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A PROSPECTIVE RANDOMISED COMPARATIVE STUDY OF USE OF VAGINAL MISOPROSTOL ALONE VS ETHACRIDINE LACTATE FOLLOED BY VAGINAL MISOPROSTOL FOR SECOND TRIMESTER TERMINATION OF PREGNANCY

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ABSTRACT:

Background: Abortion is a major social &health issue in India. 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. **Aim:** The aim of the present study was to compare efficacy of the vaginal misoprostol alone versus extra amniotic instillation of ethacridine lactate followed by vaginal misoprostol for second trimester(13 to 20 weeks of gestation) termination of pregnancy. **Materials and Methods:** This study was a prospective, randomized and comparative study which was conducted in the Department of Obstetrics and Gynaecology, for a period of 1 year. A total of 53 patients were selected and divided into 2 groups. In group 1 (28 patients) vaginal misoprostol 400 mcg was inserted followed by every 4^{th} hourly up to maximum five doses or untill expulsion of the fetus. 25 women were allocated to group 2, Ethacridine lactate followed by vaginal misoprostol was administered and all of them received the intervention. **Results:** Mean IAI in Misoprostol Alone group was 14.93 ± 2.04 hours and in Combined group was 9.72 ± 1.10 hours .The difference was significant($P<0.001$). In Misoprostol group, 85.7% had complete abortion and 14.3% underwent Suction & Evacuation i/v/o retained products of conception, in Combined group, 96% had complete abortion and 4% required Suction & Evacuation i/v/o retained products of conception. The difference was not statistically significant.($P<0.201$). There were no significant side effects seen in either group. **Conclusion:** Combined extra amniotic instillation of ethacridine lactate followed by vaginal misoprostol is more effective than vaginal misoprostol alone for second trimester termination of pregnancy, resulting in shorter induction to abortion intervals. Use of either method was safe with regard to side effects

observed and completion of procedure.

Keywords: Termination of pregnancy, abortion, amniotic instillation

Introduction:

Midtrimester termination of pregnancy is one of the most controversial areas of gynecological practice[1] . It has moral, emotional, social and technical issues. There is continuous need for termination of pregnancy in second trimester, more recently due to increase in the use of antenatal diagnostic procedures. Because of inherent morbidity and mortality, midtrimester termination done either by surgical or medical methods deserves special importance. The ideal method is still eluding us. It is debatable which method is safest, most effective and having least complications. No method is simple, safe and optimally effective. Trials are still going on. Dilation and evacuation the only acceptable surgical method is loosing its popularity due to lack of proper training schedule, its inherent complications and the challenge offered by medical methods. Nowadays, majority of mid trimester abortions are carried out medically[2]. Women suffer in silence, ignorance, lack of awareness &education in developing countries like India ..Abortion is a major social &health issue in India .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 ,The aim of our study is to establish safer and effective method for second trimester termination of pregnancy .Since January 1970, Prostaglandins have been extensively studied and evaluated for termination of pregnancy at 13 to 20 weeks of gestation ,which comes under medical termination of pregnancy act 1971.

According to medical termination pregnancy act 1971,which defined as willful termination of pregnancy before the period of viability that is before 20 weeks of gestation .Misoprostol ,a synthetic analogue of PGE1 being cheaper and safe as compared to ethacridine lactate and can be used in different dosage regimens with varying degrees of successs .The problem with the use of prostaglandins are rapid metabolic inactivation requiring multiple dosings and systemic side effects like nausea, vomiting ,diarrhea ,reduce in the blood pressure. Extra amniotic instillation ethacridine lactate has long been used for second trimester termination of pregnancy and is considered a time tested, safe and effective method. But when used alone it has a prolonged induction abortion interval and increased incidence of failure. The aim of the present study is to reduce the systemic side effects of misoprostol and improve the efficacy of the procedure by reducing the induction abortion interval and to avoid complications like hemorrhage , infection , perforation and to reduce the hospital stay. This study compared the efficacy of the vaginal misoprostol alone versus extra

amniotic instillation of ethacridine lactate followed by vaginal misoprostol for second trimester(13 to 20 weeks of gestation) termination of pregnancy.

