


Original Research Article

A comparative study of ethacridine lactate with vaginal misoprostol versus vaginal misoprostol alone for mid trimester abortion

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Abstract

Introduction: Mid-trimester termination of pregnancy is one of the most controversial areas of gynaecological practice. It has moral, emotional, social and technical issues. There is continuous need for termination of pregnancy in second trimester, more recently due to increase in the use of antenatal diagnostic procedures. The objective of the present study is to compare acceptability, safety, efficacy, complications and induction-abortion interval of ethacridine lactate with vaginal misoprostol versus vaginal misoprostol alone for mid trimester abortion

Materials and methods: This was a comparative study s200 women of 13-20 weeks pregnancy were randomized in two groups. Out of these 100 patients were selected at random for intravaginal misoprostol 400 µg stat followed by 200 µg misoprostol P/V 4th hourly and 100 cases for extra amniotic ethacridine lactate instillation with tablet misoprostol 400 µg Stat followed by tablet misoprostol 200 µg 4th hourly. The relative efficacy, induction- abortion interval, complications of each was studied.

Results: The patients studied belong to all categories of marital status, married, and unmarried, widowed. The age ranged from 15-34 years. The gestational age from 14-20 weeks most of them were primi para. Mean induction abortion interval with misoprostol is 15.2 hours while that of emcredil with misoprostol is 16.44 hours. Success rate with misoprostol is 94% while that of emcredil with misoprostol is 95%. Incomplete abortion with misoprostol 2% while that of emcredil with misoprostol 1%. No major complications are noted in both the methods.

Conclusion: Misoprostol is safer, more effective and acceptable than ethacridine for mid trimester termination of pregnancy.

Key words

Misoprostol, Ethacridine lactate, Midtrimester pregnancy termination.

Introduction

The termination of second trimester pregnancy is risky because of its complications and psychological trauma to patients. It constitutes 10-15% of all induced abortions usually done for intrauterine fetal demise (IUID), fetal congenital anomalies and medical disorders associated with pregnancy [1]. Early detection of lethal structural and chromosomal abnormalities, and IUID has increased the demand of rapid second trimester termination [2]. The termination of second trimester pregnancy is a significant problem in the presence of unfavorable cervix and is often prolonged and tedious [3]. Among various methods of second trimester termination, evacuation and curettage induces risk of bleeding, infection, uterine perforation and cervical trauma [4]. The introduction of misoprostol, a synthetic prostaglandin E1 analog (PGE1) has become an important for cervical ripening and uterotonic action [5]. It is economic, stable at room temperature and is associated with few side effects such as fever, vomiting and diarrhea [6]. There is still debate about doses, routes and regimes of PGE1 for termination of pregnancy during second [7].

The aim of this study is to compare the efficacy of two drugs for mid trimester termination of pregnancy i.e., vaginal misoprostol vs emcredil with vaginal misoprostol with respect to safety, efficacy, ease of administration and failure.

Materials and methods

This was a comparative study involving two groups of patients. Two hundred cases of second trimester pregnancy termination ranging from 14-20 weeks were studied. Out of these 100 patients were selected at random for intravaginal misoprostol 400 µg stat followed by 200 µg misoprostol P/V 4th hourly and 100 cases for

extra amniotic ethacridine lactate instillation with tablet misoprostol 400 µg Stat followed by tablet misoprostol 200 µg 4th hourly. The relative efficacy of each was studied.

The patients were admitted through Antenatal outpatient department, family planning outpatients department.

Selection of cases

Both married and unmarried patients were selected.

Patients with high risk factors hypertension, pre eclampsia, bleeding per vaginum, oligohydramnious, and previous cesarian sections were excluded from the study.

Age of the patient in the study ranged from 15 - 34 years.

Gravida – primi gravida to gravida 5

Gestational age – 14-20 weeks.

Patients with contraindication to misoprostol were also excluded – H/o asthma, glaucoma, and intracranial tension, sickle cell diseases , cardiac disease, Hypersensitivity to prostaglandins.

Drugs used were

- Misoprostol 200 µg.
- 10 ml / week of gestation of 0.1% ethacridine lactate solution (Maximum of 150 ml).

Schedules of Administration

Schedule - 1

100 cases were administered misoprostol intravaginally 400 µg stat followed by 200 µg 4th hourly.

Schedule – 2

100 cases were administered extra amniotic emcredil instillation + 400 µg Tablet. Misoprostol P/v followed by 200 µg 4th hourly.

