and 46 minutes, respectively when misoprostol is administrated orally or vaginally. Vaginal administration of misoprostol causes maximum uterine contractility and long lasting action than by oral administration.

Buccal misoprostol is also found to be effective but it causes tach systole .

SIDE-EFFECTS:-

- Nausea, vomiting,
- headache, malaise, skin rash, fever,
- diarrhoea.
- abdominal cramps.
- chills.
- rigor and fever.

All these side effects are dose dependent.

TERATOGENICITY

Misoprostol causes (Moebius syndrome) in infants

Malformations :-

Transverse limb defects

- Ring shaped constrictions of extremities
- Arthrogryposis
- Holoproscencephaly
- Hydrocephalus
- Exstrophy of the bladder

OTHERS USES OF MISOPROSTOL:-

- Second trimester induction of labour
- Third trimester for induction of labour
- In postpartum hemorrhage as a second line drug
- Cervical ripening prior to curettage
- NSAID induced gastric ulcers

MIFEPRISTONE:-

Mifepristone commonly known as RU-486 named after Roussel Ulcaf company who designed the drug. Mifepristone is a 19 nortestosterone with weak antiprogestogenic effect with a bulky-dimethylamino phenyl substituent at 11 position which induces or stabilies an inactive receptor conformation at 11β position, hydrophobic 1 propyl substituent at 17α position increases its progesterone receptor binding affinity.

Mifepristone has significant antiglucocorticoid and antiandrogenic activity.

Mifepristone is a partial agonist and competitive antagonist. At both A and B forms of prostaglandins. In the absence of progesterone (during anovulatory cycles or after menopause) it exerts weak progestational activity- induces predecidual changes , there fore it is now regarded as (progesterone receptor modulator).

Administration of the drug (150mg) during the first 3 days of the follicular phase has no effect on the menstrual cycle. Drug administration in the late luteal phase causes luteolysis and prevents pregnancy.

In medical abortions, mifepristone act by :

- blocking the progesterone receptors directly acting on
- endometrium causing decidual degeneration,
- causes cervical softening and dilatation,
- releases endogenous prostaglandins,
- also increases the sensitivity of myometrium to the contractile effects of exogenous prostaglandins and it shortens induction – abortion interval and reduction in doses of prostaglandins required.

The sensitivity to prostaglandins is about 5 fold increased by administrating mifepristone 24-48hrs prior to prostaglandins. In women with midtrimester abortions, fetal cord blood concentrations of mifepristone ranges from 200ng/ml (30minutes) to 400ng/ml (18hrs) following single oral dose of 100mg.

In 12 hrs. the peak maternal concentration is 1500ng/ml and fetal; maternal ratio is 0.33. Mifepristone 200mg is found to be effective than 600mg when given prior to prostaglandins in inducing medical abortions.

PHARMOKINECTICS:-

Mifepristone has a half-life of 26- 30hrs and it is bioavailability is 60% It is largely metabolized in liver by CYP3A4 .It is excreted in bile and faeces.

By binding to alpha acid glycoprotein ,mifepristone is found to be saturated quickly. It interacts with CYP 3A4 inhibitors (erythromycin, ketoconazole) and About 85% of the drug is absorbed after oral therapy inducers (rifampicin, anticonsvulsants)

SIDE EFFECTS

- Headache (5%)
- Gastrointestinsl symptoms of nausea, vomiting (3.5%)
- Diarrhoea
- Faintness, skin, rash
- Endometrial hyperplasia by reducing progesterone effect
- Low potassium and increase in creatinine level

Contraindications:-

- Adrenal failure
- In presence of IUCD
- Ectopic pregnancy
- Hypertension, anaemia, glaucoma, cardiovascular disease, smoker, asthmatic
- Adrenal failure
- Hemorrhagic disorders
- Inherited porphyrias
- Woman on anticoagulant, glucocortoid therapy
- Previous uterins scar, scar rupture can occur with misoprostol
- Lactating woman

Less common:-

- cough
- headache
- heartburn
- stuffy or runny nose
- tightness of chest or wheezing
- troubled breathing

OTHER USES:-

- uterine fibroids
- endometriosis
- glaucoma
- breast cancer-meningomas
- prostate cancer
- ovarian cancer
- cushing syndrome
- as emergency contraceptive

VARIOUS STUDIES OF MISOPROSTOL

ROUTES OF ADMINISTRATION:-

vaginal versus oral

Bebbington et al conducted a randomized study where two protocols of usage of misprostol – oral vs vaginal was compared in second trimester abortions. In this study, misoprostol 200microgram given vaginally every hour for 3 hours followed by 400micrograms every four hours orally or vaginally. In this study, induction to abortion interval in the vaginal group is shorter (14.5hrs) when compared to oral group (19.6hrs) significantly. In vaginal group-febrile morbidity was higher in vaginal group (25%) whereas in oral group(6.7).

Sublingual versus Vaginal :

Tang at el conducted a study comparing sublingual vs vaginal misoprostol 400micrograms given 3 hours upto maximum 5 doses in second trimester abortions. In this study, at 24 hours, vaginal misoprostol usage resulted in higher success rate 85% when compared to sulingual misoprostol which was 64%.At 48 hours, abortion rates were similar in both groups.

Sublingual versus oral versus vaginal :

Aronsson at el (2004) studied the effect of misoprostol on uterus contractility when given by different routes(sublingual, vaginal, oral).In this study, after 24 hrs of administration, the increase in uterine activity in these both groups was similar. In this study, there is more rapid effect on uterine contractility by sublingual route of administration.

Interval of administration:

Jain et al conducted a randomized study involving one hundred pregnant women between12-22 weeks, 200mg misoprostol administrated intravaginally, 6hrly orv12 hrly for upto 48 hrs. In 6 hrs group – incidence of abortion after 48 hrs of initial drug administration was 87.2% and for 12 hours group it was- 89.2% and mean abortion interval for 6 hrs -13.8 hrs and for 12 hrs group – it was 14 hrs. So, conclusion in this study, misoprostol was effective for second trimester abortion when administrated vaginally and there is no usage in shortening the dosage interval from 12 hrs to 6 hrs.

Comparison of dosage/dosage administration:

Herabutya et al showed in a randomized study involving one hundred and forty three women 14-26 weeks where 600 mcg or 800mcg of misoprostol is administrated intravaginally every 12hrs In study, mean abortion interval in 12hr group was 15.2hrs while in 800mcg group it was15.3hrs and complete abortion rate is 77.6%in 600mcg and in 800mcg group-72.4%.In this study, 600mcg given ever 12 hrs was considered to be the most effective for mid trimester abortions.

A study conducted by **Ramsey et al** concluded that maternal cardiac functions is not altered by high dosage vaginal misoprostol-600microgram by transthoracic electrical bioimpedence monitoring.

In a study conducted by Ramin KD, Og burn PL, Danielenko,, Ramsey PS, high dose oral misoprostol when compared with oxytocin infusion is effective in interruption of mid trimester pregnancy. In this study, induction to delivery interval in misoprostol -15.2 hrs and with oxytocin it was 21.7 hrs. In misoprostol cohort induction abortion – interval is shorter 15.2hrs but in oxytocin group it is 21.7hrs.

Comparison of misoprostol with other methods:

Chanduri et al conducted a study by comparing vaginal misoprostol with ethacridine lactate instilled extra amniotically. Induction to abortion interval in misoprostol group-15.5 hrs in ethacridine acetate – 31.3 hrs.

In a study conducted by Jain et al, misoprostol 200microgram administered every 12 hrs is more effective than 20mg PGE2 administered every 3 hrs for terminating mid trimester pregnancy.

Bluementhal et al conducted a study and concluded that misoprostol was most effective than PGE2 for second trimester abortions by comparing abortion interval, side effects and cost.

Ho et al conducted a study about the effect of vaginal vs oral misoprostol after pre-treatment with mifepristone for mid trimester termination of pregnancy. In this study, oral mifepristone 200mg given after 36 hrs, vaginal or oral misoprostol 200microgram every three hours upto maximum five doses. In vaginal groups, induction abortion interval, reduction of dose requirement and success rate were increased. Maximum dose used in vaginal group-600mcg and1000mcg in oral group.

In a study conducted by **Akory et al**, showed the result that vaginal misoprostol was found to be effective than those women given oral misoprostol and PGF2 instilled intraamniotically by comparing efficacy, outcome and acceptability.

In a study conducted by Gemzell-Danielsson, when mifepristone given 36-48hrs prior to prostaglandins had shorter abortion interval and misoprostol 400mcg administrated vaginally 3hrly to the total 5 vaginal doses. In this complete abortion rate was 97% and mean induction – abortion interval was 6hrs.

In a prospective randomized double-blind, controlled clinical trial conducted by Dickinson et al ,100 women between 14 and 28 weeks given 1 mg of gemeprost 3 hourly 5 doses, 200microgram misoprostol kept intravaginally 4 doses–6hourly. In this study, intravaginal misoprostol is proved as equally effective as gemeprost in second trimester termination of pregnancy.

In a study conducted by **Biswas et al,** vaginal administration of misoprostol 600microgram followed by 400microgram given 8 hourly upto maximum of 48 hrs compared with 2,150 ml ethacridine extraamniotic instillation.

Mean induction abortion interval in misoprostol administered intravaginally was 13.94 hrs when compared to ethacridine acetate – 28.86 hrs ($P< 0.0001$)

In this study they concluded that vaginal misoprostol is found to be effective with fewer side effects, cheaper and no complications.

Previous uterine scar/ previous caesarean:-

Daskalakis et al conducted a study where 108 patients were subjected with prior caesarean in midtrimester termination of pregnancy uterine rupture found to be reported in 1 case and in patients with no prior caesarean, uterine rupture had been reported in 1 of 216 patients.

In a study conducted by Borgatta (2011),where misoprostol was used alone vaginally or sublingually 400mcg of misoprostol is found to be effective than 200 mcg. Doses given every 3 hrs is found to be effective than less frequent dosage although intervals upto 12 hrs are effective when high doses of vaginal misoprostol. (600mcg or 800mcg)

The evidence based regimen of the Royal College of Obstetrics and Gynaecology [RCOG] – (2011)is 800microgram of vaginal misoprostol given followed by misoprostol 400microgram every 3 hrs up to maximum of 4 doses between 13-22 weeks.

As per ACOG guidelines (2013)-200mg of mifepristone given and 36-48hrs later 400microgram of misoprostol orally every 3hrs upto 5 doses or 800microgram of vaginal misoprostol given which is followed by 400microgram of oral misoprostol every 3 hrs to a maximum of 4 doses.

In a study conducted by **Pongsatha et al** (2014) among 157 women in which vaginal misoprostol loading dose regimen 600 mcg administrated, then 400 mcg given every 6 hrs compared with a non-loading dose regimen (400 mcg every 6 hrs). vaginal misoprostol in the loading dose regimen was effective than the non-loading dose regimen.

VARIOUS STUDIES OF MIFEPRISTONE :-

Dosage of administration:-

WebstarD, Templeton A conducted a randomized study by administrating mifepristone either 600mg or 200 mg 36 to 48 hrs prior to prostaglandins.

There is no significant difference in geometric mean induction abortion interval between two groups 1600microgram is the median dose of misoprostol in each group.

INTERVAL BETWEEN MIFEPRISTONE AND MISOPROSTOL:-

D.R.Urquhant and A .A. Templeton conducted a study by giving mifepristone 600mg 24, 36 & 48 hrs prior to prostaglandin extraamnioticin fusion. In this group-bleeding was not observed in any of the groups prior to prostaglandins infusion.

This study reported that mifepristone can be safely given prior to admission to the hospital for termination.

Mifepristone with misoprostol studies:-

Suk Wai Ngai, Oi Shan Tang and Pak Chung Ho, conducted a randomized study suggesting that oral misoprostol 400microgam is as effective as vaginal misoprostol 200microgram given every 3 hrs after priming with mifepristone in second trimester pregnancy termination.

In a randomized control study conducted by **El Refaey et al**, 600mg of mifepristone given orally and after 36-48 hours and in group 1- vaginal misoprostol 600mcg given followed by 400 mcg vaginally every 3 hrs and group-2 received 600mcg of misoprostol kept vaginally and 400mcg of oral misoprostol given every 3hrs upto 4 doses abortion rate in this study is 97%.