Materials and methods: This study was a prospective, randomized and comparative study which was conducted in the Department of Obstetrics and Gynaecology, MGM Hospital for a period of 1 year between December 2016 to November 2017. The study was approved by the Institutional Ethics Committee. A total of 53 pregnant women with obstetrical or medical indications for second trimester termination of pregnancy were enrolled in the study in accordance with the inclusion and exclusion criteria after a detailed history and examinations, USG done for confirmation of gestational age. Consent forms were prepared in Telugu , Hindi and English, signed by the pregnant woman after proper explanation in their vernacular language and informed consent obtained eligible women were selected in the study. Inclusion criteria was all women requiring pregnancy termination between 13 to 20 weeks of gestation due to various reasons, with a valid legal indication as per MTP act taken. Pregnant women with no known medical disorders. Exclusion criteria was the pregnant women with scar on uterus, low lying placenta and severe anemia (Hemoglobin less than 7 g/dl) were excluded from the study. The 53 pregnant women were randomized into two groups. 28 women were allocated to group I (Vaginal Misoprostol) and all of them received the intervention. 25 women were allocated to group II Ethacridine lactate followed by vaginal misoprostol and all of them received the intervention. All of the patients in both the groups came for follow up. Detailed history was obtained from women enrolled in the gynecology OPD requiring for second trimester MTP. A thorough examination including demographic and social data, physical examination was done to rule out any systemic diseases like hypertention, previous uterine surgery, cardiac or renal disorders, severe anemia, bronchial asthma. From the history, gestational age was determined from date of LMP, clinical examination and confirmed by ultrasonography. Ethical committee approval was taken, informed and written consent was obtained. Randomization was done using a table of random numbers. Women in group I (misoprostol group): vaginal misoprostol 400 mcg placed in posterior fornix, repeated every 4^{th} hourly, maximum of 5 doses was given or till expulsion of fetus and placenta. Women in group II (combination group): extra amniotic instillation of ethacridine lactate 10 ml/week of gestation or maximum of 150 ml would instilled by using foley's catheter placed intra cervically and foley's bulb is inflated with 30 cc of distilled water to prevent leakage of solution followed by 6 hours, later vaginal misoprostol 400 mcg inserted every 4^{th} hourly, maximum of 5 doses or till expulsion of the fetus and placenta. Women observed for 24 hours for spontaneous expulsion of products. In our study, if no

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expulsion occurred in 48 hours, the cases considered as failure. In both groups after delivery of fetus, all women received 20 units of oxytocin in 500 cc of ringer lactate. When placenta and membranes expelled with in 1 hour of expulsion of fetus, abortion considered as complete. If not, manual removal or curettage was done and the abortion was considered as incomplete. Failure of the procedure is defined as failed expulsion of the fetus at 48 hours or the occurance of systemic adverse signs and symptoms severe enough to preclude further use of the drugs. Vital signs were monitored every 4^{th} hourly , occurance of fever, chest pain, breathing difficulty, vomiting ,diarrhea ,and signs of water intoxication recorded. Completion of the abortion is defined as expulsion of both placenta and fetus without operative assistance. The induction abortion interval is defined as time from initiation of ethacridine lactate or administration of vaginal misoprostol to abortion. Discharge of the patient was done after 24 hours of abortion , if she had no complaints. Success rate ,induction abortion interval ,type of abortion , side effects, and complications noted. The collected data was entered into Microsoft office excel – 2016 and data analysis was performed by using the SPSS version 17 software. The analyzed data was presented as descriptive tables. Data between misoprostol group and Ethacridine lactate and vaginal misoprostol group was analyzed by using student t test and chi square test to find out the differences between the two means and analysis done with 5% precision and 95% interval. **Chi-square test** used as test of significance for qualitative data. Continuous data was represented as mean and standard deviation. **Independent t test** was used as test of significance to identify the mean difference between two quantitative variables. **p value** (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Results:

