

## Evaluate the Efficacy and Safety of Normal Saline Instillation in Induction of Mid Trimester Abortions

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### Abstract

*Introduction:* A number of methods were tried since decades for Termination of mid trimester pregnancy yet there is no satisfactory, highly effective and safe method. *Aim:* evaluate the efficacy and safety of normal saline instillation in induction of mid trimester abortions and if it is effective to be considered in area with limited resources. *Materials and Methods:* Eighty cases who needed mid trimester termination of pregnancy ranging from 16 – 20wks were studied. Out of these 80cases, 40 cases were instilled normal saline and ethacridine Lactate was instilled in 40 cases extraamniotically. *Results:* The indications of termination of pregnancy were studied obstetric causes for termination of pregnancy were more. Interval between instillation of the agent and expulsion of the Foleys bulb has been observed that in 87.5% of cases in normal saline group and 72.5% of case in ethacridine group the bulb expelled with in 24 hrs of instillation. Interval between the expulsion of bulb to abortion was 70% of cases in ns group and 80% of cases in EL group aborted with in 6 hrs of expulsion of the Foleys bulb. 5% and 15% of cases in NS and EL group expelled in 6–12 hrs of expulsion of bulb respectively. Induction abortion interval is the interval from the instillation of normal saline or ethacridine lactate

solution into the extra amniotic space to expulsion of the products of conception. (fetus, placenta and membranes). Mean induction abortion interval in this study in normal saline group is 23.03hrs and ethacridine group is 25.31hrs. Induction abortion interval increased for cases with gestational age 19 – 20 wks. Escalating doses of oxytocin upto 20U starting from 5U given through drip (30 drops/min) until there were moderate uterine contractions after 6 hrs of instillation of agent. It is observed that 12.5% cases in NS group and 5% cases in EL group required no oxytocin as they aborted with in 6 hrs of instillation. 82.5% of cases induced with EASI aborted completely and 90% of cases induced with ethacridine lactate aborted completely. Success rate at 36 hrs of instillation was 87.5% in NS instilled group and 85% in EL instilled group. Success rate time 48 hrs it is 92.5% and 87.5% in NS and EL groups respectively. There were 7 cases of incomplete abortion in NS group and 4 cases in EL group which required check curettage. 2 cases in NS group had fever. 3 cases required reinstallation of agent in NS group as there was no change in bishops score and the bulb didn't expel at 36 hr of instillation *Conclusions:* Normal saline is a safe and cost effective drug in mid trimester terminations of pregnancy without any major complications.

**Keywords:** Abortions; Saline Instillation.

### Introduction

Ever since the liberation of abortion law worldwide, there is an increasing demand for legal abortion. In spite of various methods described in literature and practices by obstetrician, still there is search for a better,

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safer, quicker, cost effective, convenient and feasible method of termination in second trimester. Unlike first Trimester Abortion, mid Trimester Abortion are all associated with numerous technical problems that are considerably more difficult to solve. The foetus is large and more difficult to get through the cervix, as it is not so ready for induction of labour and delivery as it does at term induction. Second trimester abortions put tremendous pressure on women because they might take longer time and associated with physical pain and emotional burden [1].

A number of methods were tried since decades for Termination of mid trimester pregnancy yet there is no satisfactory, highly effective and safe method. The aim of methods of mid trimester abortion is to ensure most physiological delivery of the foetus and placenta with minimum hazard to the mother.

The study is 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 agents. Extra amniotic normal saline instillation is an effective adjuvant for induction of mid trimester abortions, with the advantage of reversibility, lack of systemic side effects, availability, cost effective, easier storage and simple care of administration [2].

As India is still developing country, its 25% of total population is living below poverty line, most of them in rural areas with limited financial resources, so there is need to develop less expensive and effective methods for mid trimester abortions [3,4].

The study is being undertaken to evaluate the efficacy and safety of normal saline instillation in induction of mid trimester abortions and if it is effective to be considered in area with limited resources.

## Materials and Methods

Eighty patients with gestational age 16 - 20 Weeks who required termination of pregnancy, admitted at Modern Government Maternity Hospital, Petlaburj, were selected. Out of 80 cases, in 40 cases extra amniotic instillation of 150cc of Ethacridine lactate was done. In other 40 cases 150 cc of normal saline was instilled into the extra amniotic space. Patients selected for study include 80 cases who would need termination in second trimester who will be admitted in Modern Govt. Hospital, Petlaburj.