Ashok et al conducted a study by giving mifepristone 200mg orally and 36-48 hrs later, 800 microgam of misoprostol kept intravaginally then 400microgram given orally to a maximum of 4 doses at 3 hr interval. In this study, abortion rate is 97%.After the first vaginal dose, induction-abortion interval was 6.5hrs.This study shows when first dose of misoprostol given vaginally reduces the induction-abortion interval.

Haitham Hamodal, AllanTempleton, Premila W, Ashok, conducted a randomized trial by giving mifepristone 200mg and 36-48 hrs later 600microgram of misoprostol, given sublingually or 800microgram of misoprostol kept intravaginally. Then 400microgram of misoprostol given sublingually or vaginally at 3 hourly interval.

This study suggested that misoprostol when given sublingually following mifepristone is effective alternative to vaginal administration for 13-20 weeks gestation.

Rose SB, Shaud C, Simmons A conducted a prospective study among 272 women in second trimester abortion by giving mifepristone with vaginal misoprostol. This study supported that when mifepristone given prior to misoprostol reduces induction-abortion interval than misoprostol used alone.

In a retrospective analysis conducted by Sin Ee Goh, KOK Joo Thong among 386 women between 12 and 24 weeks gestation. In this study, mifepristone 200mg given orally, then 36 to 48 hrs later, 800microgram of vaginal misoprostol, 400microgram of vaginal misoprostol were given every 3hrs to a maximum 4 doses in 24hrs.

If abortion fails, 200mg mifepristone is given 3hr after the last dose of misoprostol then after 12 hrs vaginal misoprostol administrated as previous course 97.9% abortion occur within 24 hours and 99.5% within 36 hours respectively. Nulliparous woman took significantly longer time to abort. For incomplete abortion, surgical evacuation of uterus was done in about 5%.

Kapp N, Stubblefield P, Vragovic O, Moreno N conducted a randomized study, placebo controlled, double blind trial of mifepristone in termination of second trimester pregnancy using misoprostol after feticidal digoxin.

Dickinson, J.E., Brown Nell, P., McGinnis K, and NATHAN .E.A. (2010) conducted a study in second trimester termination between 14-24 weeks of gestation with fetal abnormalities diagnosed prenatally and misoprostol alone given in one group and in other group - mifepristone with misoprostol given the median induction – abortion interval in misoprostol group is 15.5hrs and in mifepristone group it is 8.6hrs which was comparatively very short.

Gynuity health projects conducting a study by giving mifepristone + buccal misoprostol vs buccal misoprostol alone for mid trimester abortion (14 – 21 weeks).

In a study of Hammond recent advances in second trimester abortion, the recommended regimen of Royal College of Obstetrics and Gynaecology. (2011)

DAY ONE:

Mifepristone 200mg given orally – 36 to 48 hrs later, misoprostol 800microgram kept intravagnally-then 3 hrs later misoprostol 400microgram given orally or vaginally every 3 hours until delivery to total of 4 doses. If undelivered after 3 hours of 4thdose, repeat 200mg of mifepristone +12 hrs later misoprostol may be recommended.

In a study conducted by Bartley+Baird-200mg of mifepristone given, 36-48 hrs later-800microgram of misoprostol vaginally followed by orally 400microgram misoprostol-4 doses every 3hrs. Success rate was 94% in 24 hrs, Induction -abortion interval was 6.1hrs.

Ngai et al conducted a study by giving 200mg of mifepristone, and 36-48 hrs later 400microgram of misoprostol given orally at 3 hrs interval to 5 doses. Success rate was 81.4% in 24 hrs. Induction -abortion interval was 10.4 hrs.

NTN Ngoc et al (2011) conducted a randomized controlled trial, that pre-treatment with mifepristone – the chance of complete uterine evacuation is more than twice -15hrs (79.8% vs 36.9%). In mifepristone + misoprostol group mean induction to abortion interval is shorter significantly-10hrs.Complete uterine evacuation in mifepristone-misoprostol group is 60%-and 20% in misoprostol only group.

Wildschut H et al (2011) did a randomized controlled trial using the combination of mifepristone and misoprostol which resulted in shortest induction-abortion interval and higher efficacy.

Wong MS et al (2012), conducted a comparative study and mifepristone plus misoprostol combination had resulted in shortest induction-abortion interval.

As per acog guidelines (2013):- 200mg of mifepristone, administered orally, and 24-48hrs later 800mcg of vaginal misoprostol administrated and 400 mcg of misoprostol administrated vaginally or sublingually 3hrly upto maximum 5 doses . 600-800mcg of misoprostol is administrated vaginally and 3 hrly 400mcg of misoprostol administrated vaginally or sublingually

RCOG Best practice in comprehensive abortion care (2015) - mifepristone 200mg is administrated orally and 24-48 hrs later, misoprostol 800mcg is administrated by vaginal route and every 3hrly 400mcg given vaginally or sublingually upto total 5 doses 600-800mcg of loading vaginal misoprostol administrated then every 3 hrly 400mcg given by vaginal or sublingual route.

MATERIALS AND METHODS

This study is designed by comparing the efficacy of mifepristone with vaginal misoprostol and with vaginal misoprostol given alone in second trimester abortion at GOVT . RSR M LYING IN HOSPITAL - CHENNAI- during August 2015-August 2016.

Study design- Prospective interventional study

Study Place- Govt. RSRM lying in hospital Chennai-

Collaborating Unit-Department of Family Welfare, RSRM

Study Population: Patients requesting abortion in their second trimester at Department of family welfare, RSRM

Period of study: August 2015- August 2016

Sample size:100 (patients were randomly subjected)

GROUP-1-50-Mifepristone+vaginal misoprostol

GROUP 2-50- vaginal misoprostol alone

Inclusion Criteria:-

- **14-20** Weeks of gestation based on menstrual history and clinical examination meet legal criteria to obtain abortion .
- Women fulfilling **MTP** indications as per **MTP** act.
- A Single live fetus.
- Present with closed cervical os, no vaginal bleeding.
- Patients consenting to this procedure only.

Exclusion criteria:-

- history of previous uterine surgery (but not a contraindication).
- Known allery or contra indications to mifepristone or misoprostol.
- Presentation in active labour.
- Lowlying placenta.
- Multiple fetus.

CONTRAINDICATION:-

- Severe asthma.
- Known or suspected ectopic pregnancy.
- Previous allergy to mifepristone and misoprostol.
- Contraindications to mifepristone-Inherited porphyria, Chronic adrenal failure, hepatic failure, coagulation disorder.
- Contraindications to misoprostol usage – glaucoma, mitral stenosis, sickle cell anemia, seizures that are poorly controlled.

Investigations done:-

- HB%
- Blood sugar, urea, creatinine,
- Urine albumin, sugar
- Blood grouping and Rh typing
- HIV
- VDRL

- ECG
- Ultrasound

Inj. Tetanus toxoid 0.5 ml is given before induction of abortion Proper consent should be obtained from the patient.

METHODOLOGY:-

Mifepristone-misoprostol group:-

Dosage schedule:-

DAY 1: Mifepristone 200mg given orally, after 36hrs pt shifted to labour ward, 800mcg misoprostol administrated vaginally, 400mcg of misoprostol administrated every 3 hrs to the total of 4 doses if undelivered mifepristone can be repeated 3 hrs after the last dose of misoprostol and 12 hrs later misoprostol may be given or termination by surgical method was considered.

Misoprostol group:-

- 800mcg of misoprostol administrated vaginally 3hrs later misoprostol 400mcg administrated vaginally every 3hrs until abortion occurs or total of 4 doses.

In case of patients with incomplete abortion, additional interventions adopted –instrumental evacuation, oxytocin infusion. Scan was done next day to check for retained products of conception.

OUTCOME:-

Complete: when both fetus or placenta were expelled within 48hrs.

Incomplete: either fetus or placenta retained.

Failure: neither fetus nor placenta was expelled.

PARAMETERS STUDIED: -

- Induction-abortion interval, complete abortion rate,
- success rate,
- side-effects
- Total number of misoprostol doses required
- Need for additional procedures like curettage, or
- oxytocin

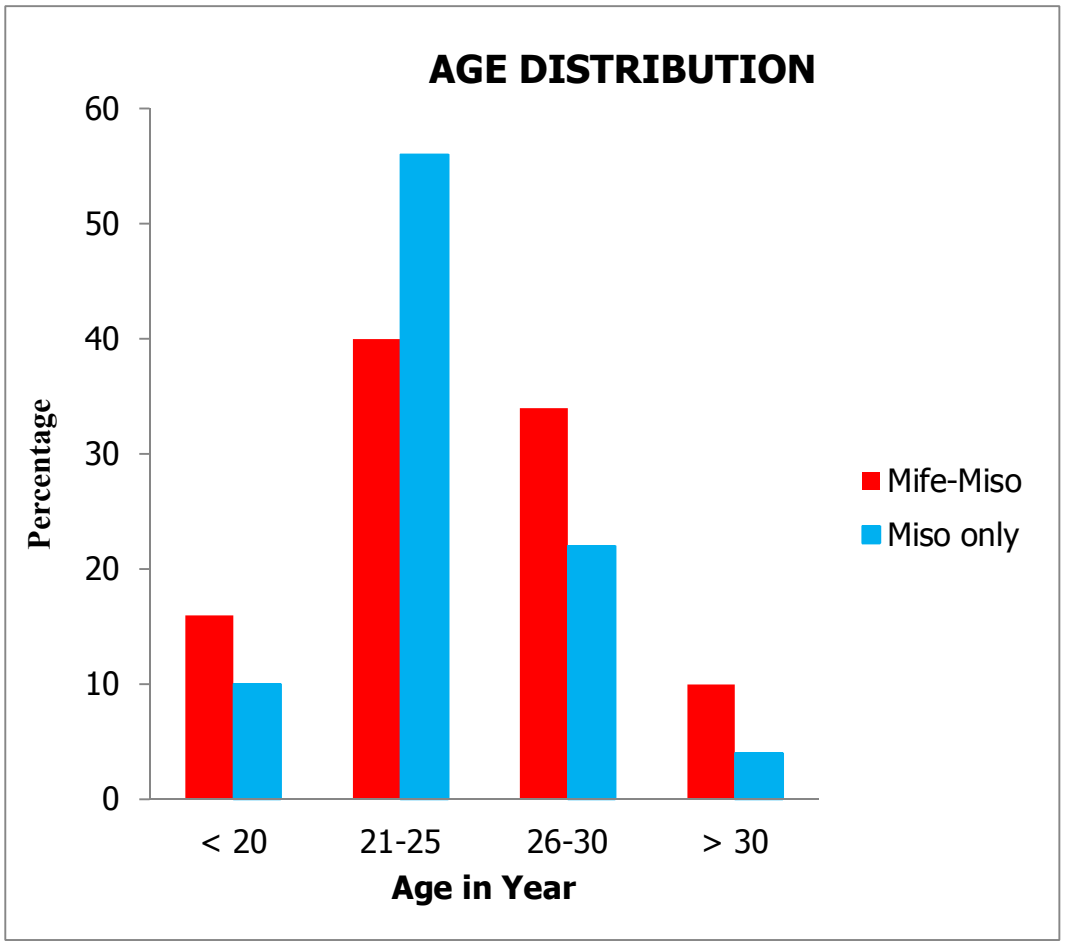
Data was analyzed using SPS version 20, Using Anova, Chi-Square test Independent sample test and p value of less than 0.05 was found to be significant.