Table 1: Demographics: Age distribution of subjects, married life distribution, registration of ANC in two groups

		Groups			
		Misoprostol Alone(Group1)		Combined(Group2)	
		Number	%	Number	%
Age	<20 years	1	3.6%	0	0.0%
	21 to 25 years	11	39.3%	15	60.0%
	26 to 30 years	12	42.9%	5	20.0%
	>30 years	4	14.3%	5	20.0%
	Total	28	100.0%	25	100.0%
Married Life (Yrs)	1 year	11	39.3%	3	12.0%
	2 to 5 years	12	42.9%	20	80.0%

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	>5 years	5	17.9%	2	8.0%
	Total	28	100.0%	25	100.0%
Registration	Booked	19	67.9%	18	72.0%
	Unbooked	9	32.1%	7	28.0%
	Total	28	100.0%	25	100.0%

Table 1 shows that in group 1, the proportion of women aged <20 years was 3.6%,21 to 25 years was 39.3% ,26 to 30 years was 42.9%,>30 years was 14.3%. In group 2, 21 to 25 years was 60%, 26 to 30 years was 20%,>30 years was 20%. Mean age of subjects in group-1 was 25.93 ± 3.51 years and in combined group was 26.04 ± 4.24 years. This difference was not satistically significant (p value was 0.216). Mean duration of married life in Misoprostol Alone group was 3.25 ± 2.17 years and in combined group was 2.80 ± 1.29 years. There was no significant difference in duration of married between two groups (p value was 0.021). In Misoprostol group, 67.9% were booked ANC and 32.1% were unbooked and in combined group, 72% were booked and 28% were unbooked. There was no significant difference in registration of ANC between two groups (p value was 0.743).

Table 2: Demographics: Locality of subjects and parity in two groups.

		Groups			
		Misoprostol Alone (Group 1)		Combined (Group 2)	
		Number	%	Number	%
Locality	Rural	6	21.4%	5	20.0%
	Urban	22	78.6%	20	80.0%
Parity	Multigravida	16	57.1%	16	64.0%
	Primigravida	12	42.9%	9	36.0%
	Total	28	100,0%	25	100.0%

Table 2 shows that in Misoprostol group, 78.6% were from urban area and 21.4% were from rural area and in combined group 80% were from urban area and 20% were from rural area. There was no significant difference in locality between two groups (p value was 0.898). In Misoprostol group, 57.1% were Multigravida and 42.9% were Primigravida and in Combined group, 64% were Multigravida and 36% were Primigravida. There was no significant difference in parity between two groups (p value was 0.610).

Table 3: Period of gestation distribution of subjects in two groups.

		Groups			
		Misoprostol Alone (Group 1)		Combined (Group 2)	
		Number	%	Number	%
Period of Gestation	13	1	3.6%	0	0.0%
	14	2	7.1%	0	0.0%

	15	2	7.1%	6	24.0%
	16	2	7.1%	3	12.0%
	17	2	7.1%	2	8.0%
	18	2	7.1%	2	8.0%
	19	6	21.4%	0	0.0%
	20	11	39.3%	12	48.0%

Table 3 shows that mean period of gestation in Misoprostol Alone group was 18.11 ± 2.23 weeks and in Combined group was 17.92 ± 2.2 weeks. There was no significant difference in period of gestation between two groups. In Misoprostol group, 39.3% were in 20 weeks of gestation (39.3%), 19 weeks of gestation in 21.4% and in Combined group, 48% were in 20 weeks of gestation and 24% were in 15 weeks of gestation. There was significant difference in period of gestation between two groups.

