



Cervicovaginal Misoprostol Preferable To Extraamniotic Ethacridine Lactate With Or Without (Pge2) For Abortions At 13–20 Weeks Of Pregnancy

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ABSTRACT

Several different second trimester abortion methods are still being used in some countries, and very few studies have compared them to currently recommended methods.

Material and Methods In a search for effective, safe and cheap prostaglandin as abortifacient, we conducted a prospective, randomized trial comparing the efficacy and safety of misoprostol, a prostaglandin E1 analogue (200 µg intravaginally every 12 hours) (1) with the efficacy and safety of conventional 150 ml of extraamniotic ethacridine lactate without (PGE2) (2) or a combination of extra-amniotic (PGE2) tablet (0.5mg)crushed dissolved in 150 ml of 0.1% ethacridine lactate solution) . for abortions at 13–20 weeks of pregnancy

Methods.

The study population included ninety - pregnant women between 14 and -20 weeks' gestation who were undergoing termination of pregnancy for various reasons .The women underwent termination of pregnancy for intrauterine fetal death or medical or genetic reasons. They were randomized in three groups requiring abortion between 14 and 20 weeks of gestation. Group A received ethacridine lactate and group B received additional PGE2. and group c Patients, received misoprostol (PGE1) alone

Results

At 12.53 hours, misoprostol was 83.3 % effective in inducing abortion versus 90% with the ethacridine lactate regimen with a combination of extra-amniotic primi prost (PGE2) tablet at 26.15 hours and 93.3 % effective in inducing abortion (at 15.31 hours) with ethacridine alone The misoprostol cohort experienced fewer complications than the ethacridine cohort (6casesout of 30)while the complications were maximum in group b(20out of 30), We conclude that in the absence of mifepristone, misoprostol alone is preferable to the other ethacridine based regimens for the termination of pregnancy in the second trimester, because it is safer (fewer complications). faster, (higher success rate in a shorter period of time) and easier than other two regimes

Keywords : Misoprostol; PGE2 ; Abortifacient Agents ;ethacridine lactate ; prostaglandin; abortifacient; Pregnancy ;Second Trimester

Introduction:

India has provided safe and legal pregnancy termination at women's request. Most abortions occur in the first trimester, and a small proportion in the second trimester.²For the last several years, ethacridine lactate or the combination of ethacridine lactate, and PGE2 has been the standard procedure for abortions between 13– 20 weeks of pregnancy in hospitals.³Ethacridine lactate is an organic acridine compound used as an antiseptic in solutions. When used as an agent for second trimester abortion, it is thought to spur endogenous prostaglandin production.³ . The most widely used medical method of terminating second-trimester pregnancy is the intravaginal administration of prostaglandin E2 (dinoprostone [PGE2]). This treatment is highly effective but is associated with severe side effects .

Procedure:

Up to 150 ml of 0.1% ethacridine is instilled extra-amniotically, using a Foley catheter and usually after 20–40 hours, labour ensues. Due to limited access to and cost of mifepristone in many developing countries, including India, second trimester abortions are often performed by the administration of misoprostol alone, using a variety of doses and routes.^(3,4)

We decided to test this misoprostol regimen and to compare

its efficacy and safety with an ethacridine lactate regimen.

Methods:

We conducted a prospective study of a cohort of patients who received vaginal misoprostol for the termination of pregnancy in the second trimester, using -recommended second trimester regimens, and compared them with an historical group of patients who received extra-amniotic ethacridine.

We conducted a prospective, randomized trial comparing the efficacy and safety of misoprostol, a prostaglandin E1 analogue (200 micrograms intravaginally every 12 hours), with the efficacy and safety of PGE2 (intravaginally). In order to achieve statistical significance a minimum of 90 cases were needed. The study population included ---90----pregnant women between 14 and 20 weeks' gestation who were undergoing termination of pregnancy for either intrauterine fetal death (women) or medical or genetic reasons (women).

Statistical analysis

Quantitative analyses were conducted with SPSS 14.0. The three cohorts were assessed on socio-demographic and reproductive characteristics to assure comparability. Student t-tests were used for detecting differences between means,

and odds ratios were calculated to identify significant differences between proportions. This protocol was reviewed and approved by the Commission of Ethics and of the Scientific Council of the Institution.