OBSERVATION

PATIENT CHARCTERISTICS: AGE DISTRIBUTION

TABLE1: AGE DISTRIBUTION

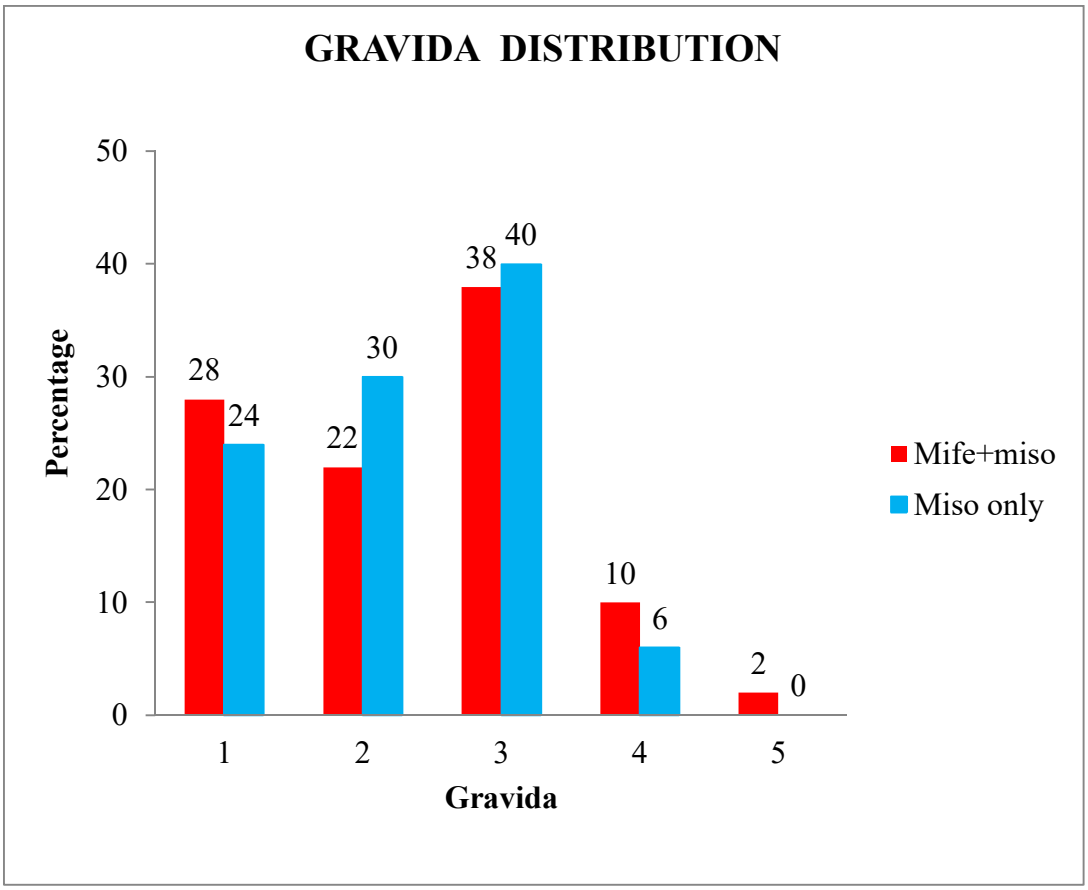
Age Group (Years)	Mife+Miso N=50		Miso only N=50		TOTAL		P VALUE
	N	%	N	%	N	%	
< 20	8	16%	5	10%	13	13%	0.679
21-25	20	40%	23	46%	43	43%	
26-30	17	34%	19	38%	36	36%	
>30	5	10%	3	6%	8	8%	
TOTAL	50	100%	50	100%	100	100%	
Mean Age In Years	25.54		25.22				
SD	4.546		4.239				



Most of the patients are in the age group of 21-25yrs in either groups.

TABLE 2: GRAVIDA

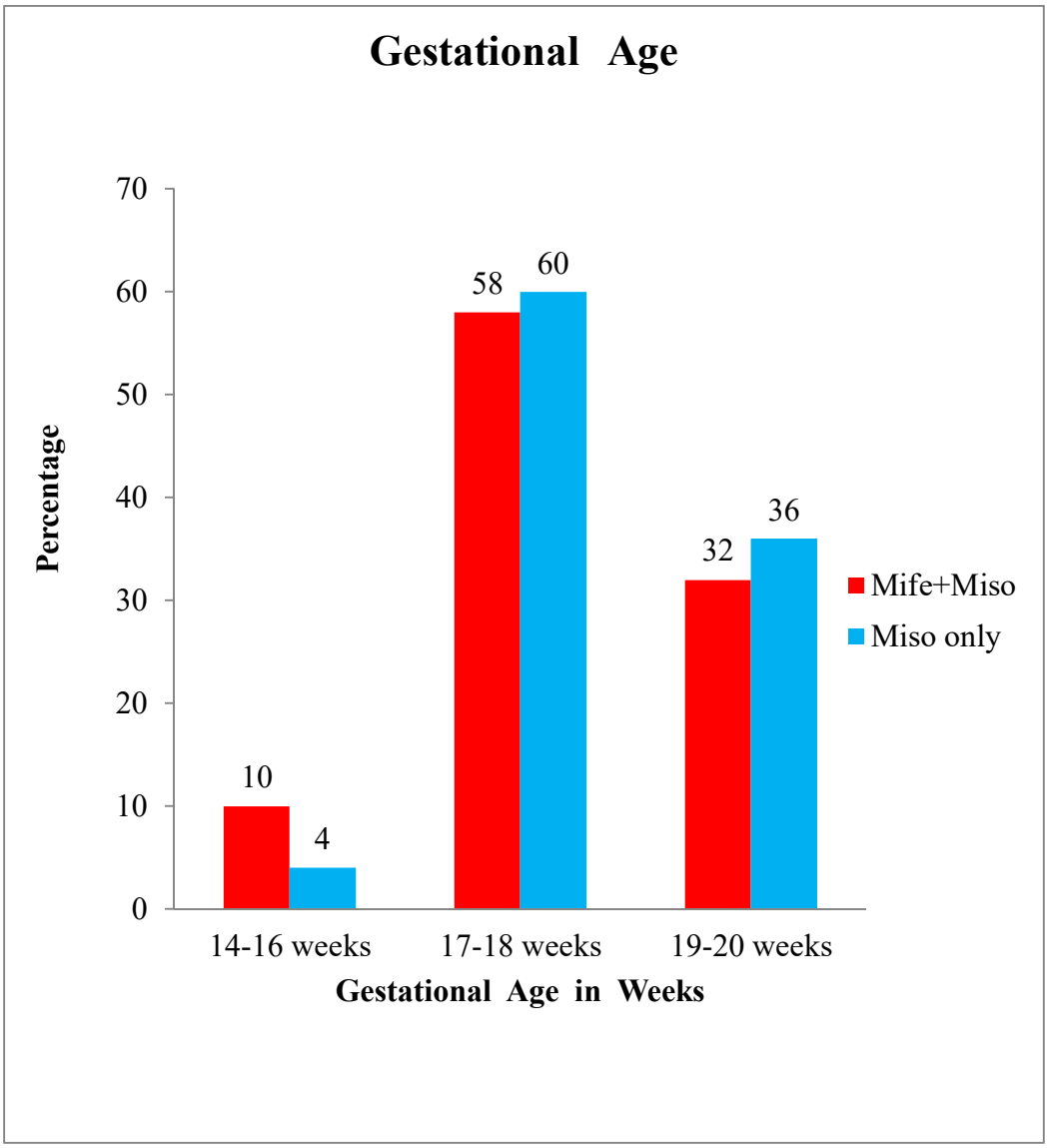
Gravida	Mife+Miso N=50		Miso only N=50		TOTAL		P VALUE
	N	%	N	%	N	%	
1	14	28%	12	24%	26	26%	0.682
2	11	22%	15	30%	26	26%	
3	19	38%	20	40%	39	39%	
4	5	10%	3	6%	8	8%	
5	1	2%	0	0%	1	1%	
TOTAL	**50**	**100%**	**50**	**100%**	**100**	**100%**	



In mifepristone + misoprostol group, gravida 3 and above -50% in misoprostol group it was -48%.

TABLE 3: GESTATIONAL AGE GROUP

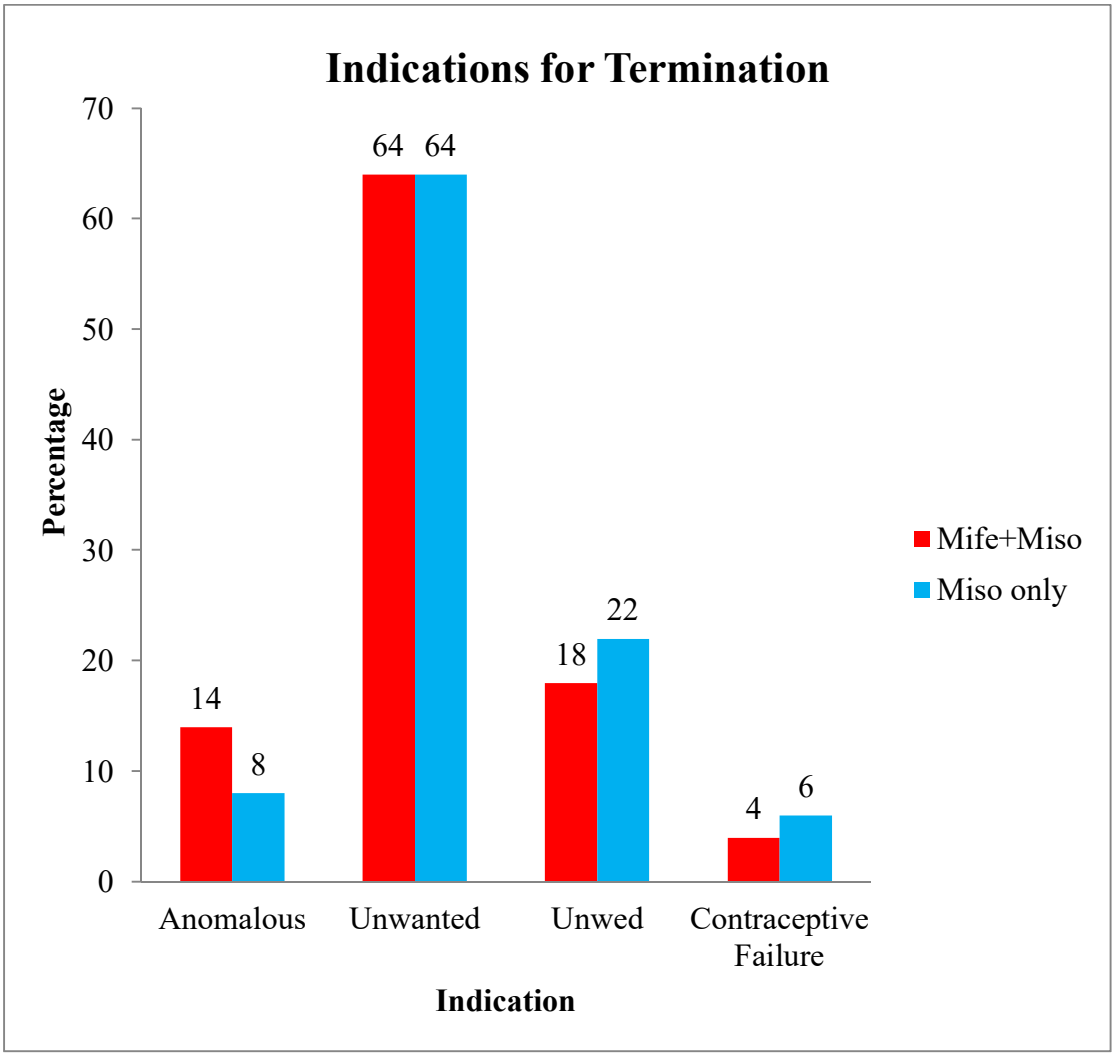
GA (Weeks)	Mife+Miso N=50		Miso only N=50		TOTAL		P VALUE
	N	%	N	%	N	%	
14-16 weeks	5	10%	2	4%	7	7%	0.492
17-18 weeks	29	58%	30	60%	59	59%	
19-20 weeks	16	32%	18	36%	34	34%	
TOTAL	50	100%	50	100%	100	100%	
Mean	18.22		18.4				
SD	1.314		1.214				



In both groups, at 17to 18wks most of the pregnancies were terminated.

TABLE 4: INDICATIONS FOR TERMINATION

Indication	Mife+Miso N=50		Miso only N=50		Total		P Value
	N	%	N	%	N	%	
ANOMALOUS	7	14%	4	8%	11	11%	0.145
UNWANTED	32	64%	32	64%	64	64%	
UNWED	9	18%	11	22%	20	20%	
CONTRACEPTIVE FAILURE	2	4%	3	6%	5	5%	
TOTAL	**50**	**100%**	**50**	**100%**	**100**	**100%**	



In both groups, unwanted pregnancies accounts for sixty four percent.

