

# A Comparative Study of Extra-Amniotic Instillation of Normal Saline versus Ethacridine Lactate for Induction of Labour in Antepartum Fetal Death

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## Abstract

**Objective:** To compare the efficacy of extra-amniotic saline with extra-amniotic ethacridine lactate in inducing labor in pregnancies with intrauterine fetal death.

**Material and methods:** This was a prospective randomized controlled study. 50 women with intrauterine fetal death after 20 weeks of gestation were assigned to receive either extra-amniotic infusion (150 ml) of normal saline or ethacridine lactate (150 ml) through a Foley catheter with a 30-ml inflated balloon. We induced labor using intravenous oxytocin drip only when patient did not go into spontaneous labor 6 hours after catheter expulsion.

**Result:** The mean age was  $22.6 \pm 3.2$  yrs and  $22.5 \pm 3.3$  yrs and mean parity was  $1.52 \pm 1.1$  and  $1.4 \pm 1.2$  respectively in the normal saline and ethacridine lactate group. Mean induction to onset of uterine contraction was  $10.4 \pm 6.95$  in saline and  $14.5 \pm 7.3$  in ethacridine group. Induction to delivery interval was  $20 \pm 9.2$  and  $24.7 \pm 8.0$  in both the groups respectively.

**Conclusion:** Extra-amniotic saline infusion is successful in inducing labour in antepartum fetal deaths. This method has been shown to be safe and well tolerated by the women and can be considered in areas with limited resources.

## INTRODUCTION

Interval between diagnosis of antepartum fetal death and birth is a time of great distress. When the diagnosis of fetal death has been made and confirmed by ultrasound examination, women require the time to adjust. Women should be made aware of the various options available. The main advantage of an active policy to delivery in women with a dead fetus is that a post-mortem diagnosis may be easier in the absence of maceration. If labor is induced, cervical ripening and labour induction should mimic the physiologic process of spontaneous ripening and labour as closely as possible. There are only two classes of drug which are seriously considered in induction, namely oxytocin and certain of the prostaglandins.

Despite notable improvements in the standard of living in India in recent years, poverty in India is a severe endemic problem. Of its nearly 1 billion inhabitants, 25% live below the poverty line as of 2002<sup>1</sup>, a majority of them in rural areas and 44% of them live on less than \$ 1 a day. With limited financial resources in the developing countries, even

preparations like ethacridine lactate and prostaglandins are becoming increasingly unavailable and hence the need to explore other less expensive but similarly effective methods that could be used in such circumstances.

In order to ascertain whether it is the fluid volume injected or the drug like ethacridine lactate that produces the result, it is necessary to try other fluids. Extra-amniotic saline infusion is as effective adjuvant to both midtrimester and term labour inductions. Advantage of extra-amniotic normal saline infusion includes reversibility and lack of systemic side effects, readily and freely available to patients in public hospitals. In view of its cost effectiveness and simple care of administration with its easier storage, this study was undertaken to evaluate the safety and efficacy of normal saline instillation in inducing labour and if effective to be considered in areas with limited resources.

## MATERIAL AND METHODS

Fifty women after ultrasound scan confirmation of intrauterine fetal death after 20 weeks of gestation were

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recruited from Chigateri General Hospital, Bapuji Hospital and Women and Children Hospital following hospital ethics committee approval. This was a randomized controlled trial. Inclusion criteria were (1) singleton gestation, (2) intact membranes and (3) Bishop score  $\leq 4$ . Patients were excluded for the following reasons: (1) placenta previa, or unexplained vaginal bleeding, (2) previous uterine surgical procedure and (3) evidence of chorioamnionitis.