Results

Characteristics of participants

For the period of the study, eligible women presented to the facility for second trimester pregnancy termination. Among those eligible to participate, 30 women with pregnancies of 13–20 weeks chose misoprostol. While 30 each were selected for other two groups as well. In the three groups, the women tended to be young with similar reproductive histories and mean weeks of pregnancy. They were comparable as regards age, education level, ethnic background, rendering them appropriate for comparison.

The successful abortion rate within 24 hours was similar for both groups (81% for PGE2 and 89% for misoprostol; $p = 0.47$). For both groups, the mean intervals between treatment and abortion among women who successfully delivered the conceptus within 24 hours were not statistically different (10.6 hours for PGE2 and 12 hours for misoprostol; $p = 0.33$). Every woman in the misoprostol group successfully aborted within 38 hours.

The rate of successful abortions within 24 hours was 81 percent (22 of 27 women) with GROUP A and 89 percent (25 of 28 women) with misoprostol ($P = 0.47$).

All the women who received misoprostol had successful abortions within 38 hours. Among those who had an abortion within 24 hours, the mean interval from treatment to abortion was DISIMILAR in THREE groups (10.6 hours with A and 12 hours with B AND 12.37 hours WITH C, $P = 0.33$).

The rate of complete abortion, defined as the passage of the fetus and the placenta simultaneously, was 81 percent for A and 89 percent for B AND 89 percent FOR C ($P = 0.56$).

At 12.53 hours, misoprostol was 83.3 % effective in inducing abortion versus 90% with the ethacridine lactate regimen with a combination of extra-amniotic prostaglandin (PGE2) tablet at 26.15 hours and 93.3 % effective in inducing abortion (at 15.31 hours) with ethacridine alone. The misoprostol cohort experienced fewer complications than the ethacridine cohort (6 cases out of 30) while the complications were maximum in group b (20 out of 30). We conclude that in the absence of mifepristone, misoprostol alone is preferable to the other ethacridine based regimens for the termination of pregnancy in the second trimester, because it is safer (fewer complications), faster, (higher success rate in a shorter period of time) and easier than other two regimens.

Efficacy of the three methods

In the misoprostol cohort (group c), the regimen used led to a higher efficacy in the 16–20 week group as against in the 14–16 week group (100% versus %) in group A also a high-

er efficacy in the 16–20 week group as against in the 14–16 week group was noticed (% versus %) The results of group b were similar (% versus %)

Success was maximum in group b but complications were also higher and time to induce abortion was high as well (mean 24.12 in 14–16 week abortions and 19 hours in 17–20 weeks abortions) on the other hand the time interval was least in group c (mean 13.01 in 14–16 week abortions and 12.37 hours in 17–20 weeks abortions) (table 1, 2, 3)

Side-effects and complications⁽⁶⁾ were minimal in the form of nausea, vomiting, diarrhea and comparable between the groups. Except that 1 case of bleeding occurred in group a and c but overall complications. Certain side effects were more frequent in the women receiving PGE2 group b (table 4)

The Cost of PGE1 was less and As tablets of PGE1 do not require refrigeration, they can be used in the remote areas of India. Thus, PGE1 turned out to be a very effective and cheap abortifacient which is technically easy to administer and does not need refrigeration, and has a wide scope of use in Indian population (table 5)

Limitations of the study we had only limited number of cases as 2nd trimester abortion is less common^(6,7)

Discussion

This study shows what has long been argued: that there are better ways than ethacridine to provide second trimester abortion. Misoprostol was more likely to yield complete expulsion within the first 24 hours (vs. . it can safely be assumed, that long inpatient stays due to longer induction-to-abortion times are less acceptable to both women and are clearly more costly. 11–14 As in most studies of misoprostol, 15 we found minimal discomfort with the misoprostol method, and high acceptability.

Conclusion

We conclude that misoprostol alone for second trimester termination of pregnancy, using a fixed dose of vaginal misoprostol, is preferable to ethacridine regimens because it works faster, safer and cheaper. For medical abortion where mifepristone⁽⁶⁾ is unavailable, we recommend the incorporation of misoprostol alone into clinical guidelines for the medical termination of pregnancy as a first-line option in the second trimester.

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