### *Inclusion Criteria*

- Women with Gestational age 16 to 20 weeks with

### *Social Causes*

Intra uterine fetal demise

Obstetric causes which need termination

Medical causes which needs termination

- Single fetus
- Intact membranes
- Bishops score less than 4
- Women with one previous lower segment caesarean section

### *Exclusion Criteria*

- Placenta covering the os or unexplained vaginal bleeding
- Previous uterine surgical procedure (except one previous LSCS)
- Evidence of chorioamnionitis

General examination, systemic Examination, Bimanual Examination of Pelvic organs and All Laboratory investigations with USG for localisation of placenta were done.

### *Procedure*

Eighty women all of whom were 16-20 weeks of gestational age, who required termination, has detailed medical history taken. After obtaining written informed consent women will be assigned to receive transcervical extra amniotic normal saline instillation. All women were subjected to physical examination, obstetric and speculum examination, vagina will be cleared with povidine iodine (betadine) solution. Under aseptic precautions 18" no: French gauge Foleys catheter will be inserted transcervically into extra amniotic space above the internal cervical os. The balloon will be inflated with 30 cc distilled water and 150 ml (10ml/gest wk) of normal saline will be infused through central lumen of Foleys catheter in half of the cases and half of the cases will be instilled with 150-200 ml (10 ml/Gest wk) ethacridine lactate. The Foleys catheter will be taped to the inner aspect of the thigh with slight traction to obliterate the internal os.

Prophylactic antibiotics will be given to all patients. (InjectionTaxim 1 gm IV BD and injection Metrogy1 IV TID). The labour will be augmented with oxytocin infusion after 6 hours of instillation. Escalating dose of oxytocin given, starts from 5 units - maximum of 20 units. Oxytocin drip containing 5 U of syntocinon in 500 ml of 5% Dextrose was started at a rate of 30 drops per minute. The concentration

increase by 5 units after every 100ml, till uterine contractions were noted. There is no uniformity in the technique of Foleys catheter placement described in literature. In the present study the catheter was left in situ until it expelled spontaneously.

If the catheter did not expel even at 36 hours reinstallation of the agent was done. Ultra sound examination for retained product of conception (RPOC) was done after 24 hours of abortion. If there were RPOC check curettage was done.

## Results

Eighty cases who needed mid trimester termination of pregnancy ranging from 16–20wks were studied. Out of these 80 cases, 40 cases were instilled normal saline and ethacridine Lactate was instilled in 40 cases extraamniotically. Distribution of cases for normal saline and ethacridine Lactate instillation.

Out of cases distributed, 90% of the cases are in the age group between 15-29 years in the Normal

saline method (Table 2). The youngest and eldest were at the age of 16 years and 35 years respectively. In the ethacridine Lactate method 93% of the cases were in the age group of 16-29 years.

The religion-wise distribution of cases revealed that higher percentage of cases were Hindus for both Normal saline group (52.5%), Ethacridine Lactate group (50%), Muslims account for 37.50% in Normal Saline method and 42.5% in ethacridine lactate group and Christians being 10% in Normal Saline method and 7.5% in Ethacridine Lactate method.

Cases categorised on basis of gestational age revealed that all cases are between 16-20 weeks of gestation. In the Normal Saline group highest percentage of cases were between 17-18 weeks of gestation and in Ethacridine Lactate group highest percentage of cases were between 15-16 weeks of gestation.

The examination of cases based on gravida revealed that primi gravida were maximum with 42.55% in Normal Saline group and 40% in Ethacridine Lactate group.

**Table 1:** Demographic distribution

Age in Years (Range)	Normal Saline No. of Cases (%)	Ethacridine Lactate No. of Cases (5)
16-19 Years	1(2.5%)	2(5%)
20-24 years	17(42.5%)	20(50%)
25-29 Years	19(47.5%)	15(37.5%)
30-34 Years	2(5%)	3(6.1%)
35-39 Years	1(2.5%)	0
<b>Religion</b>		
Hindus	21(52.50%)	20(50%)
Muslims	15(37.50%)	17(42.50%)
Christians	4(10%)	3(7.5%)
<b>Gestational Age</b>		
15-16 weeks	8(20%)	14(35%)
17-18 weeks	18(45%)	13(32.50%)
19-20 weeks	14(35%)	13(32.5%)
<b>Gravida</b>		
Primi	17(42.5%)	16(40%)
Gravida -I	12(30%)	16(40%)
Gravida -III	05(12.5%)	06(15%)
Gravida -IV	05(12.5%)	00(0%)
Gravida -V	05(12.5%)	02(5%)

**Table 2:** Indications for termination

Indication	Normal Saline	Ethacridine Lactate
Congenital anomalies	9(22.50%)	9(22.50%)
Intra uterine demise	15(37.50%)	18(45%)
Severe preeclampsia	9(22.50%)	10(25%)
Imminent eclampsia	3(7.5%)	0
Antepartum eclampsia	4(10%)	4(10%)
Anhydramnios	1(2.50%)	0
One previous LSCS	7(17.50%)	14(35%)

The distribution of cases between gravid II and gravid V are 57 % in extra amniotic saline group and 60% in ethacridine group.