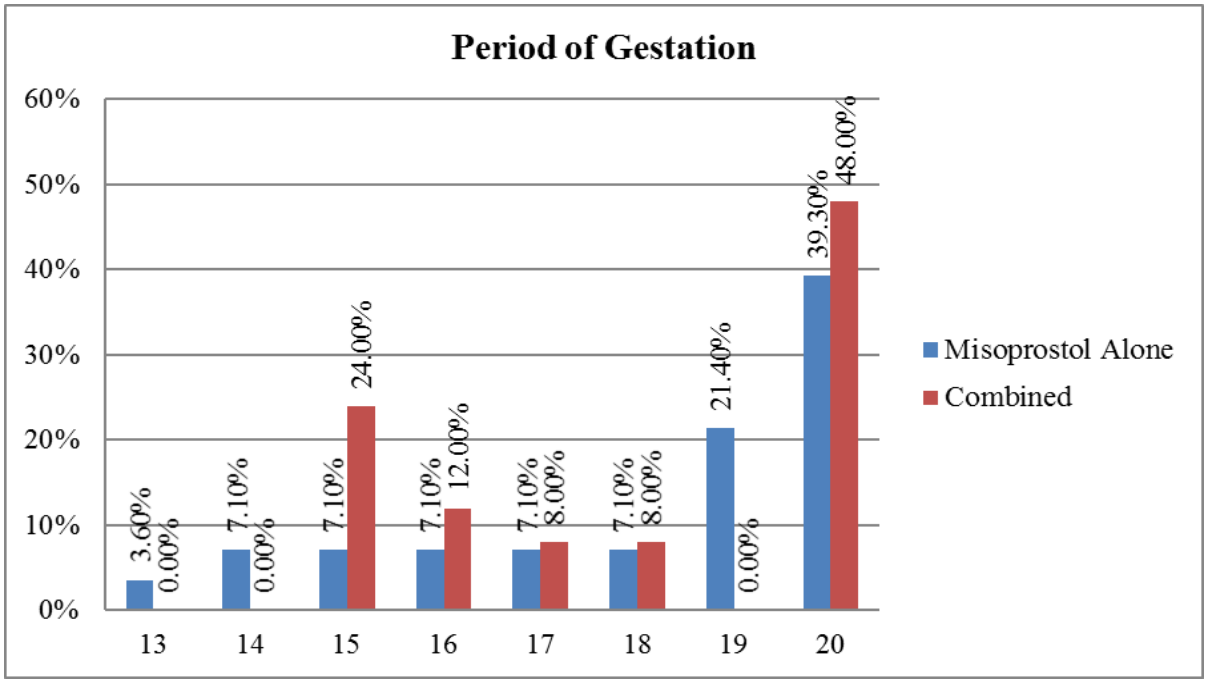

Figure 1: Period of gestation distribution of subjects in two groups.

Table 4: IAI (hrs) distribution of subjects in two groups

		Groups			
		Misoprostol Alone (Group 1)		Combined (Group 2)	
		Number	%	Number	%
IAI hrs	8	0	0.0%	3	12.0%
	9	0	0.0%	8	32.0%
	10	1	3.6%	9	36.0%
	11	0	0.0%	3	12.0%
	12	3	10.7%	2	8.0%
	13	3	10.7%	0	0.0%

	14	3	10.7%	0	0.0%
	15	6	21.4%	0	0.0%
	16	6	21.4%	0	0.0%
	17	3	10.7%	0	0.0%
	18	3	10.7%	0	0.0%

Table 4 shows that mean IAI in Misoprostol Alone group was 14.93 ± 2.04 hrs and in Combined group was 9.72 ± 1.10 hrs. This difference was statistically significant (p<0.001).