TABLE 5: INDUCTION –ABORTION INTERVAL

Induction Abortion	Mife+Miso N=50	Miso only N=50	P VALUE
Mean	8.3Hrs	13.9Hrs	<0.001** SIGNFICANT.
Std Deviation	**3.598**	**7.535**	

MEAN induction interval in in mifepristone+misoprostol group was 8.3hrs which is less when compared with misoprostol group which was 13.9hrs , found to be statistically significant.

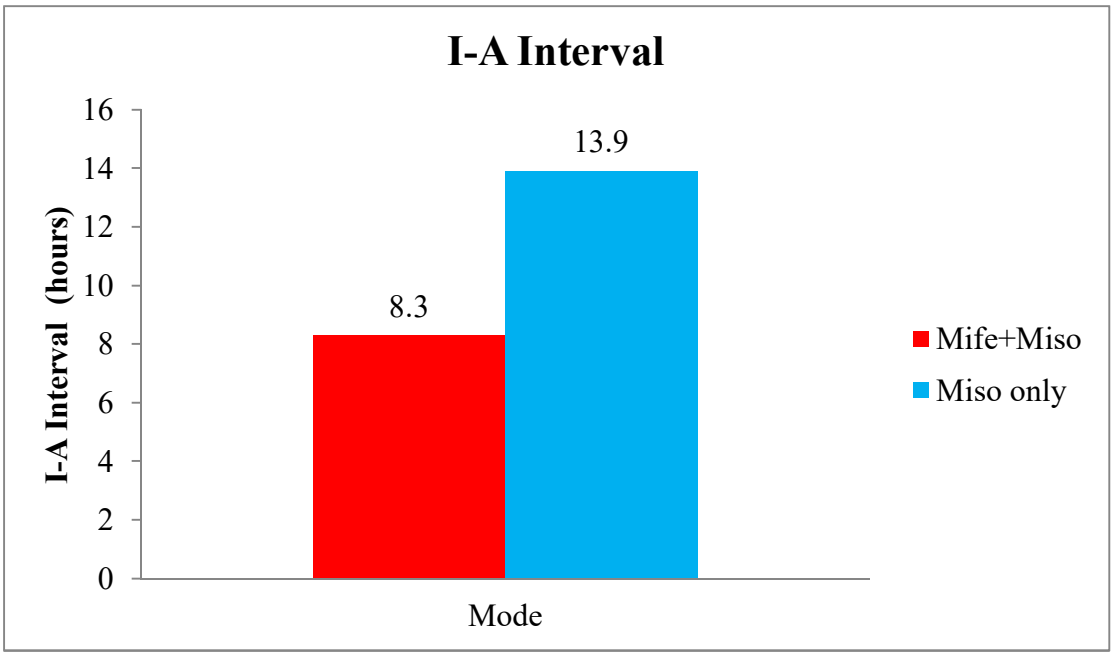
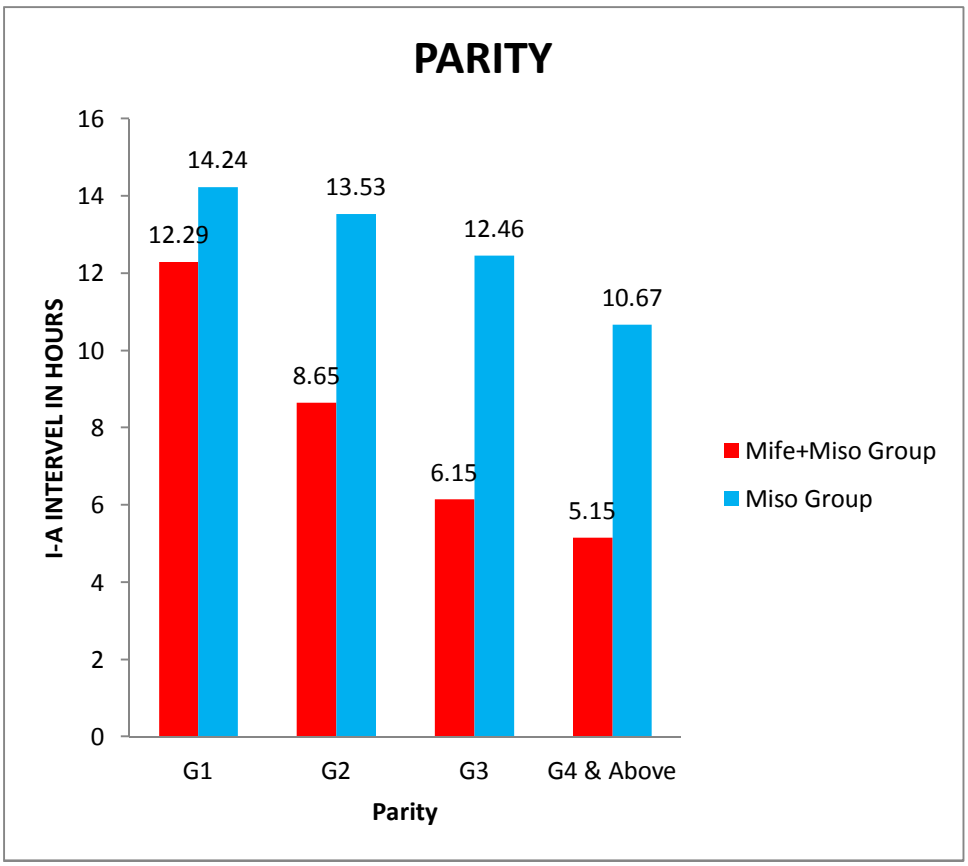


TABLE 6: INDUCTION – ABORTION INTERVAL & PARITY

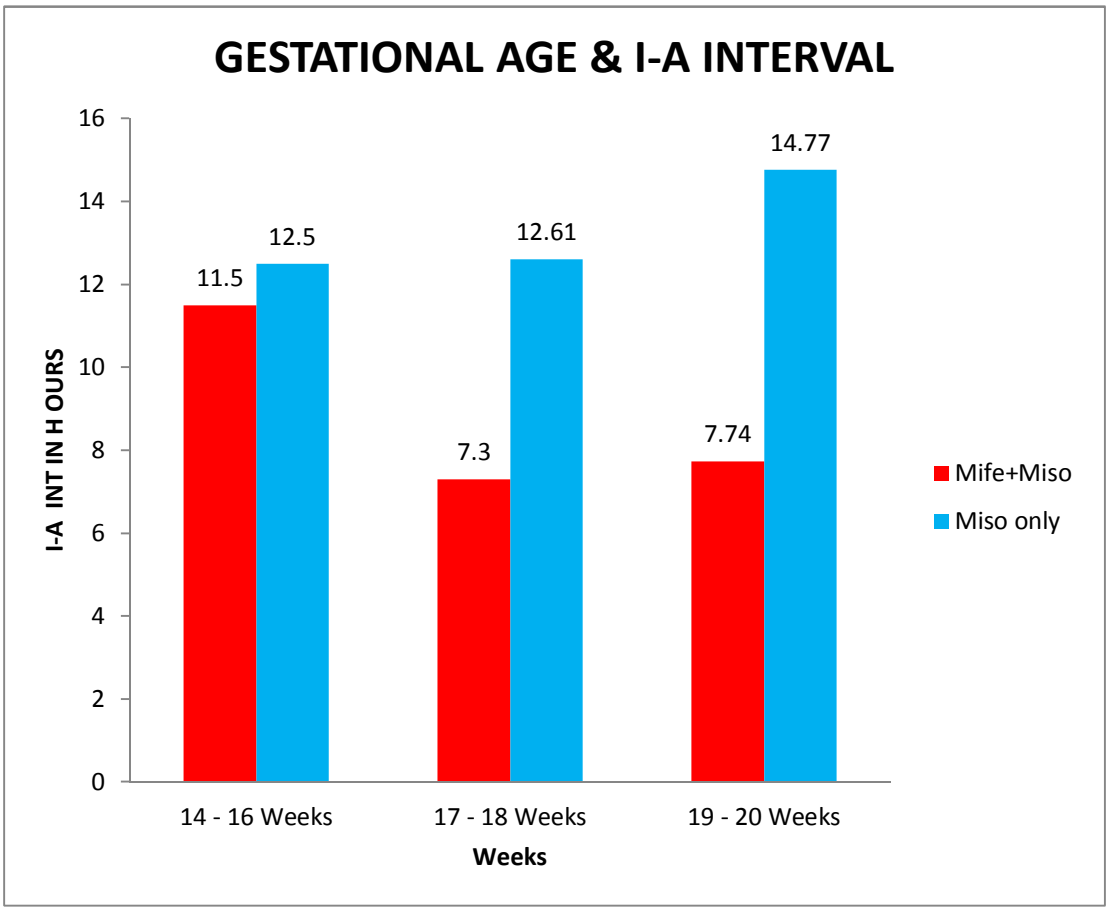
Parity	Mife+Miso Group Hrs	Miso Group Hrs
G1	12.29	14.24
G2	8.65	13.53
G3	6.15	12.46
G4 & Above	5.15	10.67
P Value	<0.001**	0.876



In Primigravida, induction abortion interval prolonged than in multigravida in both groups. It is statistically significant in mifepristone + misoprostol group

TABLE 7: INDUCTION –ABORTION INTERVAL&GESTATIONAL AGE

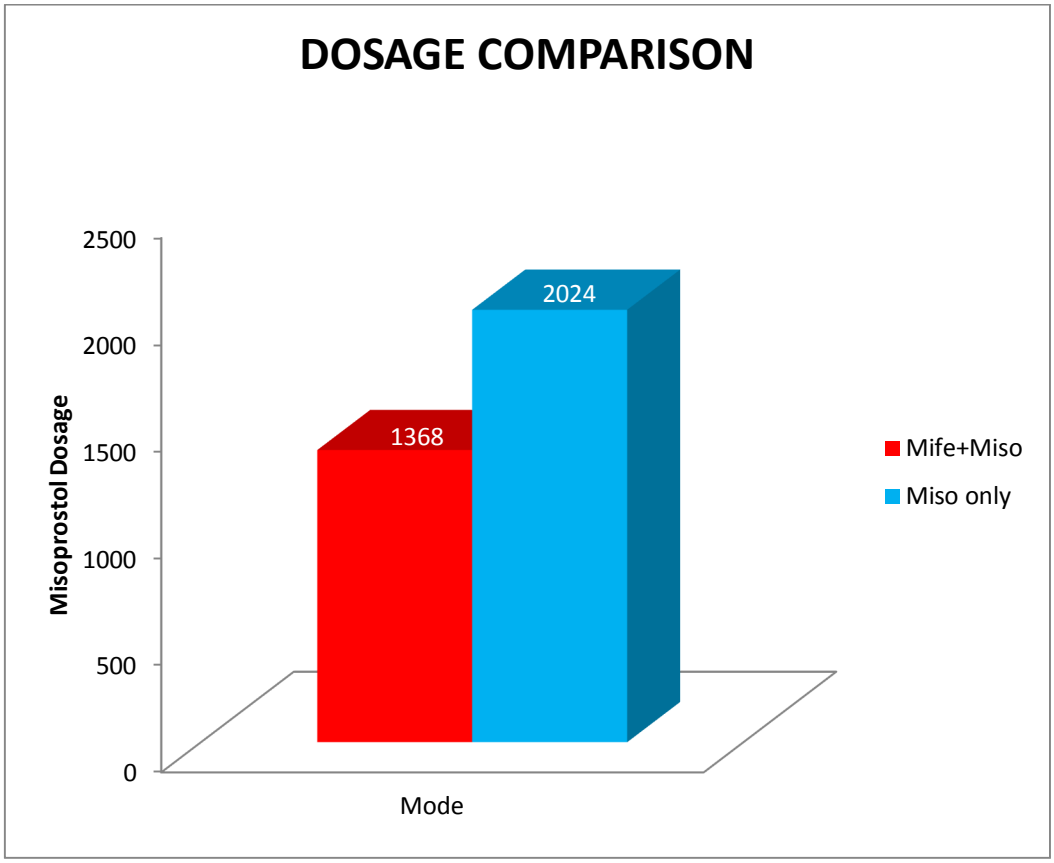
Gestational age	Mife+Miso Group Hrs	Miso Group Hrs
14 -16 Weeks	11.5	12.50
17-18 Weeks	7.30	12.61
19-20 Weeks	7.74	14.77
P Value	0.126	0.676



According to gestational age, induction –abortion is not statistically significant.