The indications of termination of pregnancy were studied obstetric causes for termination of pregnancy were more. The cases who came for termination for spacing, failure of contraception and social grounds were relatively low. The main indications being congenital anomalies(neural tube defects), intra uterine demise, severe preeclampsia, imminent eclampsia, antepartum eclampsia, anhydramnios. One previous LSCS being 17.5% in normal saline group and 35% in Ethacridine Lactate group.

In this study the interval between instillation of the agent and expulsion of the Foleys bulb has been studied. It is observed that in 87.5% of cases in normal saline group and 72.5% of case in ethacridine group the bulb expelled with in 24 hrs of instillation. In 12.5% of cases bulb expelled between 24 -30 hrs in

ethacridine group. In 5% of cases in NS group and 15% of cases in EL group bulb expelled in 30-36 hrs. 3 cases that is 7.5% of cases in NS group took more than 36 hrs to expel, these cases were considered for reinstallation of the agent.

Interval between the expulsion of bulb to abortion was observed, 70% of cases in ns group and 80% of cases in EL group aborted with in 6 hrs of expulsion of the Foleys bulb. 5% and 15% of cases in NS and EL group expelled in 6-12 hrs of expulsion of bulb respectively.

25% and 5% of cases took more than 12hr to abort in NS and EL groups respectively.

Induction abortion interval is the interval from the instillation of normal saline or ethacridine lactate solution into the extra amniotic space to expulsion of the products of conception (fetus, placenta and membranes). Induction abortion interval is less than 12 hrs in 20% of cases in normal saline group and

**Table 3:** Instillation to expulsion of foleys bulb interval and induction abortion interval(IEI)

Instillation to expulsion of foleys bulb interval	Normal Saline	Ethacridine Lactate
Less than 24 hours	35 (87.5%)	29(72.5%)
24 - 30 hours	--	5(12.5%)
30 - 36 hours	2(5%)	6(15%)
Above 36 hours	3(7.5%)	-
<b>Expulsion of foleys bulb to abortion interval (EAI)</b>		
Less than 6 hours	28(70%)	32(80%)
6 - 12 Hours	2(5%)	6(15%)
More than 12 hours	10(25%)	2(5%)
<b>Induction Abortion interval</b>		
Less than 12 hours	08 (20%)	4 (10%)
12-24 hours	15 (37.50%)	18 (45%)
25-36 hours	12 (30%)	12 (30%)
37-48 hours	02 (5%)	5 (12.5%)
49-60 hours	00	01 (2.5%)
Above 60 hour	03 (7.5%)	00(0%)

**Table 4:** Variables at abortion

Period of gestation	Normal saline	Ethacridine lactate
15 - 16 wks	8 cases - 23.7hrs	14cases - 23.7hrs
17 - 18 wks	18cases - 22.8hrs	13cases - 22.4hrs
19 - 20 wks	14cases - 19.4hrs	13cases - 29.8hrs
<b>Parity</b>		
Primi para	17cases - 27.4hrs	16cases - 26.9 hrs
Multipara	23cases - 23.5 hrs	24cases - 22.05hrs
<b>Concentration of Syntocin</b>		
Did not require	5(12.5%)	2(5%)
5 U	--	--
10 U	5(12.5%)	8(20%)
15 U	12(30%)	15(37.5%)
20 U	18(45%)	15(37.5%)
<b>Abortion</b>		
Complete Abortion	33 (82.5%)	36 (90%)
Incomplete Abortion	07 (17.5%)	04 (10%)

**Table 5:** Comparison of complications

Complication	Normal Saline No. of Cases & %	Ethacridine Lactate No. of cases & %
Incomplete Abortion	07 (17.5%)	04 (10%)
Infection/Fever	02 (5%)	00
Haemorrhage	00	00
Cervical Tears	00	00
Vomiting	00	00
Reinstillation	3(7.5%)	00

