ORIGINAL ARTICLE

THERAPEUTIC EFFICACY OF MISOPROSTOL VERSUS ETHACRIDINE LACTATE IN SECOND TRIMESTER ABORTION – RANDOMISED CONTROLLED STUDY

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ABSTRACT

Background: Abortion is a major health and social issue in our country .Techniques for abortions are highly varied in different areas of country. Present study is to compare newer abortificient misoprostol versus traditionally used ethacridine lactate method.

Objective: To observe the efficacy and safety of misoprostol as a second trimester abortificient and to compare it with ethacridine lactate.

Methods: This is a prospective study of 100 women with 12 – 20 weeks of gestation. Inclusions were according to MTP Act. 400ug misoprostol was inserted vaginally followed by 200ug every 4 hourly in study group (n=50).150-200ml of ethacridine lactate was injected extraamniotically in control group (n=50).Latent phase, active phase and induction abortion interval was noted and compared

Results: Average induction abortion interval was 12.24 hours in misoprostol as compared to 27.6 hours in ethacridine lactate (P value <0.01). The women undergoing D & E due to incomplete abortion was higher with ethacridine group 12(24%) as compared to misoprostol group 8 (14%) (P <0.05).

Conclusion: Misoprostol is faster, convenient, and safer than ethacridine lactate for 2nd trimester abortion.

Keywords: Extra amniotic ethacridine lactate infusion, Intravaginal Misoprostol.

INTRODUCTION

Women suffer in silence, ignorance, lack of awareness & education in developing countries like India. Abortion is a major social & health issue. As a cause of maternal mortality, abortion is one of the major neglected health issues in India (1). It is estimated that nearly 15 million abortions are taking place in our country every year. About 15,000 to 20,000 women die from complications arising out of legal abortions every year (1, 2) the aim of our study is to establish safer and effective method for 2nd trimester abortion. Since January 1970, Prostaglandins (PGs) have been extensively studied and evaluated for termination of pregnancy at various gestational ages. Misoprostol, a synthetic 15-deoxy 16 hydroxy methyl analogue of PGE1 being cheaper and safe as compared to ethacridine lactate & can be used in different dosage regimens with varying degrees of success(2, 3, 4). The aim of the present study is to show the comparison of prostaglandins (misoprostol) locally for cases of second trimester abortion with established method – Ethacridine Lactate. Primary outcome of the study is to compare latent, active periods and induction abortion interval between two groups and decide better effective drug. Other outcome is to compare incomplete abortion and side effects between two groups and decide safety.

MATERIAL & METHODS

Present study was double blinded randomised case controlled study where 100 patients admitted in Sheth VS general hospital for 2nd trimester abortion from January 2010 to December 2010 were enrolled. The indications for termination were consonance with the MTP act (6). Each woman was counselled in detail about the method of termination, its procedure and its side effects. Then written consent of both women and spouse were taken. Intrauterine 2nd trimester pregnancies were assessed clinically and by sonography, 50 patients were enrolled randomly in misoprostol study group and 50 were enrolled in ethacridine lactate group. Hypersensitivity to prostaglandins & ethacridine lactate ruled out. History of renal disease, hepatic disease, bronchial asthma ruled out. History of haematological

disorder, glaucoma, heart disease ruled out. Emotional stability and the capacity to understand is necessary pre requisite. Conditions which are contraindications to the use of prostaglandins and ethacridine lactate were not taken.

In misoprostol group (50 patients); the patient was asked to pass urine .then vagina was cleansed and initially 400 mcg of misoprostol was kept vaginally in posterior fornix and women was kept supine followed by 200 mcg every four hourly till abortion maximum three trials. In ethacridine lactate group (50 patients); a Foley's catheter No. 16 was introduced inside the cervix in the extra amniotic space. About 150-200 ml of ethacridine lactate was injected. Patient was transferred to labour room after 24 hours, or earlier if patient had onset of uterine contractions. The uterine contractions were augmented using intravenous oxytocin drip. If the abortion process was incomplete, then D & E was performed in either group. All patients were monitored clinically with two hourly assessments of maternal temperature, pulse, blood pressure and respiratory rate.

Latent period was decided as the time period between introduction of drug and onset of uterine contractions. Active period was decided as the duration between onset of uterine contraction and expulsion of products of conception. Induction abortion interval was decided as the time duration from introduction of drug to the expulsion of products of conception. Notes regarding onset of abdominal pain, bleeding per vaginum and their interval were also made depending upon the method used and associated need of surgical procedure (D & E) stay of patients varied from 48 hours to 72 hours. On discharge, per vaginal examination was done in each patient. They were advised to come in OPD with an interval of 7 days. At the time of follow up thorough pelvic examination was carried out and patients were asked about any abdominal pain or abnormal vaginal bleeding.