Schedule – 1 Procedure

After initial evaluation of the case, 2 tablets misoprostol are kept in posterior fornix patient is asked to report 4th hourly for 1 tablet misoprostol to be kept per vaginally. Patient is asked to report in case of pain or bleeding or any side effects in the form of gastrointestinal upset. Lack of response in 24 hours is considered failure. Such failures were completed with repeat administration of misoprostol in same dosage or emcredil instillation.

Schedule – II

Ethacridine lactate + per vaginal Tab. Misoprostol 400 µg followed by Tab. Misoprostol 200 µg 4th hourly.

Procedure

After necessary investigations, informed consent for MTP is taken for all patients. For unmarried girls the parent or guardian consent is taken. Patient was admitted a day before the procedure. Preparation of the part was done patient is asked to pass urine. She is put in lithotomy position, perineum cleaned and draped. Posterior vaginal wall is retracted with Sims speculum, anterior lip of cervix is held with a sponge holding forceps. Foleys catheter is passed through the cervix, 2 cm above the internal OS, between the membranes and uterine wall and tested for any bloody tap. If any bloody tap is encountered, the procedure is abandoned. The catheter bulb is inflated with 30 cc distilled water. The catheter is then connected to vecredil infusion set. The catheter is occluded by a knot. Then 400 µg tablet misoprostol is kept in the posterior fornix. Patient is asked to report 4th hourly for 1 tablet misoprostol to be kept per vaginal. The patient is asked to report at the onset of pains, bleeding or at the expulsion of catheter.

Lack of response in 24 hours is considered as failure. Such failures encountered are taken up

for completion with tablet misoprostol or for D & C.

Duration of Hospital Stay

Patients were discharged after 24 hours of abortion when there is no contemplation for sterilization. They are advised to take antibiotics for 5 days. Patient is advised to report immediately if there is fever, bleeding or pain abdomen. Patient is advised to come for a check up 2 weeks later when pelvic examination is performed for evidence of infection or bleeding.

Multipara are advised a permanent sterilization method. Some patents were advised an intrauterine contraceptive device and some were prescribed oral contraceptive pills.

Results

One hundred each schedule is studied:

100 cases of Misoprostol group (Schedule – I)

100 cases of Emcredil with Misoprostol group (Schedule – II)

The maximum number of patients in both the schedule is from the married sector. The maximum number of patients seeking mid trimester abortion are in the age group of 20 – 24 years in both schedules. 30 – 34 years age group is least in both schedules (**Table – 1**).

Most of the patients seeking abortion in both the groups are Primi gravida. Maximum number of women seeking abortion in both groups is in 17 – 20 weeks gestational group (**Table – 1**).

In Schedule-I: 43% aborted within 12 hours and 6% aborted more than 12 hours (considered failure) as per **Table – 2**.

In Schedule-II: None of the patients aborted within 12 hours, 49% aborted within 12 – 16 hours. 5% aborted > 24 hrs (Considered failure) as per **Table – 2**.

In Schedule-I: 18% of 3rd gravida aborted within 12 hours. 14% of primi also aborted

within 12 hours. 4% of primi and 2% of 3rd gravida failed to abort (**Table – 3**).

In Schedule-II: None of the patients aborted within 12 hours, 32% of primis aborted within 12 – 18 hours. 4% of primi and 1% of 3rd gravida failed to abort (**Table – 3**).

Table – 1: Demographic data.

VARIABLE	Schedule – I	Schedule – II
No. of cases	100	100
Marital status		
Married	56 (56%)	51 (51%)
Unmarried	42 (42%)	46 (46%)
Widowed	2 (2%)	3 (3%)
Age in Years		
15 – 19 years	10 (10%)	14 (14%)
20 – 24 years	48 (48%)	46 (46%)
25 – 29 years	38 (38%)	36 (36%)
30 – 34 years	4 (4%)	4 (4%)
Gravida		
Primi	44 (44%)	48 (48%)
Second	18 (18%)	18 (18%)
Third	36 (36%)	34 (34%)
Fourth	1 (1%)	--
Fifth	1 (1%)	--
Gestational Age In weeks		
14 – 16 weeks	22 (22%)	33 (33%)
17 – 20 weeks	78 (78%)	67 (67%)

Table – 2: Induction abortion interval.