**Table 6:** Gravida and abortion intervals in studies

	Present Study		I Gupta U Mahajan study <sup>7</sup>	
	Normal Saline (NS)	Ethacridine lactate (EL)	Normal Saline (NS)	Ethacridine lactate (EL)
Primi	17 (42.5%)	16 (40%)	25 (24%)	29 (28%)
Multi	23 (57.5%)	24 (60%)	80 (76%)	75 (72%)
<b>Abortion Interval</b>				
Primi	27.44 hours	26.92 hours	15 hours 5 minutes	22 hours 11 minutes
Multi	23.5 hours	22.05 hours	19 hours 27 minutes	19 hours 26 minutes

**Table 7:** Completeness and success rate of abortion

Completeness of abortion	Present Study	I Gupta U Mahajan study <sup>7</sup>
Normal Saline (NS)	82.5%	76%
Ethacridine lactate (EL)	90%	66%
<b>Success rate</b>		
NS	75%	76%
EL	70%	66%

10% in ethacridine group. It is between 12-24 hrs in 37.5% cases in normal saline group and 45% in ethacridine group, between 25-36 hrs in 30% cases in normal saline group and 30% in ethacridine group and in 37- 48 hrs interval 5% of cases in normal saline group and 12.5% of cases in ethacridine group aborted. Three cases (7.5%) in normal saline group required reinstillation.

Mean induction abortion interval in this study in normal saline group is 23.03hrs and ethacridine group is 25.31hrs.

Mean induction abortion interval is 23.7hrs for cases with gestation age 15 – 16 wks. Mean induction abortion interval is 22.8hrs and 19.4 hrs for cases between 17–18 wks and 19–20 wks respectively. In ethacridine group the induction abortion interval almost same for cases between 16–17 wks as normal saline group, but the induction abortion interval increased for cases with gestational age 19–20 wks. primi s is 27.4 hrs in saline group and it is 26.9 hrs in ethacridine group. It is almost similar in both the groups. In multi para the induction abortion interval is 23.5 hrs in saline group and 22.05 hrs in ethacridine group. In both the groups the interval is increased in primi para when compared to multipara but the I/ A interval is almost the same in normal saline and ethacridine groups.

Escalating doses of oxytocin upto 20U starting from 5U given through drip (30 drops/min) until there were moderate uterine contractions after 6 hrs of instillation of agent. It is observed that 12.5% cases in NS group and 5% cases in EL group required no oxytocin as they aborted with in 6 hrs of instillation. There was no response with a concentration of 5U of oxytocin in both the groups. Maximum no of cases in both groups responded to concentration of 20U in both the groups (45% and 37.5% of cases in NS and EL groups respectively). 30% and 37.5% of cases responded to a concentration of 15U in NS and EL groups respectively 12.5% and 20% of cases responded to a concentration of 10U in NS and EL groups.

82.5% of cases induced with EASI aborted completely and 90% of cases induced with ethacridine lactate aborted completely. 17.5% that is 07 cases induced with normal saline and 10% that is 04 cases induced with ethacridine had incomplete abortion. Cases which had incomplete abortion needed curettage in both the group.

Success rate at 36 hrs of instillation was 87.5% in NS instilled group and 85% in EL instilled group. Success rate t 48 hrs it is 92.5% and 87.5% in NS and EL groups respectively. In the present study, 3 cases needed re-instillation in NS group. Hence, NS can be

safely used for termination of second trimester pregnancy.

There were 7 cases of incomplete abortion in NS group and 4 cases in EL group which required check curettage. 2 cases in NS group had fever. 3 cases required reinstillation of agent in NS group as there was no change in bishops score and the bulb didn't expel at 36 hr of instillation.

## Discussion

The aim of mid trimester medical termination of pregnancy is to ensure most physiological delivery of the foetus with minimum hazards to the mother. The ideal mid trimester abortifacient should have the following prospects:

1. Wide margin of safety between the pharmacological and toxic dose.
2. Effective and high success rate
3. Minimal side effects and complications
4. If introduced inadvertently into the systemic circulation should not cause any ill effects
5. Easily available and economically feasible

Numerous studies are available extolling the varieties of extra amniotic instillation of ethacridine lactate [5,6,7] for mid trimester termination of pregnancy. In Indian literature, there are fewer studies on extra amniotic saline infusion for second trimester termination of pregnancy [7]. A comparison of extra amniotic physiological saline and ethacridine dye instillation for induction of mid trimester abortion where study concluded that normal saline is a cheap easily available safe abortifacient. It is efficient as ethacridine lactate [8]. In this 30 cases needed mid trimester abortions where instilled normal saline extra amniotically. This study also concluded extra amniotic saline infusion is an effective method for cervical ripening in second trimester abortion.