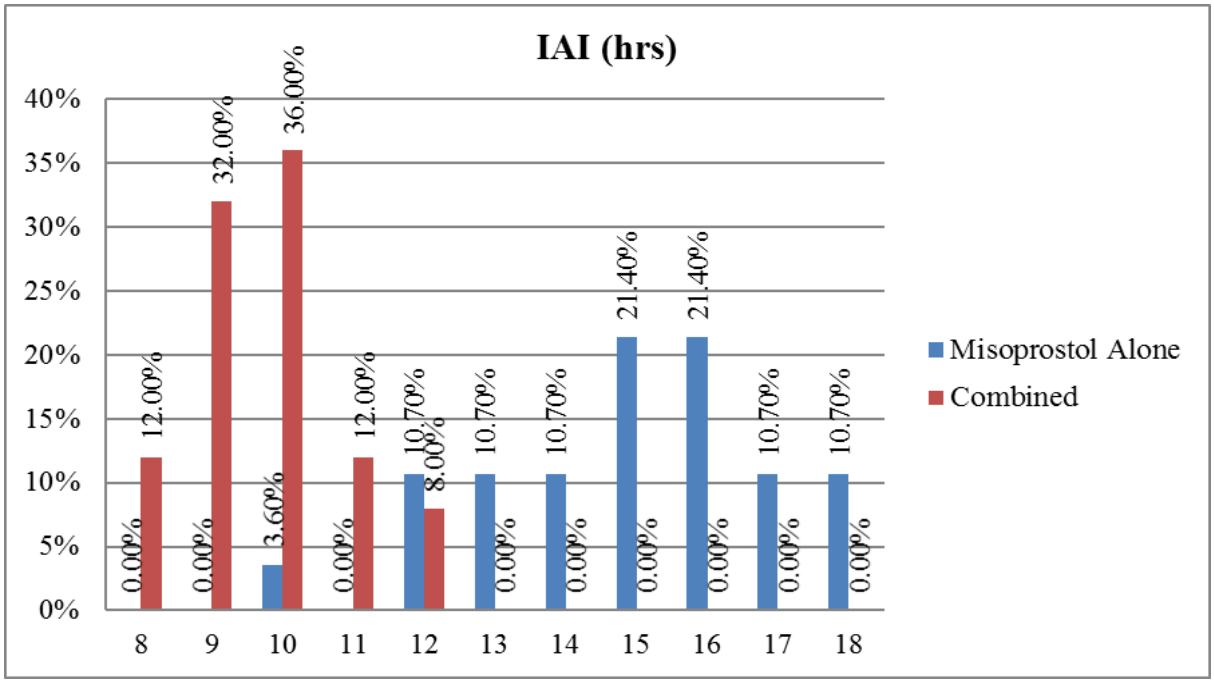

Figure 2: IAI (hrs) distribution of subjects in two groups.

Table 5: Outcome comparison between two groups (RPOC requiring evacuation)

		Groups			
		Misoprostol Alone (Group 1)		Combined (Group 2)	
		Number	%	Number	%
Outcome	Complete abortion	24	85.7%	24	96.0%
	Incomplete abortion (RPOC)	4	14.3%	1	4.0%

Table 5 shows that in group 1, 85.7% had complete expulsion with misoprostol alone and 14.3% required suction & evacuation in view of retained products of conception, in group 2, the proportion were 96% and 4% respectively. There was no significant difference among the two groups (p value was 0.201).

Table 6: Indication for termination among the two groups

		Groups			
		Misoprostol Alone (Group 1)		Combined (Group 2)	
		Number	%	Number	%
Indication	Missed miscarriage	16	57.1%	15	60.0%

	Fetal anomalies	9	32.1%	8	32.0%
	Fetal Anhydramnios	3	10.7%	2	8.0%

Table 6 shows that in Misoprostol group, most common indication for induction was missed miscarriage in 57.1%, fetal anomalies in 32.1% and Anhydramnios and others in 10.7% .In thecombined group, most common indication for induction was missed abortion in 60%, fetal anomalies in 32% and Maternal or Anhydramnios in 8%. There was no significant difference in indication for induction between two groups.