No. of hours	Schedule – I	Schedule – II
0 – 12 hrs	43 (43 %)	--
12 – 16 hrs	7 (7 %)	49 (49%)
16 – 20 hrs	18 (18 %)	27 (27 %)
20 – 24 hrs	26 (26%)	19 (19 %)
Failures	6 (6 %)	5 (5 %)

In Schedule-I, 8 of the patients of gestational age between 14 – 16 weeks had an induction abortion interval less than 12 hours, 35 of the patients of gestational age between 17 – 20 weeks had an induction abortion interval < 12 hours. They

were 6 failures, 4 of them between 14 – 16 weeks and 2 from 17 – 20 weeks (**Table – 4**).

Table – 3: Parity and induction abortion interval.

Schedule – I Misoprostol

Parity	< 12 hrs	12 – 18 hrs	18 – 24 hrs
Primi	14 (14 %)	--	26 (26 %)
Second	9 (9 %)	--	9 (9 %)
Third	18 (18 %)	10 (10%)	6 (6 %)
Fourth	1 (1 %)	--	--
Fifth	1 (1 %)	--	--

Schedule – II Emcredil with Misoprostol

Parity	< 12 hrs	12 – 18 hrs	18 – 24 hrs
Primi	---	32 (32 %)	12 (12 %)
Second	---	18 (18 %)	---
Third	---	14 (14 %)	19 (19 %)
Fourth	---	--	--
Fifth	---	--	--

In Schedule-II, 18 patients aborted in 12 – 18 hours in 14 – 16 weeks age group. 12 patients aborted in 18 – 24 hrs, none aborted in < 12 hrs. In 17 – 20 weeks age group, 46 aborted in 12 – 18 hrs and 19 aborted in 18 – 24 hrs. They were 5 failures, 3 of them from 14 – 16 wks and 2 from 17 – 20 weeks (**Table – 4**).

Table – 4: Gestational age and induction – abortion interval.

Schedule – I Misoprostol

Gestational Age	< 12 hrs.	12 – 18 hrs.	18 – 24 hrs.
14 – 16 weeks	8 (8 %)	4 (4%)	6 (6 %)
17 – 20 weeks	35 (35 %)	6 (6 %)	35 (35 %)

Schedule – II Emcredil with Misoprostol

Gestational Age	< 12 hrs	12 – 18 hrs	18 – 24 hrs
14 – 16 weeks	---	18 (18 %)	12 (12 %)
17 – 20 weeks	---	46 (46 %)	19 (19 %)

Bleeding controlled with 0.2 mg methergine IV, incomplete abortion needed instrumental evacuation. No major complications like septicemia, coagulation failure, cervical tear,

uterine rupture were observed in any group (Table – 5).

Table - 5: Complication of abortions.

Complications	Schedule I	Schedule II
Bleeding / Hypotension	1 (1%)	2 (2%)
Incomplete abortion	2 (2%)	1 (1%)
Nausea / Vomiting / diarrhoea	3 (3%)	---
Sepsis	1 (1%)	2 (2%)
Chills / Pyrexia	1 (1%)	8 (8%)

Out of the 100 cases of misoprostol group, 6 of them failed to abort in 24 hours, 2 cases were followed by repeat misoprostol schedule. They aborted within 12 hours. 4 cases were followed by Emcredil instillation aborted within 18 hours. Out of the failures, 4 were primi and 2 were 3rd gravida. 4 of them between 4 – 16 weeks and 2 were from 17 – 20 weeks (Table – 6).

Out of the 100 cases in Schedule-II, 5 of them failed to abort within 24 hours. 3 cases were followed by 600 micrograms misoprostol and aborted between 12 hours. 2 cases D&C was done. 4 were primes and 1 was 3rd gravida. 3 of them were 14 – 16 weeks, 2 were 17 – 20 weeks (Table – 6).

Table - 6: Study of failures.

Total no. of failures with Misoprostol: 6

Subsequent method used	Time response
Repeat misoprostol schedule	2 cases aborted <12 hours
Emcredil instilled	4 cases aborted <18 hours

Total no. of failures with Emcredil with misoprostol: 5

Subsequent method used	Time response
600 µg misoprostol	3 cases aborted <12 hours
D & C	2 cases aborted

Discussion

The aim of this study is to compare the efficacy of two drugs for mid trimester termination of pregnancy i.e., vaginal misoprostol vs emcredil with vaginal misoprostol with respect to safety, efficacy, ease of administration and failure.