TABLE 8: DOSES REQUIRED

	Method Group	N	Mean	Std. Deviation	P VALUE
Total Dosage	Mife+Miso	50	1368	498.749	<0.001**
	Miso only	50	2024	382.559	

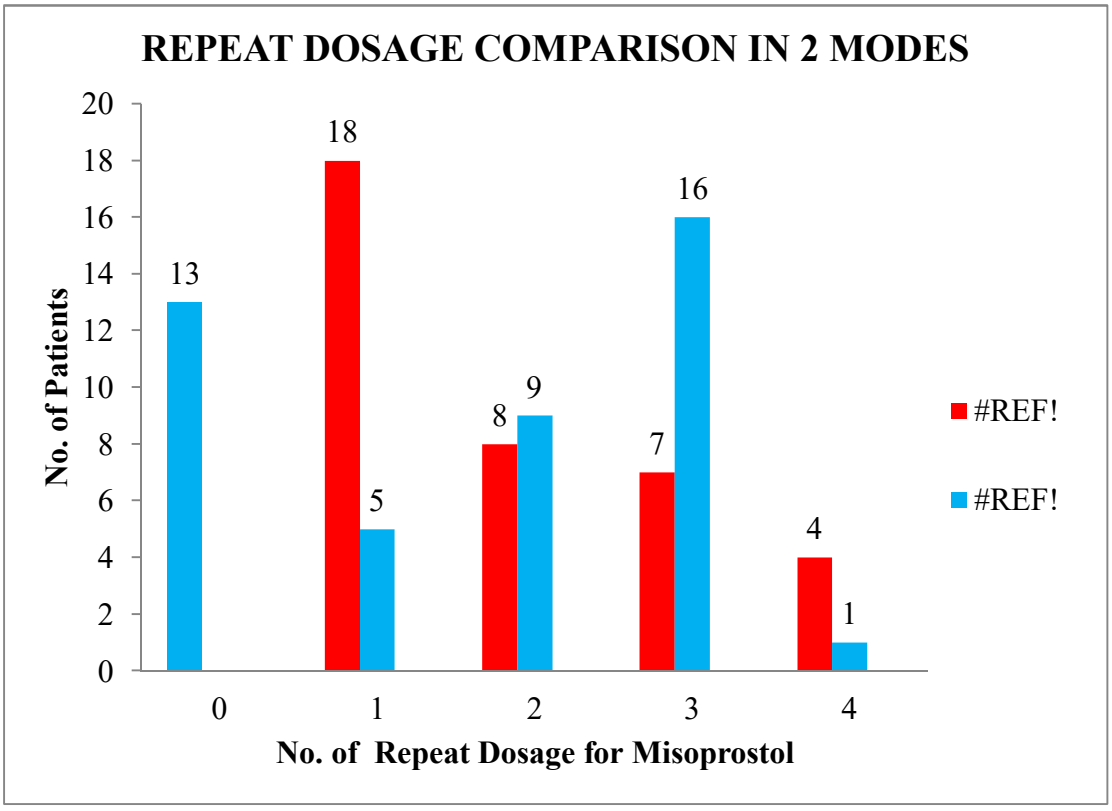


Mean dose required in mifepristone+misoprostol group -1368mcg, in miso group it was 2024mcg.

TABLE 9: REPEAT DOSE OF MISOPROSTOL REQUIRED FOR ABORTION

Mode	Number of Doses					P-Value
	0	1	2	3	4	
Mife+Miso	13	18	8	7	4	<0.001**
Miso	0	5	9	16	20	

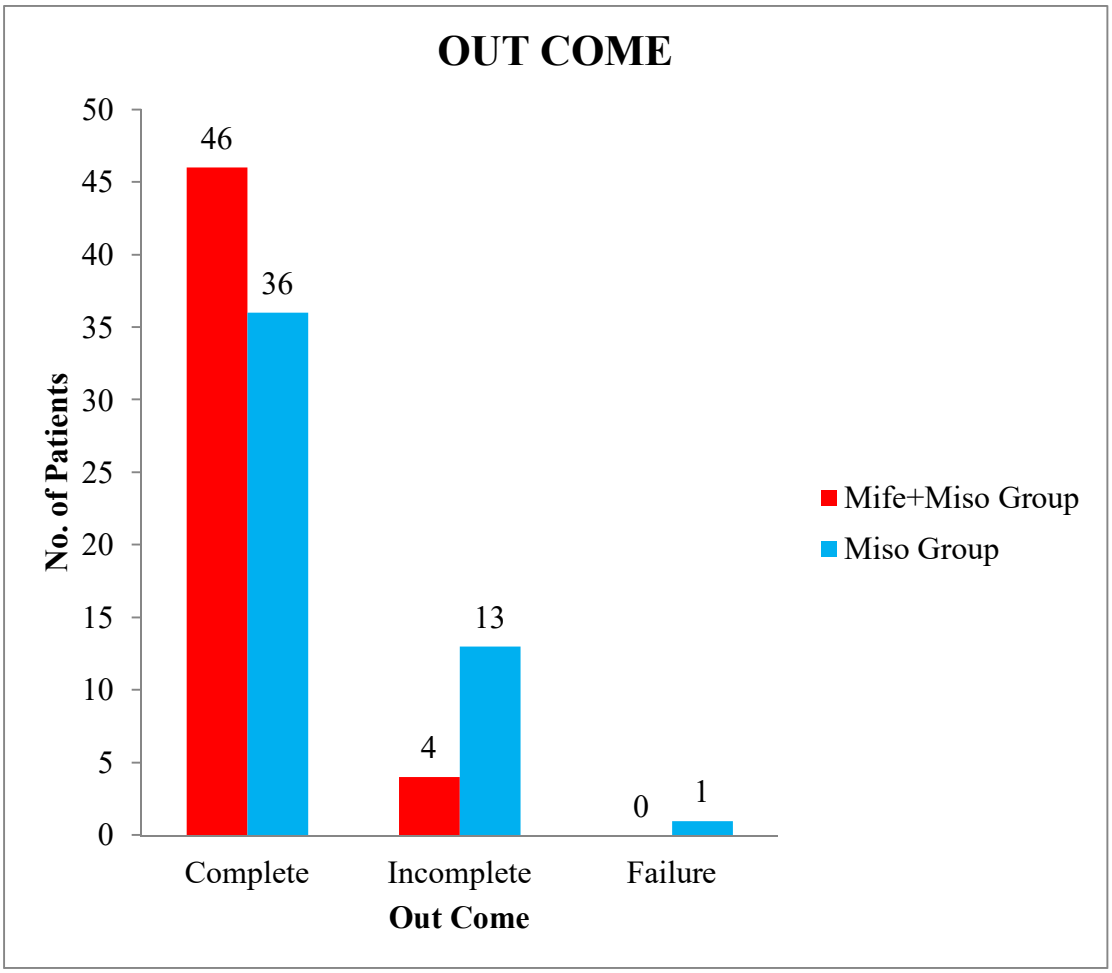
The repeat dose required in misoprostol group is comparatively more than in mifepristone+misoprostol group.



ABLE 10: OUTCOME IN BOTH GROUPS

	Mife + Miso Group		**Miso Group**		**P-Value**
	N	**%**	**N**	**%**	
Complete	46	92%	36	72%	**<0.030**
Incomplete	4	8%	13	26%	
Failure	0	0	1	1	

In mifepristone +misoprostol group, 92% aborted completely while in misoprostol group it was 72% which was not statistically significant.

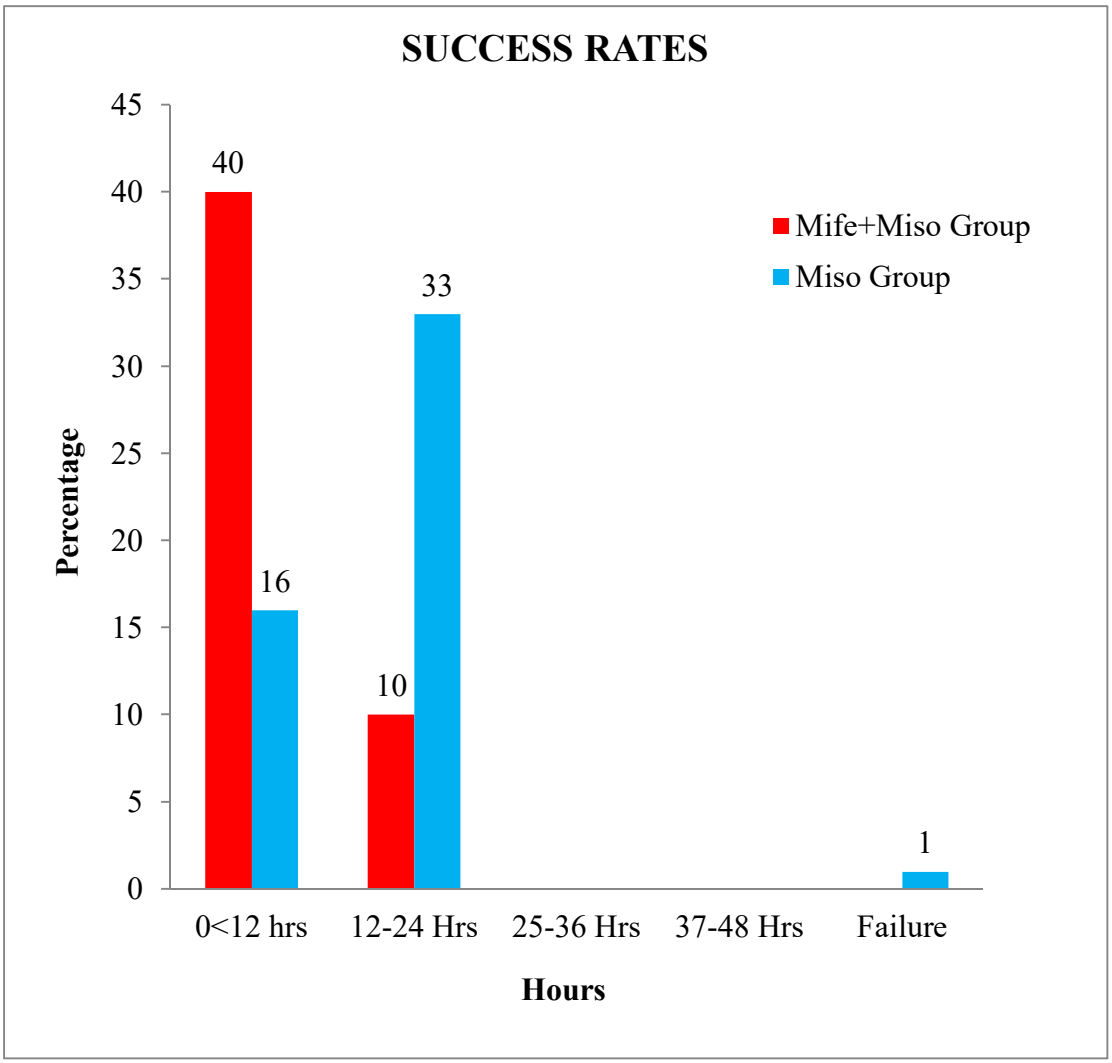


In mifepristone + misoprostol group, the percentage of incomplete is 8% , in misoprostol group -26% which was not statistically significant. 1% of failure in misoprostol group and there is no failure in mifepristone +misoprostol group.

TABLE 11: SUCCESS RATES IN BOTH GROUPS

Hours	Mife + Miso group		Miso Group		P-Value
0<12 hours	40	80%	16	32%	<0.001**
12-24 hours	10	20%	33	66%	
25-36 hours					
37-48 hours					
Failure			1	2%	

In mifepristone+misoprostol group -100%aborted successfully while misoprostol group -98% aborted successfully within 48 hrs.