After informed consent was obtained, women were assigned to receive either extra-amniotic normal saline (n = 25) or extra-amniotic ethacridine lactate (n = 25). All women underwent a speculum examination. The cervix was prepared with povidone-iodine (Betadine) solution and under aseptic precaution an 18-gauge Foley catheter balloon was inserted to above the internal cervical Os. The balloon was inflated to 30 mL with sterile normal saline solution, and 150 ml of normal saline or 150 ml of ethacridine lactate was instilled through the central lumen of the Foley catheter. The Foley catheter was taped to the inner aspect of the thigh with slight traction to obliterate the internal Os. Prophylactic antibiotics were given to all patients.

The Foley catheter was removed for the following reasons: (1) 24 hours had elapsed since the initial placement (2) spontaneous rupture of membranes occurred and (3) the catheter was expelled spontaneously. Oxytocin infusion was started six hours following catheter expulsion in those women who failed to set into labour. If catheter did not expel within 24 hours of initiation the alternate regime was prescribed. No patients withdrew from the protocol.

Baseline data included maternal age, gravidity, parity, estimated gestational age, Bishop score prior to catheter insertion and after catheter expulsion. The primary outcome measure were onset of labour pain, need for augmentation with oxytocin and time taken to achieve vaginal delivery. Other outcome variables included time from initiation of the procedure to catheter expulsion and maternal morbidity. To determine the significance of difference between averages and proportions, t-test and Chi square ( $\chi^2$ ) test, as applicable were performed using SPSS 10.0 for Windows.

## RESULTS

All women completed the study; hence data were available from all patients. The characteristics of the study population are presented in Table 1. The groups were similar with respect to maternal age and parity. There were no significant differences in the mean initial Bishop score or the score after

catheter expulsion when compared between the groups.

### Figure 1

Table 1: Characteristics of patients in the study population.

Characteristic	Extra-amniotic normal saline	Extra-amniotic ethacridine lactate
Age (y)*	22.6 $\pm$ 3.2	22.5 $\pm$ 3.3
Parity (No.)*	1.52 $\pm$ 1.1	1.4 $\pm$ 1.2
- Primiparous (No.)	4 (16%)	7 (28%)
- Multiparous (No.)	21 (84%)	18 (72%)
Gestational age (wk)*	32 $\pm$ 3.7	30 $\pm$ 6.5
Bishop score*		
- Before induction	3.4 $\pm$ 1.3	3.4 $\pm$ 1.3
- After catheter expulsion	6.6 $\pm$ 1.4	6.6 $\pm$ 1.3

\*Data are presented as mean  $\pm$  SD.

In the groups, 96% in normal saline and 80% in ethacridine groups respectively had onset of uterine contraction with in 24 hours of instillation. Three fourth of the women from both the group expelled catheter within 12 hours, and 64% from saline and 52% from ethacridine groups delivered within 24 hours. Almost same number of women from both the groups required augmentation with oxytocin (Table 2).

### Figure 2

Table 2: Comparison between the two groups related to onset of contraction and delivery.

Characteristic	Extra-amniotic normal saline	Extra-amniotic ethacridine lactate
Induction to onset of contraction interval*	10.4 $\pm$ 6.95	14.5 $\pm$ 7.3†
- within 24 hours (No.)	24 (96%)	20 (80%)
- 24 to 48 hours (No.)	1 (4%)	5 (20%)
Catheter expulsion time*	10.2 $\pm$ 5.0	13.5 $\pm$ 5.2
- within 12 hours (No.)	19 (76%)	18 (72%)
- 13 to 24 hours (No.)	6 (24%)	7 (28%)
Induction to delivery interval*	20.0 $\pm$ 9.2	24.7 $\pm$ 8.0†
- within 24 hours (No.)	16 (64%)	13 (52%)
- 24 to 48 hours (No.)	9 (36%)	11 (44%)
Augmentation with oxytocin		
- Required (No.)	10 (40%)	11 (44%)
- Not required (No.)	15 (60%)	14 (56%)

\*Data are presented as mean  $\pm$  SD.

†Statistically significant, p < 0.05

Table 3 shows various characteristics compared between primigravida and multigravida in both the group. Initiation to catheter expulsion, on-set of labour pain and delivery interval time was shorter in multigravidas as compared with primigravidas in both the groups.