Present study consists of 80 cases that require second trimester pregnancy termination. Gestational age between 16-20 weeks was studied. Out of these, 40 cases were instilled 150 ml of ethacridine lactate extra amniotically and 40 cases were instilled normal saline extra amniotically. Both groups were administered with oxytocin after 6 hours. Oxytocin drip containing 5 units of syntocinon in 500 ml of 5% dextrose was started at the rate of 30 drops per minute. The concentration was increased by 5 minutes after every 100ml until there were moderate uterine contractions. Maximum percentage of cases required max concentration of 20 U oxytocin for initiation of

response (45% and 37.5% in NS and EL groups respectively). Prophylactic antibiotics were given to all subjects in both groups for 5 days.

Study included women from age 16-40 years and gestational age 16-20 weeks. Majority in this study were between 20-30 years. These included mostly women who needed termination for medical causes such as intra uterine demise (IUD), severe pre-eclampsia, antepartum eclampsia. Most common cause for termination was IUD and fetalanomalies (neural tube defects). Distribution of cases based on parity was studied. Majority were primi gravida in both the groups. 42.5% of primi gravida in normal saline group and 40% in ethacridine group.

Most of the cases in both the groups that is normal saline group and ethacridine group, aborted between 12 and 24 hours from the time of instillation. 37.5% in normal saline group and 45% in ethacridine lactate group. 2 cases in normal saline group aborted after 60 hours of instillation, which required re-instillation. Distribution of cases based on IAI was studied. Mean induction abortion interval in normal saline group is 23.03 hours and 25.31 hours in ethacridine group (P value 0.001). Both groups had less significant difference in mean IAI. In I Gupta and U Mahajan study, mean IAI interval was 18 hours 25 minutes in normal saline group and 20 hours 12 minutes in ethacridine group. No specific pattern has been observed in IAI with regards to the gestational age, but IAI in primies were more than in multies in both groups in the study.

Distribution based on completeness of abortion was studied. In the present study, 82.5% aborted completely in normal saline group and 90% in ethacridine group. 7 cases in normal saline group and 4 cases in ethacridine group required curettage for incomplete abortion.

In I Gupta U Mahajan study, majority were multies as in the present study. Primies are more in the present study when compared to the I Gupta U Mahajan study.

Mean IAI in primies and multies was studied and was compared to I Gupta U Mahajan [7] study. In both groups (NS and EL), mean IAI in primies is more than in multies in present study. In the present study, IAI in primies in normal saline group is more (27.44 hours) than multies and the IAI in I Gupta U Mahajan study, multies is more when compared to primies in normal saline group.

In the present study, 82.5% in NS group 90% in EL group aborted completely. 4 cases in EL group and 7 cases in NS group required curettage for incomplete abortion. In I Gupta U Mahajan study, 76% in NS

and 66% in EL group were aborted completely. The difference is not being statistically significant.

### Success Rate

Success rate at 36 hrs of instillation was 87.5% in NS instilled group and 85% in EL instilled group. Success rate at 48 hrs it is 92.5% and 87.5% in NS and EL groups respectively. In the present study, 3 cases needed re-instillation in NS group. Success rate in I Gupta and U Mahajan study at 30hrs after instillation compared to the present study. It is observed that the success rate at 30hrs of instillation were similar in NS group in both the studies. Success rate EL group was 66% in I Gupta U Mahajan study and 70% in the present study at 30 hrs of instillation of agent.

Himmelmann [9] reported 200 cases of extra-amniotic ethacridine lac-tate in the dosage of 10 ml. per gestation week, maximum upto 150 ml. The catheter was withdrawn after 24 hours. The success rate was reported to be 80% with a low complication rate. Martin [10] combined the immediate uterotonic property of prostaglandins and the delayed oxytocic response of ethacridine lactate. During the first hours, 750 µgm of PGF<sub>2</sub> α were supplemented and the catheter was withdrawn after 12 hours, giving rise to the success rate of 75%. In India, Anjaneyulu et al [5] from Poona reported the success rate of 81.4%, in 72 hours.

### Complications

In I Gupta and U Mahajan study, there was case which required hystrotomy and tubal ligation because of profuse bleeding after the placement of catheter and another case needed blood transfusion but in the present study no surgical intervention or blood transfusions were needed in any case. No major complications were observed in the present study.

### Conclusion

Majority of cases in whom pregnancy was terminated were primi gravida and majority being terminated for medical causes in the present study.

1. Normal saline is a safe and cost effective drug in mid trimester terminations of pregnancy without any major complications.

2. No untoward incidents were seen.
3. Success rate being 100%.

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