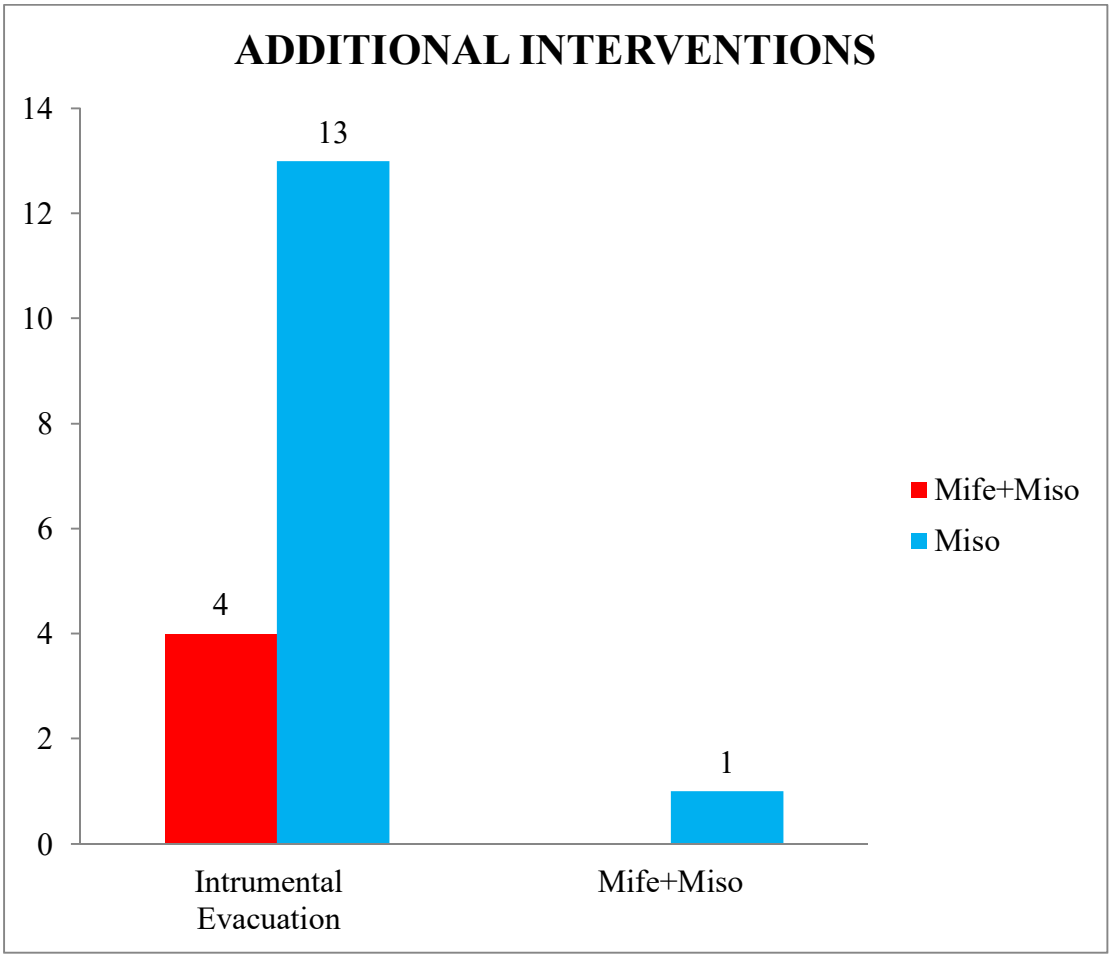


Patients who expelled within 12 hrs in mifepristone+misoprostol group was 80% which was comparatively high when compared with misoprostol group which was only 32%.

TABLE 12: ADDITIONAL INTERVENTIONS

Intervetions	**Mife+Miso**	**Miso**	**P VALUE**
Intrumental Evacuation	4	13	**0.582**
Mife+Miso	0	1	
TOTAL	**4**	**14**	
	8%	28%	

Additional procedures done are CU-Tinsertion and tubectomy in muitigravida.



About 8% of patients in mifepristone= misoprostol group needed additional interventions which is less when compared to misoprostol which was found to be 28% instrumental evacuation was done in both groups.

DISCUSSION

According to the global statistics for abortion rates reported by WHO, 1 in 5 pregnancies were aborted worldwide in 2008 (segh,2012), almost half of these abortions were considered unsafe.

Second trimester termination of pregnancy has tremendous improvement in management by the usage of prostaglandins.

Mifepristone given prior to prostaglandins in second trimester abortions resulted in shorter induction-abortion interval and success rate is found to be high though the cost is high.

This current study reveals that when mifepristone combined with misoprostol resulted in shorter induction–abortion interval and the repeated dosage of the drugs is reduced and also their side effects.

The study done at **GOVT. RSRM LYING IN HOSPITAL** is prospective interventional study involving about 100 patients between 14-20wks. Group1-mifepristone 200mg is given and after 36hrs-48hrs 800mcg of vaginal misoprostol given and subsequent doses of 400mcg given 3hrly for maximum 4 doses Group2-800mcg of vaginal misoprostol followed by 400mcg of vaginal misoprostol 3hrly upto 4 total doses.

PATIENT CHARACTERISTICS :-

AGE :-

In this study, mean age of patients in mifepristone and misoprostol group was 25.54 years and in misoprostol group it was 25.22.yrs. The age distribution is found to be maximum among 21-25 yrs and above 30yrs it was less.

The mean age group in mifepristone and misoprostol was 25.7 years and in misoprostol group was 25.5yrs in a study conducted by KAPP which was comparable.

GRAVIDA :-

In this current study patients with atleast one prior delivery constitute for 22% in mifepristone+ misoprostol group, 30% in misoprostol group But in the study conducted by JAN E DICKINSON it was 57.8% in mifepristone+ misoprostol group and in misoprostol it was 60.3%.

GESTATIONAL AGE :-

In this study, the mean gestational age in mifepristone=misoprostol group was18.22 weeks and in misoprostol group it was 18.40weeks But in the study conducted by JAN E DICKINSON mean gestational age 19.1weeks in mifepristone + misoprostol and in misoprostol group 19.6weeks.

INDICATION:-

In this study, unwanted pregnancy was found to be the most common indication for termination of pregnancy and it was about 64% in both groups.

PARAMETERS STUDIED:-

Induction- abortion Interval:-

In this study, in mifepristone + misoprostol group, the mean induction – abortion interval was 8.2hrs and in misoprostol group, it was 13.9hrs which was found to be statistically significant. Induction-abortion interval is prolonged in primigravida than in multigravida in both groups.

In the study conducted by JAN E DICKINSON, mifepristone+ misoprostol and in misoprostol group was found to be 8.6 hrs and in misoprostol group it was 15.5hrs.

INDUCTION ABORTION INTERVAL IN PARITY:-

Induction abortion interval was prolonged with increasing gestational age in misoprostol group which was comparable with other studies.

Mean dosage of misoprostol required;-

In our study, the mean dose of misoprostol in mifepristone + misoprostol group was 1368mcg, but in misoprostol group, it was 2024mcg Repeat dosage of misoprostol required for abortion.

In misoprostol group, the repeat doses required was found to be comparatively more than in mifepristone – misoprostol group.

OUTCOME:-

In mifepristone+ misoprostol, the percentage of complete abortion was 92% and in misoprostol group it was 72% In mifepristone+ misoprostol group, the rate of incomplete abortion was only 4% and in misoprostol group it was comparatively high 26%.

Hence when mifepristone given prior to prostaglandins, induction-abortion interval was found to be shorter and repeated doses of misoprostol given was reduced.

SUCCESS:-

In Mifepristone + misoprostol, 80% aborted successfully, but in misoprostol group only 36% aborted within 12hrs.

In Mifepristone + misoprostol group 100% aborted successfully at 24and 48 hrs and in misoprostol group it was 98 % and was compared with other studies.

Additional Interventions :

About 4 patients in mifepristone+ misoprostol group required additional interventions which was comparatively less compared to misoprostol group where 13 patients required additional interventions.

Most of the patients in misoprostol group required additional interventions than in mifepristone + misoprostol group.

Side- effects;-

In mifepristone + misoprostol group, one patient and in misoprostol group, three patients presented with bleeding managed by surgical evacuation Fever was present in mifepristone- misoprostol group was 3% and in misoprostol group 11% had fever.

6%of the patients had nausea when mifepristone given with vaginal misoprostol and 15% of the patients had nausea in misoprostol group 16% of the patients had when vaginal misoprostol alone given which was comparatively less in mifepristone +misoprostol group (6%).

Other complications:-

No major complications were reported with this present study and was comparable to other groups.

SUMMARY

In this study, patients who are opting for second trimester termination of pregnancy and those with anomalous fetus were subjected.

In fifty patients, 200mg Mifepristone given after 36hrs, 800mcg of vaginal misoprostol administered and 400mcg of misoprostol administrated every 3 hrly upto 4 maximum doses or till delivery occurs.

In another fifty patients ,8oomcg 0f vaginal misoprostol given , then 400mcg of misoprostol administrated vaginally every 3 hrs to total 4 doses or until delivery occurs.

In both groups, patient age, parity gestational age were compared when abortion was induced.

The maximum age distribution was among 21-25years in both groups and the mean age in in mifepristone group was 25.54 and misoprostol group it was 25.22. Most of the pregnancies were terminated between 17-18 weeks in both groups.

In both groups majority of them were multigravida when compared with primigravida

Induction-abortion interval is less in multigravida than in primigravida and this was found to be statistically significant of P value of 0.01 in mifepristone+ misoprostol group.

Unwanted pregnancies which is due to social causes was the most indication in both groups.

In mifepristone+misoprostol group, the induction–abortion interval was 8.3 hrs which was very less than misoprostol group which was 13.9hrswhich was found to be statistically significant with (p value0.0001)

By comparing the parameters between induction- abortion interval and gestational age in both groups was not statistically found to be significant.

In mifepristone+ misoprostol group about 100% aborted completely while in misoprostol group it was – 98% which is of not statistically significant.

The percentage of incomplete abortion in misoprostol group was 26% which was comparatively more when compared to mifepristone + misoprostol group which was only 8%.

In misoprostol group 1% failure rate was reported and in mifepristone+ misoprostol group there was no failure of abortions which was not statistically significant.

In mifepristone+misoprostol group, within 12 hrs the complete abortion rate was 80% which was comparatively high than misoprostol group where the complete abortion rate was 32%.

In mifepristone+ misoprostol group, 100% of patients aborted successfully within 48hrs and in misoprostol group it was 98%.

Only 8% required additional interventions in mifepristone+ misoprostol group, which was comparatively less when compared to misoprostol which was about 26%. The procedure adopted commonly was instrumental evacuation in both groups.

The mean dose of misoprostol was 1368mcg in mifepristone+ misoprostol group and in misoprostol group alone it was 2024 mcg Sideaffects like nausea, pain vomiting, rigor , fever were reported more in misoprostol group. There was no major complications in both groups.

Mifepristone given prior to prostaglandins causes no bleeding and it can be administrated safely before admission to the hospital.

CONCLUSION

In this study abortifacient efficacy of combination of mifepristone with vaginal misoprostol and with vaginal misoprostol alone in the termination of second trimester was compared and following are the conclusion:-

In Mifepristone + misoprostol combination, the success rate less than 12 hrs was 80% but in misoprostol group it was comparatively less - 32% success rare at 24hrs in mifepristone+ misoprostol group was 100%

The induction-abortion interval was very less Mean induction-abortion interval in mifepristone+ misoprostol group was 8.3 hrs which was very less when compared to misoprostol group which was comparatively high -13.9hrs.

There was no failure of abortion in mifepristone with misoprostol group.

Side-effects like nausea, pain, vomiting , fever were reported more in misoprostol group.

Mifepristone + misoprostol combination resulted in shorter induction- abortion interval and need for repeated doses of misoprostol was reduced.

Vaginal misoprostol is found to be economical than mifepristone.

Hence mifepristone+ misoprostol combination was found to be more effective than misoprostol used alone in second trimester termination of pregnancy.