Discussion:

Ethacridine lactate for mid-trimester abortion has a long history of use in our country and its safety has documented. There are no apparent contraindications for its use. Its use alone has certain disadvantages like longer induction abortion interval, higher failure rate and more chances of incomplete abortion.[3] However, by combining Ethacridine lactate with tab Misoprostol per vaginally these disadvantages have largely been overcome leading to shorter induction abortion time and higher success rates in terms of complete abortion. Hence, this regime is now better alternative for either agent used alone. In present study majority of the women seeking abortion were in the age group of 20 and 30 years (80%). Mean age of subjects in Misoprostol Alone group was 25.93 ± 3.51 years and in combined group was 26.04 ± 4.24 years. There was no significant difference in mean age between two groups. Gangwal Mamta et al[3] conducted a study, they reported that mean age group was 25 years which was similar to the present study. In present study, mean duration of married life in Misoprostol Alone group was 3.25 ± 2.17 years and in Combined group was 2.80 ± 1.29 years. There was no significant difference in duration of married between two groups. In present study Misoprostol group, 67.9% were booked ANC and 32.1% were unbooked and in combined group, 72% were booked and 28% were unbooked. There was no significant difference in registration of ANC between two groups. In present study, Misoprostol group, 78.6% were from urban area and 21.4% were from rural area and in combined group 80% were from urban area and 20% were from rural area. There was no significant difference in locality between two groups. In study conducted by Desai GS et al[4], similar results were observed that mean age 25.4 ± 3.2 years, range 23–32 years; mean BMI 22.3 ± 3.4 kg/m^2; mean parity 2.1 ± 1.4, average gestational age 17.9 ± 2.4 weeks) underwent second trimester termination of pregnancy at our institution. Gangwal Mamta et al 2016[3] randomized 60 women for mid-trimester termination of pregnancy (13-20 weeks) in 2 groups . Group-A (30 cases) received intravaginal tab Misoprostol 600 g followed by 400 g 8 hourly and Group-B

(30 cases) received extra-amniotic Ethacridine lactate 0.1% followed 6 hours later by intravaginal Misoprostol 400 g 3 hourly until abortion occurred or upto 48 hours. Most women came from urban areas (66.67%) which is similar to present sudy. In present study Misoprostol group, 57.1% were Multigravida and 42.9% were Primigravida and in Combined group, 64% were Multigravida and 36% were Primigravida. There was no significant difference in parity between two groups. Gangwal Mamta et al [3] showed most women with mean parity 1.51 (majority were Para 1 and Para 2).This is similar to present study most pregnant woman are multipara. They were multiparous women with average of 2 children in the family. In present study, mean period of gestation in Misoprostol Alone group was 18.11 ± 2.23weeks and in Combined group was 17.92 ± 2.2 weeks. In Misoprostol group, 39.3% were in 20 weeks of gestation (39.3%), 19 weeks of gestation in 21.4% and in Combined group, 48% were in 20 weeks of gestation and 24% were in 15 weeks of gestation. There was no significant difference in period of gestation between two groups.The average duration of pregnancy at the time of MTP was 18 to 20 weeks. In Atima Bharti et al study[5], women having gestational age of 17-20 weeks, 100% aborted within 24 h and 76% aborted within 24 h in women having gestational age of 13-16 weeks. About 88% of cases with gestational age of 13-20 weeks had complete abortion within 24 h and did not require surgical evacuation. Exactly 12% of patients with gestational age of 13-16 weeks required surgical evacuation for placental bits and membrane. This observation was found statistically significant. Gangwal Mamta, et al[3] study showed that majority of women had mean gestational age of 16.8 weeks compared to present study. In present study the average duration of pregnancy at the time of MTP was 18 to 20 weeks. In present study, Misoprostol group, most common indication for induction was missed abortion in 57.1%, fetal anomalies in 32.1% and Anhydramnios and others in 10.7% and in combined group, most common indication for induction was missed abortion in 60%, fetal anomalies in 32% and Anhydramnios and others in 8%. There was no significant difference in indication for induction between two groups. According to Gangwal Mamta, et al[3] study showed main indication of MTP was on Medical grounds followed by Eugenic then Social grounds. In Suryaprakash Jagdevappa et al study[7], 60 women were studied and Group A consisted of 30 pregnant women who were administered intravaginal misoprostol 400 initially followed by 400 micrograms every 6 hourly if required. Group B consisted of 30 pregnant women who were administered extra-amniotic 0.1% ethacridine lactate 150 cc. In Group A complete abortion has occurred in 28 cases (93.33%) and in Group B in 12 cases (52.17%). In present study Mean IAI in Misoprostol Alone group was 14.93 ± 2.04 hrs and in Combined group was 9.72 ± 1.10 hrs. The average induction abortion interval

