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Prospective Comparative Evaluation of Intra-Amniotic Versus Extra-Amniotic Routes for Ethacridine Lactate for Second Trimester M.T.P.: No Difference

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Summary

This study has been carried out to determine whether the intra-amniotic route of instillation of ethacridine lactate was superior to extra-amniotic route of instillation for second trimester medical termination of pregnancy (MTP). This was a prospective comparative study of women between 14 and 20 weeks of gestation admitted for pregnancy termination. Pregnancy termination was done in 100 women each by intra amniotic and extra-amniotic route. There was no difference in the over-all success rate. There was an insignificant decrease in mean instillation abortion interval (35.7 hours versus 38.5 hours).

Introduction

Cohen first described the use of Ethacridine lactate by extra-amniotic route for termination of second trimester pregnancy in 1946 (Marett 1998). Since then it has been conventionally used for second trimester pregnancy termination by extra-amniotic route. However this procedure has its drawbacks in the form of a longer instillation-abortion interval, a higher incidence of incomplete abortion and more chances of the fetus being born alive. So as to overcome these shortcomings many alternatives and additions to the procedure have been suggested. This includes instillation of ethacradine lactate by intra-amniotic route. This prospective study was carried out to evaluate the efficacy of this drug when used by intra-amniotic route as compared to the conventional extra-amniotic route.

Materials and Methods

Study subjects included 200 women seeking second trimester pregnancy termination and presenting to outpatient department of S.S.G. Hospital Medical College-Baroda, from Jan, 95 to Dec., 97. In all the cases, pregnancy termination was elective and was for different reasons. Routine hematological investigations and ultrasonography for placental localization was done in all cases. Informed consent was obtained on admission.

One hundred women were randomized to have pregnancy termination using 150 c.c. of 0.1% ethacridine lactate instilled through extra-amniotic route using no. 16/18 Foley's catheter. In other 100 subjects, 0.1% 150 c.c. ethacridine lactate was instilled through intra amniotic route. After bladder evacuation and with atropine as premedication, local anaesthetic 3 cc of 1% lignocaine was infiltrated at the site of needle insertion under all aseptic and antiseptic precautions. The site of needle insertion was decided on the basis of sonographic placental localization. A Touhey's needle was introduced vertically downwards through the abdomen into the amniotic sac. The intra-amniotic location was confirmed by aspiration of a small amount of liquor and 150-cc 0.1% ethacridine lactate was instilled in all cases.

In both groups vital signs of the subjects were

monitored. Vaginal examination was done 12 hourly after first 12 hours to assess cervical dilatation. When the cervix was 2 cm. dilated, uterine contractions were augmented with oxytocin drip (10 units in 5% dextrose) till the fetus and placenta were aborted. Curettage was done routinely in all cases. The amount of material curetted out was noted. Those cases, which did not have cervical dilatation of 2 cm. and more by 72 hours of procedure were considered failures. In these subjects, the procedure was repeated. Antibiotics were given routinely in all cases. Instillation abortion interval and complications of the procedure in the form of failure to abort, fever, hemorrhage, requirement of blood transfusion, sepsis, readmission for curettage was noted. The instillation abortion interval was defined as the time from the completion of procedure to abortion of fetus. Hemorrhage was defined as an estimated blood loss exceeding 500 ml. or the need for blood transfusion. Fever was defined as a temperature 100.4 F or more occurring 24 hours or more after pregnancy termination.

Results

Two hundred subjects were included in the study, 100 being assigned to each group. The 2 groups, were comparable as regards their demographic and obstetric characteristics, including mean maternal age, number of previous pregnancies, estimated age and indication of termination.

Table I: Instillation-Abortion Interval

Instillation-abortion Interval (IAI)[On hours]	Intra-amniotic (N=100)	Extra-amniotic (N=100)
12 hrs.	00	02
12-24 hrs.	21	25
24-48 hrs.	68	56
48-72 hrs.	11	15
>72 hrs.	00	02
Mean IAI	35.7	38.5

Table I shows instillation abortion intervals for each group. The mean instillation-abortion interval was 35.7 hours in intra amniotic group as compared to 38.5 hours in extra-amniotic group. Thus the difference was of barely 3 hours.

Table II: Success Rate

	Intra-amniotic (N=100)	Extra-amniotic (N=100)
Over all success rate	98	98
% of subjects aborting within 48 hrs.	89	83

Table II reveals that the over-all success rate was similar in both groups being 98%. However 89% of patients aborted within 48 hours in intra amniotic group as compared to 83% patients in extra amniotic group. The difference was not statistically significant. (P > 0.5)

Table III: Gestational Age and Success rate

Week of Gestation	Intra-amniotic Success Rate		Extra-amniotic Success rate	
	No.	(%)	No.	(%)
14-16	2	50%	2	100
18	50	98%	50	98
20	48	100%	48	97.9%

The success rates related to gestational age was calculated as shown in Table III. For intra-amniotic route, the success rate was 50%, 98% and 100% respectively for 14-16 wks, 18 wks, and 20 wks. For extra-amniotic group the success rate was 100%, 98% and 97.9% respectively.

There were 2 failures in each group. In both groups, the procedure was repeated. All the 4 subjects aborted within 48 hours of reinstallation.

1 subject in extra-amniotic group had excessive bleeding per vagimum requiring blood transfusion. 1 patient in each group had fever. Retained placenta (>2 hours) was found in 1 case in intra-amniotic group and in 3 cases in extra-amniotic group. Therapeutic curettage was done in all cases. No patient required manual removal of placenta. None of the subjects were found to have sepsis. There were no cervical injuries or maternal deaths. At follow-up visit after 15 days, none of the subject of either group complained of excessive bleeding or showed any evidence of infection.

Discussion

Ethacridine lactate has been used with wide margin of safety for second trimester termination of pregnancy over many years of clinical experience. There are no apparent contra-indications to its use. However with the conventional extra-amniotic route, it was found to have a longer instillation-abortion interval, a higher failure rate and more chances of incomplete abortion. Intra-amniotic instillation of hypertonic saline that was previously widely used is now abandoned following high complication rates including maternal deaths. The other drugs used by intra-amniotic route are urea, glucose, mannitol but not without drawbacks of a high failure rate, increased incidence of incomplete abortion and sepsis and inability to use them in medically high risk patients (Castadot, 1983, Chakrabarty and Duttagupta, 1993).

This study was carried out to evaluate efficacy of ethacridine lactate when used by intra-amniotic route. Raut and Aggarwal (1989), showed a superiority of route. However we did not get similar results. We found an insignificant decrease in mean instillation abortion interval and a larger number of subjects aborting within 18 hours, the overall success rates in both groups being similar. Also the incidence of complications did not differ significantly in both groups. After failure of the procedure, reinstallation had 100% success rate within 18 hours in both groups. This observation is consistent with the earlier study by Sofat and Jindal (1994). They also observed that ethacridine lactate was equally effective and safe when instilled through intra-amniotic route as compared to extra-amniotic route.

Thus the route of administration of ethacridine lactate does not alter the overall success rate for second trimester pregnancy termination.

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