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PROFORMA

DATE:

NAME:
AGE:

IP NO:

SOCIOECONOMIC CLASS:

OCCUPATION:

RELIGION:

D.O.A:
D.O.D

ADDRESS & CONTACT NO:

MENSTRUAL HISTORY : REGULAR / IRREGULAR

LMP

MARITAL HISTORY: MARRIED SINCE

UNMARRIED

OBSTETRIC HISTORY: G _ P_ L_A_

PERIOD OF GESTATION

HISTORY OF PREVIOUS MTP DONE:

HOW MANY WEEKS

METHOD ADOPTED

REASONS FOR MTP –SOCIAL CAUSE

FAILURE OF CONTRACEPTION

CONGENITAL ANOMALIES

UNMARRIED PREGNANCY

UREA, CREATININE

ECG

USG

DATE/TIME OF ADMINISTRATION OF MIFEPRISTONE:

DATE / TIME OF ADMINISTRATION OF VAGINAL MISOPROSTOL:

NUMBER OF DOSES:

DATE / TIME OF EXPULSION OF FOETUS:

DATE / TIME OF EXPULSION OF PLACENTA:

OUTCOME:

COMPLETE

INCOMPLETE

FAILED

IF INCOMPLETE ADDITIONAL METHODS USED FOR COMPLETING THE ABORTION:

ADDITIONAL INTERVENTIONS IF NEEDED:

INDUCTION-ABORTION INTERVAL IN HOURS:

SIDE EFFECTS: NAUSEA

VOMITING

DIARRHOEA

HEADACHE

RIGOR

FEVER

HAEMORRHAGE

PAIN

ADDITIONAL PROCEDURES: COPPER T / TUBECTOMY

CONSENT FORM

I agree to participate in the study entitled ' COMPARATIVE STUDY OF MIFEPRISTONE PLUS VAGINAL MISOPROSTOL VERSUS VAGINAL MISOPROSTOL ALONE' FOR SECOND TRIMESTER ABORTION'

I confirm that I have been told about this study in my mother tongue and have had the opportunity to clarify my doubts.

I understand that my participation is voluntary and I may refuse to participate at any time without giving any reasons and without affecting my benifits.

I agree not to restrict the use of any data or results that arise from this study.

Name of the participant :

Sign / Thumb print:

Name of the investigator: Dr.P.Anitha

Sign of Investigator :

சுய ஒப்புதல் படிவம்

இரண்டாம் டிரைமெஸ்டர் கருகலைப்பில் - மிபிபிரிஸ்டோன் - பிற்பபுறுப்பு வழியாக மிஸோபிராஸ்டால் மற்றும் - பிறப்புறுப்பு வழியாக மிஸோபிராஸ்டால் மருந்துகளின் செயல்பாட்டை ஒப்பிடுதல்

ஆய்வாளர் : மரு. ப. அனிதா
முதுநிலை பட்ட மேற்படிப்பு மாணவர்
மகப்பேறு மற்றம் பெண்கள் நலத்துறை
ஆர்.எஸ்.ஆர்.எம்.மருத்துவமனை
ஸ்டான்லி மருத்துவ கல்லூரி - சென்னை

வழிகாட்டி மரு. டாக்டர். கலைவாணி,
பேராசிரியர்.
மகப்பேறு மற்றம் பெண்கள் நலத்துறை
ஆர்.எஸ்.ஆர்.எம்.மருத்துவமனை
ஸ்டான்லி மருத்துவ கல்லூரி - சென்னை

பெயர் : வயது : உள்ளிருப்பு எண் :

இந்த மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது என்னுடைய சந்தேகங்களை தீர்க்கவும் அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது

நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்த காரணத்தினாலும் எந்த கட்டத்திலும் எந்த சட்டசிக்கலும் இன்றி இந்த ஆய்விலிருந்து விலகிக் கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.

நான் ஆய்விலிருந்து விலகிக்கொண்டாலும் ஆய்வாளர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கோ அல்லது உபயோகிக்கவோ என் அனுமதி தேவையில்லை எனவும் அறிந்து கொண்டேன் என்னை பற்றிய தகவல்கள் ரகசியமாக பாதுகாக்கப்படும் என்பதையும் அறிவேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும் பரிசோதனை முடிவுகளையும் ஆய்வாளர் அவர் விருப்பத்திற்கேற்ப பயன்படுத்திக் கொள்ளவும் அதனை பிரசுரிக்கவும் முழுமனதுடன் சம்மதிக்கிறேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன் எனக்கு கொடுக்கப்பட்டுள்ள அறிவுரைகளின்படி நடந்து கொள்வதுடன் ஆய்வாளருக்கு உண்மையுடன் இருப்பேன், என்றும் உறுதி அளிக்கிறேன்.

உடல்நலம் பாதிக்கப்பட்டாலோ வழக்கத்திற்கு மாறான ஏதேனும் நோய்குறி தென்பட்டாலோ அதனை தெரிவிப்பேன் என்றும் உறுதி கூறுகிறேன்.

இந்த ஆய்வில் எனக்கு எவ்விதமான பரிசோதனைகளையும் சிகிச்சைகளையும் மேற்கொள்ள நான் முழுமனதுடன் சம்மதிக்கிறேன்.

இப்படிக்கு,

P. Arun

ஆய்வாளரின் கையொப்பம்

நோயாளியின் கையொப்பம்

INSTITUTIONAL ETHICAL COMMITTEE, STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work	:	Comparative study of Mifepristone plus Vaginal misoprostol versus Vaginal misoprostol alone for second trimester abortion at Stanley Medical College.
Principal Investigator	:	Dr. P Anitha
Designation	:	PG, MS (O & G)
Department	:	Department of O & G Government Stanley Medical College, Chennai-01

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 24.03.2016 at the Council Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.

K Vasanthan

MEMBER SECRETARY,
IEC, SMC, CHENNAI

MEMBER SECRETARY
ETHICAL COMMITTEE,
STANLEY MEDICAL COLLEGE
CHENNAI-600 001.

MASTER CHART

S NO	NAME	AGE	I.P.NO	PARITY	GA	INDICATION	METHOD	INITIAL DOSAGE - 800 mcg	REPEAT DOSAGE 400 mcg	TOTAL DOSAGE	INDUCTION - ABORTION INTERVAL IN HRS	RESULT	ADDL. INTERVENTION	SIDE - EFFECTS	ADDL PROCEDURE
1	PRABHA	19 YR	11445	PRIMI	16 WKS	UN WED	MISO ONLY	1	3	2000 m g	11hrs	complete		fever	
2	SUGANYA	20 YR	9837	PRIMI	16 WKS	UN WED	MISO ONLY	1	4	2400 m g	14 hrs	complete			
3	MOHANA	20 YR	8596	PRIMI	18 WKS	UN WED	MISO ONLY	1	3	2000 m g	14 hrs	complete		Rigor, vomiting	
4	KOKILA	20 YR	8348	PRIMI	20 WKS	UN WED	MISO ONLY	1	4	2400 m g	14.3 hrs	complete			
5	DHANABAKIYAM	20 YR	448	PRIMI	20 WKS	UN WED	MISO ONLY	1	3	2000 m g	13 hrs	complete			
6	MARIYAMMAL	19 YR	5062	PRIMI	16 WKS	UN WED	MIFE + MISO	1	3	2000 m g	12hrs	complete			
7	SUMITHRA	20 YR	7448	PRIMI	16 WKS	UN WED	MIFE + MISO	1	3	2000 m g	12hrs	complete		Rigor, fever	
8	ANGAMMAL	20 YR	1959	PRIMI	16 WKS	UN WED	MIFE + MISO	1	4	2400 m g	16 hrs	In complete	IE	Rigor, fever, vomiting	
9	VANI	19 YR	2949	PRIMI	16 WKS	UN WED	MIFE + MISO	1	4	2400 m g	16.5 hrs	In complete	IE	pain	
10	KALIAMMAL	20 YR	2062	PRIMI	16 WKS	UN WED	MIFE + MISO	1	4	2400 m g	17 hrs	In complete	IE	Bleeding	
11	JAYAMALINI	21 YR	7773	PRIMI	20 WKS	UN WED	MISO ONLY	1	4	2400 m g	14.5 hrs	complete		Rigor, vomiting	
12	AMALA	23 YR	6633	PRIMI	20 WKS	UN WED	MISO ONLY	1	4	2400 m g	16 hrs	In complete	IE	rigor, vomiting, diarrhoea	
13	KEERTHIKA	23 YR	6773	PRIMI	20 WKS	UN WED	MISO ONLY	1	4	2400 m g	14.2 hrs	complete		nausea, pain	
14	DILSATH NISHA	21 YR	7383	PRIMI	20 WKS	UN WED	MISO ONLY	1	4	2400 m g	14.4 hrs	complete		pain	
15	MANJU	22 YR	7400	PRIMI	18 WKS	UN WED	MISO ONLY	1	3	2000 m g	14 hrs	complete		rigor, fever	
16	SHENBAGAM	24 YR	7468	PRIMI	18 WKS	UN WED	MISO ONLY	1	3	2000 m g	14.5 hrs	complete		rigor, fever	
17	THILAGA	20 YR	7725	PRIMI	20 WKS	UN WED	MIFE + MISO	1	1	1200 m g	7 hrs	complete			
18	SUGANYA	19 YR	8216	PRIMI	20 WKS	UN WED	MIFE + MISO	1	2	1600 m g	10 hrs	complete			
19	RAJESWARI	22 YR	8410	PRIMI	18 WKS	UN WED	MIFE + MISO	1	3	2000 m g	13 hrs	complete		nausea, vomiting, pain	
20	UMA	23 YR	6311	PRIMI	20 WKS	ANOMALOUS	MIFE + MISO	1	1	1200 m g	6.5 hrs	complete			
21	SALMA	20 YR	2329	PRIMI	20 WKS	UN WED	MIFE + MISO	1	3	2000 m g	12 hrs	complete			
22	BANUMATHI	25 YR	6704	PRIMI	20 WKS	ANOMALOUS	MIFE + MISO	1	2	1600 m g	11 hrs	complete			
23	ERONICA	24 YR	6776	PRIMI	18 WKS	ANOMALOUS	MIFE + MISO	1	2	1600 m g	10 hrs	complete			
24	MARIYA VERINIYA	22 YR	1531	PRIMI	18 WKS	ANOMALOUS	MIFE + MISO	1	4	2400 m g	16 hrs	In complete	IE	nausea,diarrhoea, vomiting	
25	SANGEETHA	22 YR	6029	PRIMI	18 WKS	ANOMALOUS	MISO ONLY	1	4	2400 m g	17 hrs	In complete	IE	pain	C u - T
26	ANUSHA	24 YR	9916	G2 A1	18 WKS	ANOMALOUS	MISO ONLY	1	4	2000 mg	14.5 hrs	complete		pain,	C u - T
27	SATHYA	25 YR	11485	G2 P1 L1	20 WKS	ANOMALOUS	MISO ONLY	1	1	2400 m g	17.5 hrs	In complete	IE	rigor, vomiting, diarrhoea	