RESULTS

Table 1: Distribution of the patients according to age in both groups

Age in years	Ethacridine Lactate Group (n = 50) (%)	Misoprostol Group (n = 50) (%)
18 to 20	04 (08)	05 (10)
21 to 30	40 (80)	41 (82)
>30	06 (12)	04 (08)

Table 1 shows age distribution of the patients. Age was ranging from 18 to 38 years of age. Maximum numbers of patients (80-82%) were between 21-30 years of age. Only 8-10% was below age of 20 years.

Majority (62-70%) of patients were third and fourth gravid. Common indications were contraceptive failure 52%, unaware of pregnancy 18% and congenital malformation 9% of cases.

Table 2 – Distribution according to gestational age

Gestational age in weeks	Ethacridine Lactate Group (n = 50) (%)	Misoprostol Group (n = 50) (%)
12-14	13 (26)	20 (40)
14-16	15 (30)	12 (24)
16-18	16 (32)	13 (26)
18-20	06 (12)	05 (10)

Table 2 shows gestational age of pregnancy in weeks. 30% of patients in ethacridine group had gestational age between 14-16 weeks & 32% had gestational age between 16-18 weeks.

In misoprostol group 24% of patients had gestational age 14-16 weeks while 40% had gestational age 12-14 weeks.

Table 3: Comparison of latent phase between extra amniotic infusion of ethacridine lactate and misoprostol

Latent period (hrs)	Ethacridine lactate (n-50) (%)	Misoprostol (n-50) (%)
0-12	12 (34)	49 (98)
13-24	29 (58)	1 (2)
25-36	2 (4)	0
>36	4 (4)	0
Average latent period*	18.2 hrs	8.08 hrs

* P value < 0.05

Latent period is <12 hours in almost all cases of abortion by misoprostol and 13 – 24 hours in about 50 % cases of abortion by ethacridine lactate. The p value is <0.05 which is showing significance.

Table 4 - Comparison of Active phase between extra amniotic infusion of ethacridine lactate and misoprostol

Active period (hrs)	Ethacridine lactate (n-50) (%)	Misoprostol (n-50) (%)
0-12	46 (92)	50(100)
13-24	4 (8)	0
25-36	0	0
>36	0	0
Average active period*	9.4 hrs	4.06 hrs

* P value < 0.05

Whatever method used for termination of second trimester pregnancy it has very little effect on active phase, however duration was considerably shorter in misoprostol termination (P value<0.05).

Table 5 shows the relationship of induction abortion interval in both groups. In this study minimum induction abortion interval in cases of ethacridine lactate was 8 hours and maximum 42 hours while the same for induction by misoprostol were 6 hours and 22 hours. Induction abortion interval was less in cases of abortion by misoprostol, statistically significant

(p<0.01). The mean induction abortion interval in ethacridine group was 16.24 ± 2.12 hrs while misoprostol group was 9.32 ± 2.16 hrs.

Table 5: Comparison of induction abortion interval between ethacridine lactate and misoprostol

Induction abortion interval (hrs)	Ethacridine lactate (n-50) (%)	Misoprostol (n-50) (%)
0-12	11(22)	29 (58)
13-24	28 (56)	21(42)
25-36	7 (14)	0
>36	4 (8)	0
Average interval	27.6 hrs	12.14 hrs

* P value < 0.01

In this study 7 (14%) had incomplete abortion and required D&E in misoprostol group against 12(28%) in ethacridine lactate group . Nausea, vomiting & GI side effects were common with the use of misoprostol. Complication like sepsis or uterine rupture did not found in this study.

DISCUSSION

In this study primary outcome was to determine effectiveness of misoprostol over ethacridine lactate.average induction abortion interval was significantly low in misoprostol group (12.14 hrs).In one study Berg at al (8) they noted interval 40.5 hrs with ethacridine lactate then 26.9 hrs with misoprostol. We found that misoprostol are having less latent phase, active phase and induction abortion interval as compared to ethacridine lactate (p < 0.05). Thus misoprostol is very efficient & timesaving drug as compared to ethacridine lactate. The success rate was 96% in misoprostol group as compared to 82% in ethacridine group. The proportion of women undergoing D & E due to incomplete abortion was higher with ethacridine group 12(24%) as compared to misoprostol group 7(14%).P Value <0.05 shows significance .Carbonell at al (9) had D&E rate 16%. Thus misoprostol was safer then ehtacridine lactate.

CONCLUSION

Use of vaginal misoprostol for 2nd trimester abortion is effective, safe, better & convenient in comparison to ethacridine lactate.

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