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**Figure 3**

Table 3: Various characteristic comparison between primigravida and multigravida.

Characteristic	Primigravida (n=10)	Multigravida (n=40)
Initial Bishop Score*	2.55 ± 1.57	3.69 ± 1.19
Bishop Score after catheter expulsion*	6.36 ± 1.03	6.67 ± 1.42
Induction to onset of contraction interval*	19.81 ± 7.93	10.01 ± 6.37
- within 24 hours (No.)	7 (70%)	39 (97.5%)
- 24 to 48 hours (No.)	3 (30%)	1 (2.5)
Catheter expulsion time*	15.27 ± 6.21	10.72 ± 4.83
- within 12 hours (No.)	4 (40%)	26 (65%)
- 13 to 24 hours (No.)	6 (60%)	14 (35%)
Induction to delivery interval*	30.31 ± 6.89	20.12 ± 8.05
- within 24 hours (No.)	1 (10%)	28 (70%)
- 24 to 48 hours (No.)	9 (90%)	12 (30%)
Augmentation with oxytocin		
- Required (No.)	7 (70%)	13 (32.5%)
- Not required (No.)	3 (30%)	27 (67.5%)

\*Data are presented as mean ± SD.

The possible complications associated with the procedure are shown in Table 4.

**Figure 4**

Table 4: Comparison of problems possibly associated with the procedure.

Characteristic	Extra-amniotic normal saline	Extra-amniotic ethacridine lactate
Postpartum blood loss > 500ml	3 (6%)	2 (4%)
Pyrexia pre/post delivery	9 (18%)	8 (16%)
Leakage of fluid	42 (84%)	44 (88%)

As the procedure was performed by the author in all 50 women, there was no rupture of membranes during insertion of the catheter. Majority of the women from both the group complained of wetness of the bed from leakage of fluid which did not unduly disturb them. 18% from saline and 16% from ethacridine group had pyrexia, but in none was the temperature noted to be more than 38°C. Our institute caters mainly to middle and lower socio-economic population; hence they could not afford post-mortum to know the cause of fetal death. Fetal anomalies were noted in 5.3% of cases such as anencephaly (3.3%), spina bifida (1.3%) and hydrocephalus (0.7%), and in the rest the cause of fetal death is often unknown. However, 10 (20%) were associated with gestational hypertension and 2 (1.3%) with gestational diabetes mellitus.

### DISCUSSION

Extra-amniotic saline infusion is an important method for cervical ripening, whose effectiveness has been demonstrated by various authors both in live and dead fetuses in term pregnancies, and also in second trimester abortions<sup>2, 3, 4, 5, 6, 7</sup>. Through this study it has been noted that it is not the drug (ethacridine lactate) but the fluid that is

important for successful induction of labour. In both the groups 150 ml of fluid was used which showed similar outcome in terms of induction-contraction-delivery interval. These results are consistent with study done by Mahomed K and by Sherman DJ<sup>8, 9</sup>, who reported its effectiveness when used in women with fetal death. Mekbib TA used condom-Foley catheter method in pregnant women with intra-uterine foetal death and had 100% success rate with an induction-abortion time interval of 14.6 hr<sup>10</sup>. The advantages of the extra-amniotic saline infusion method over the prostaglandin preparations are simplicity, reversibility and safety. This method is safe and cheap, and entirely without contraindications. Maternal side effects and complications were infrequent in both the groups. Therefore, it may be considered in areas with limited resources and can be used in cases when other methods would have been dangerous or failed. As for the mechanism of action of extra-amniotic instillation of normal saline/ethacridine lactate is probably by the secretion of intrinsic prostaglandins, produced by the decidual cells and the catheter left in-situ aids in mechanical stimulation of uterus, which release oxytocin and initiates uterine contraction.

### CORRESPONDENCE TO

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