S NO	NAME	AGE	I.P.NO	PARITY	GA	INDICATION	METHOD	INITIAL DOSAGE - 800 mcg	REPEAT DOSAGE 400 mcg	TOTAL DOSAGE	INDUCTION - ABORTION INTERVAL IN HRS	RESULT	ADDL. INTERVENTION	SIDE - EFFECTS	ADDL PROCEDURE
28	SUMALATHA	23 YR	17668	G2 P1 L1	20 WKS	ANOMALOUS	MISO ONLY	1	2	1600 m g	10 hrs	complete		nausea, pain	
29	ANJALAI	24 YR	13566	G2 P1 L1	17 WKS	UN WANTED	MISO ONLY	1	3	2000 m g	13 hrs	complete		rigor, fever	
30	KALAISELVI	22 YR	5154	G2 P1 L1	18 WKS	UN WANTED	MISO ONLY	1	4	2400 m g	16.5 hrs	In complete	IE	Vomiting, Bleeding	
31	RIYANA BANU	25 YR	2917	G2 P1 L1	18 WKS	UN WANTED	MISO ONLY	1	4	2400 m g	15 hrs	In complete	IE	fever, vomiting	
32	SUGUNA	22 YR	18125	G2 P1 L1	17 WKS	UN WANTED	MISO ONLY	1	3	2000 m g	13 hrs	complete			C u - T
33	SUGANTHI	23 YR	18446	G2 P1 L1	17 WKS	UN WANTED	MISO ONLY	1	4	2400 m g	16.3 hrs	In complete	IE	nausea, vomiting , pain	
34	JAYALAKSHMI	24 YR	14206	G2 P1 L1	18 WKS	UN WANTED	MISO ONLY	1	3	2000 m g	13 hrs	complete		vomiting, diarrhoea	
35	INDRA	25 YR	14346	G2 P1 L1	18 WKS	UN WANTED	MISO ONLY	1	4	2400 m g	14 hrs	complete		rigor, vomiting	
36	SUBALAKSHMI	22 YR	6931	G2 P1 L1	18 WKS	UN WANTED	MISO ONLY	1	2	1600 m g	10 hrs	complete		nausea	C u - T
37	KAVITHA	21 YR	4484	G2 P1 L1	17 WKS	UN WANTED	MISO ONLY	1	4	2400 m g	13 hrs	incomplete	IE	rigor, fever	
38	PREMA	23 YR	11445	PRIMI	20 WKS	ANOMALOUS	MIFE + MISO	1	3	2000 m g	13 hrs	complete		nausea, vomiting , diarrhoea	
39	DURGA DEVI	24 YR	8926	G2 P1 L1	17 WKS	ANOMALOUS	MIFE + MISO	1	3	2000 m g	12.5 hrs	complete		rigor, fever	
40	BHAVANI	25 YR	6100	G2 P1 L1	18 WKS	ANOMALOUS	MIFE + MISO	1	2	1600 m g	10 hrs	complete			C u - T
41	RANI	24 YR	206	G2 P1 L1	18 WKS	UN WANTED	MIFE + MISO	1	0	800 m g	5 hrs	complete			C u - T
42	MEGALA	25 YR	439	G2 P1 L1	18 WKS	UN WANTED	MIFE + MISO	1	2	1600 m g	10 hrs	complete			C u - T
43	KRISHNAVENI	21 YR	1690	G2 P1 L1	17 WKS	UN WANTED	MIFE + MISO	1	2	1600 m g	9.2 hrs	complete			C u - T
44	SANDHIYA	23 YR	10542	G2 P1 L1	18 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	7 hrs	complete		`	C u - T
45	ANUSIYA	24 YR	5616	G2 P1 L1	18 WKS	UN WANTED	MIFE + MISO	1	3	2000 m g	11 hrs	complete			C u - T
46	LAVANYA	25 YR	8342	G2 P1 L1	18 WKS	CONTRACEPTIVE FAILURE	MIFE + MISO	1	2	1600 m g	10 hrs	complete			C u - T
47	DEEPA	25 YR	3561	G2 P1 L1	18 WKS	CONTRACEPTIVE FAILURE	MISO ONLY	1	3	2000 m g	11 hrs	complete		nausea	C u - T
48	SENJIAMMA	23 YR	4949	G2 P1 L1	17 WKS	UN WANTED	MISO ONLY	1	3	2000 m g	13 hrs	complete		rigor, fever	
49	SUNDARI	24 YR	14059	G2 P1 L1	18 WKS	UN WANTED	MISO ONLY	1	3	2000 m g	13.2 hrs	complete		pain	
50	CHENNAMMAL	24 YR	7303	G3 P2 L2	18 WKS	UN WANTED	MISO ONLY	1	4	2400 m g	17 hrs	incomplete	IE		
51	YASMIN	28 YR	1980	G3 P2 L2	18 WKS	CONTRACEPTIVE FAILURE	MISO ONLY	1	4	2400 m g	16.2 hrs	In complete	IE	nausea, vomiting	
52	RENU	30 YR	8655	G3 P2 L2	17 WKS	UN WANTED	MISO ONLY	1	2	1600 m g	9.2 hrs	complete		pain	T A T
53	SELVI	29 YR	7950	G3 P2 L2	18 WKS	UN WANTED	MISO ONLY	1	4	2400 m g	14.5 hrs	complete		rigor, fever	

S NO	NAME	AGE	I.P.NO	PARITY	GA	INDICATION	METHOD	INITIAL DOSAGE - 800 mcg	REPEAT DOSAGE 400 mcg	TOTAL DOSAGE	INDUCTION - ABORTION INTERVAL IN HRS	RESULT	ADDL. INTERVENTION	SIDE - EFFECTS	ADDL PROCEDURE
54	REETA	28 YR	4594	G3 P2 L2	18 WKS	UN WANTED	MISO ONLY	1	1	1200 m g	8.2 hrs	complete		nausea	T AT
55	VALLI	27 YR	14925	G3 P2 L2	18 WKS	UN WANTED	MISO ONLY	1	3	2000 m g	13 hrs	In complete	IE	rigor, fever	
56	SABRIN BANU	28 YR	16636	G3 P2 L2	18 WKS	UN WANTED	MISO ONLY	1	3	2000 m g	13 hrs	complete		nausea, vomiting	
57	NADHIYA	27 YR	14705	G3 P2 L2	17 WKS	UN WANTED	MISO ONLY	1	3	2000 m g	13 hrs	complete			
58	CHITHRA	23 YR	11960	G2 P1 L1	17 WKS	UN WANTED	MIFE + MISO	1	0	800 m g	4 hrs	complete			C u - T
59	PRABHAVATHI	22 YR	12937	G2 P1 L1	17 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	9.5 hrs	complete			
60	NITHYA	25 YR	13405	G2 P1 L1	18 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	7 hrs	complete			C u - T
61	GANDHIMATHI	25 YR	14619	G3 P2 L2	18 WKS	UN WANTED	MIFE + MISO	1	0	800 m g	4 hrs	complete			T AT
62	INDUMATHI	24 YR	16729	G3 P2 L2	17 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	7 hrs	complete			T A T
63	SIVASANKARI	22 YR	18387	G3 P2 L2	17 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	7 hrs	complete			
64	DURGA	28 YR	2460	G3 P2 L2	18 WKS	UN WANTED	MIFE + MISO	1	2	1600 m g	10 hrs	complete			
65	PRIYANKA	29 YR	7797	G3 P2 L2	18 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	5 hrs	complete			
66	ELIZABETH	30 YR	10267	G3 P2 L2	17 WKS	CONTRACEPTIVE FAILURE	MIFE + MISO	1	1	1200 m g	7 hrs	complete			
67	BHUVANESHVARI	27 YR	9065	G3 P2 L2	18 WKS	UN WANTED	MIFE + MISO	1	0	800 m g	4.2 hrs	complete			T AT
68	AKILA	28 YR	13567	G3 P2 L2	18 WKS	UN WANTED	MISO ONLY	1	3	2000 m g	11 hrs	complete		rigor, fever	
69	NAGAVALLI	26 YR	4461	G3 P2 L2	17 WKS	UN WANTED	MISO ONLY	1	4	2400 m g	16 hrs	In complete	IE	pain	
70	SUDHA	27 YR	11015	G3 P2 L2	17 WKS	UN WANTED	MISO ONLY	1	2	1600 m g	10 hrs	complete		nausea, pain	
71	REBEKA	26 YR	761	G3 P2 L2	18 WKS	CONTRACEPTIVE FAILURE	MISO ONLY	1	2	1600 m g	11 hrs	complete		nausea, pain	
72	NEELAVATHI	26 YR	11516	G3 P2 L2	18 WKS	UN WANTED	MISO ONLY	1	2	1600 m g	11 hrs	complete		pain	
73	RAMYA	28 YR	14031	G3 P2 L2	20 WKS	UN WANTED	MISO ONLY	1	4	2400 m g	19 hrs	In complete	IE	bleeding	
74	ROHINI	29 YR	15470	G3 P2 L2	20 WKS	UN WANTED	MISO ONLY	1	2	1600 m g	10 hrs	complete		nausea, pain	
75	RAJESHWARI	30 YR	8410	G3 P2 L2	19 WKS	UN WANTED	MISO ONLY	1	1	1200 m g	7 hrs	complete		nausea, pain	
76	SUBHA	26 YR	11015	G3 P2 L2	18 WKS	UN WANTED	MIFE + MISO	1	0	800 m g	4.5 hrs	complete			
77	NALINI	26 YR	11516	G3 P2 L2	18 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	7.2 hrs	complete			T AT
78	MANJULA	28 YR	2184	G3 P2 L2	18 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	7 hrs	complete			
79	JOSPHINE	27 YR	10453	G3 P2 L2	17 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	7.3 hrs	complete		nausea, pain	
80	FARIDHA	28 YR	9853	G3 P2 L2	18 WKS	UN WANTED	MIFE + MISO	1	0	800 m g	4.2 hrs	complete			T A T

S NO	NAME	AGE	I.P.NO	PARITY	GA	INDICATION	METHOD	INITIAL DOSAGE - 800 mcg	REPEAT DOSAGE 400 mcg	TOTAL DOSAGE	INDUCTION - ABORTION INTERVAL IN HRS	RESULT	ADDL. INTERVENTION	SIDE - EFFECTS	ADDL PROCEDURE
81	PADMA	30 YR	8607	G3 P2 L2	18 WKS	UN WANTED	MIFE + MISO	1	0	800 m g	4 hrs	complete			
82	RAJAKUMARI	27 YR	11485	G3 P2 L2	20 WKS	UN WANTED	MIFE + MISO	1	0	800 m g	5 hrs	complete			
83	JAYA	28 YR	1747	G3 P2 L2	20 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	7.4 hrs	complete			
84	ARIFA	27 YR	16893	G3 P2 L2	20 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	7 hrs	complete			
85	GIRIJA	28 YR	17843	G3 P2 L2	19 WKS	UN WANTED	MIFE + MISO	1	0	800 m g	5 hrs	complete			
86	BANUPRIYA	26 YR	16769	G3 P2 L2	20 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	7 hrs	complete			
87	SUJATHA	39 YR	16015	G4 P3 L3	20 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	6.4 hrs	complete			T A T
88	RENUKA	30 YR	16176	G4 P2 L2	20 WKS	UN WANTED	MIFE + MISO	1	0	800 m g	4 hrs	complete			T A T
89	MALLIGA	36 YR	837	G5 P4 L4	19 WKS	UN WANTED	MIFE + MISO	1	0	800 m g	4 hrs	complete			T A T
90	HEMAVATHI	34 YR	15874	G4 P2 L2	20 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	6.5 hrs	complete		nausea, pain	T A T
91	SARASU	35 YR	16469	G4 P2 L2	20 WKS	UN WANTED	MIFE + MISO	1	0	800 m g	5 hrs	complete			T A T
92	SUMATHI	27 YR	2245	G3 P2 L2	17 WKS	UN WANTED	MIFE + MISO	1	1	1200 m g	7 hrs	complete		nausea, pain	T A T
93	MAHESWARI	33 YR	5754	G4 P2 L2	18 WKS	UN WANTED	MIFE + MISO	1	0	800 m g	5 hrs	complete			T A T
94	SURYA	29 YR	10356	G3 P2 L2	20 WKS	UN WANTED	MISO ONLY	1	2	1600 m g	9 hrs	complete			T A T
95	JAINBEE	28 YR	15478	G3 P2 L2	19 WKS	UN WANTED	MISO ONLY	1	1	1200 m g	6.5 hrs	complete			T A T
96	VANITHA	32 YR	17980	G4 P3 L3	20 WKS	UN WANTED	MISO ONLY	1	1	1200 m g	7 hrs	complete		nausea, fever	T A T
97	JOTHI	36 YR	1554	G4 P3 L3	20 WKS	UN WANTED	MISO ONLY	1	4	2400 m g	16 hrs	In complete	IE	nausea, pain	T A T
98	SOUNDARYA	33 YR	3693	G4 P3 L3	20 WKS	UN WANTED	MISO ONLY	1	2	1600 m g	9 hrs	complete		pain	T A T
99	RIBILA	29 YR	12712	G3 P2 L2	19 WKS	UN WANTED	MISO ONLY	1	4	2400 m g	18 hrs	In complete	IE	bleeding	T A T
100	AMULU	26 YR	18002	G3 P2 L2	20 WKS	UN WANTED	MISO ONLY	1	3	2000 m g	11.5 hrs	complete		nausea, pain	T A T

GA - GESTATIONAL AGE
IE - INSTRUNENTAL EVACUATION
TAT - TRANSABDOMINAL TUBECTOMY

ABBREVIATIONS

GA	Gestational age
HRS	Hours
I-A Int	Induction Abortion Interval
mcg	Microgram
mg	milligram
MTP	Medical Termination of Pregnancy
Mife+Miso -	mifepristone+misoprostol
Miso	Misoprostol
NS	Not Significant
PG	Prostaglandin
S	Significant
SD	Standard Deviation
WK	Week