The maximum number of women seeking mid trimester abortions are primi in the age group 20 – 24 years. This reflects the need to motivate the safe measures and avoid pre-marital sex. Educate the women and protect them from criminal abortions there is necessity to evolve safe method of second trimester abortion and my study fulfill it to a large extent.

More number of patients was scheduled to misoprostol group because it was found to be equally effective before 14 -16 weeks and 17-20 weeks. Same is not true with emcredil and misoprostol because emcredil instillation is technically difficult at 14 weeks and more failures were noted at that gestational age. The practice of asking the patient to revisit the hospital 2-3 weeks later, when she comes first at 14 weeks to procure an abortion can be dispensed with by using misoprostol safely for such patients.

There is not much difference in the induction abortion interval with a mean difference of 1.22 hours misoprostol group aborted faster.

Mean induction abortion interval with misoprostol is 15.2 hours while that of emcredil with misoprostol is 16.44 hours.

In this study the misoprostol group for second trimester termination are compared with a study done by Wong KS, et al. [8] in Dept of Obst & Gynaec Chiang Mai University, Thailand to demonstrate the efficacy of vaginal misoprostol. The mean induction abortion interval in present study is in accordance with their study i.e., 15.2 hours. This with respect to induction abortion interval taken as criteria for the efficacy of the

drug misoprostol is effective and fairly acceptable in our setup.

In their study 40% of patients had diarrhoea while in my study diarrhoea is noted in only 3% this is because of using of anti- diarrhoeal which are easily available and effective. Thus the side effects of diarrhoea did not form a drawback for a wide acceptance of drug. Thus my study is in support of the previous study to prove misoprostol an efficient agent in mid trimester pregnancy termination.

Minimal side effects encountered in both the schedules. They are managed easily and as such are not considered disadvantages.

In this study the emcredil with misoprostol group is compared with the results of previous study by Nayak and Palal [9] 1989, at Dept. of Obst & Gynaec T.N.M.C and B.Y. L. Nair charitable Hospital Bombay.

The induction abortion interval of 16.44 hours in my study is well in conformity with Nayak, et al. which shows that the usage of emcredil to procure an abortion within a reasonable time frame is acceptable.

Success rate with misoprostol is 94% while that of emcredil with misoprostol is 95%.

Incomplete abortion with misoprostol 2% while that of emcredil with misoprostol 1%.

Significant number of cases of misoprostol group aborted in less than 12 hours thus decreasing the duration of hospital stay.

Incidence wise incomplete abortion was 2% in schedule – I and 1% in schedule – II is of marginal statistical significance.

Analysis shows at 14-16 weeks gestation misoprostol is successful and emcredil with misoprostol is a failure.

Primis and multis are responding better in misoprostol group as evidenced by success number and induction – abortion interval.

The failures in present study are three times of previous study. The only explanation offered could be a difference in the selection criteria of the patients with respect to gestational age emcredil with misoprostol being a failure in early second trimester and they not being selected for this study by Nayak, et al. [9]. Misoprostol was proved successful at the early gestation.

The cost incurred for procuring an abortion with misoprostol is Rs.60/- while emcredil with misoprostol is Rs. 195/- economic wise there is definite advantage with misoprostol alone in second trimester because the pregnancy being unexpected many of times due to Lactational amenorrhea the women has to spend money for confirmation of pregnancy and investigations, thus a certain advantage is gained by low cost of misoprostol.

Misoprostol administration is easy needing only intravaginal administration while the schedule – II is cumbersome. Misoprostol being uterotonic minimizes bleeding; hence its usage can be extended for office administration of the drug in the morning and the women being admitted in the afternoon, just as it is done in the first trimester abortions.

Misoprostol is pharmacologically active compound capable of terminating pregnancy at any gestation compared with emcredil which is relatively inert drug.

Mean induction abortion interval with misoprostol is less than emcredil with misoprostol. This minimizes the hospital stay for the patient. The women can return to work earlier and also reduces the financial constraints to hospital.

Conclusion

The result of the study indicates that vaginal misoprostol in second trimester termination is

- effective in terminating second trimester abortion completely
- Safe without any complications
- With minimal and tolerable side effects.
- Convenient for patients and also privacy is maintained
- Cost effective which is concern in developing countries
- Minimal handling and less invasive.
- No complications of anaesthesia and surgery.
- No trauma to cervix and uterus
- Less risk of introducing infection.

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