was 11 hours in the present study .It ranged from 8 hours to 18 hours . There was significant difference in mean IAI between two groups.(P<0.001). Biswas Subhash Chandra, Dey Ramprasad et al[6] randomized 50 women for mid-trimester termination of pregnancy (13-20 weeks) in 2 groups. Mean induction-abortion interval was 13.94 hours in Group I v/s 28.86 hours in Group II. In Group I 84% aborted within 24 hours and 92% within 36 hours whereas in Group II 16% aborted within 24 hours and 68% within 36 hours. 32% women in Group I and 44% in Group II experienced complications. Hence used alone, Misoprostol is safer, more effective and acceptable than Ethacridine for midtrimester pregnancy termination. Compare topresent study IAI for misoprostol group was shorter than ethacridine lactate ,It can be due to usage of ethacridine lactate alone so that it is less effective than misoprostol. Gangwal Mamta, et al 2016 et al[3] randomized 60 women for mid-trimester termination of pregnancy (13-20 weeks) in 2 groups . .In mean induction-abortion interval in Group-A was 24.9 +/- 10.83 hours and in Group-B it was 18.3 +/- 6.1 hours [P-value was 0.0063 statistically significant] . Thus, induction-abortion interval was significantly less in the Ethacridine lactate + Misoprostol group (B) than the Misoprostol alone group(A). This is similar to present study that is IAI is less with ethacridine lactate followed by vaginal misoprostol group compared to present study. IAI for misoprostol group was longer ,probably due to decreased frequency of dosages. In present study Misoprostol group(group1), 85.7% had complete expulsion and 14.3% required Suction & Evacuation in view of retained products of conception, in Combined group (group2), 96% had complete expulsion and 4% required Suction & Evacuation in view of retained products of conception. There was no significant difference in Outcome between two groups. (P<0.201). Biswas Subhash Chandra et al[6] randomized 50 women for mid-trimester termination of pregnancy (13-20 weeks) in 2 groups. Misoprostol was found to be 92% effective as compared to Ethacridine with 80% effectiveness. In Group I 84% aborted within 24 hours and 92% within 36 hours whereas in Group II 16% aborted within 24 hours and 68% within 36 hours. 32% women in Group I and 44% in Group II experienced complications. Hence used alone, Misoprostol is safer, more effective and acceptable than Ethacridine for mid trimester pregnancy termination compared to present study ethacridine lactate was less effective than misoprostol can be contributed to usage of etacridine lactate alone. Gangwal Mamta et al[3] study showed that complete abortions occurred in 83.33% of cases of Group-B v/s 70% cases of Group-A. Therefore, incomplete abortions were less in Group-B than Group-A (16.67% v/s 23.33%).. The efficacy of abortion is higher (100%) in Ethacridine lactate + Misoprostol group as compared to Misoprostol alone group [93.33%] .This is similar to present study showed that ethacridine

lactate followed by vaginal misoprostol was more effective than misoprostol alone group for complete abortion. In present study there is no satistically significant side effects seen among two groups compared to Gangwal Mamta et al[3] study showed significant side effects. .In this study side effects and complications were more common in Misoprostol alone group than Ethacridine lactate + Misoprostol group. Cramping abdominal pain, nausea and fever were more common side effects in Group-A than Group-B. Complications like cervicovaginal tear and uterine haemorrhage requiring blood transfusion were 6.66% in Group-A as compared to nil in Group-B. In Mohammed et al study[8], of the 146 patients, 55 patients received misoprostol alone, 13 cases used foley's catheter alone, 67 cases received misoprostol in combination with foley's catheter and hysterotomy done in 9 patients (4 after failed induction and the rest as primary procedure). The most common complication was retained placenta except those who used Foley's catheter as they had no retained placental parts. In Kour S et al[9] study, concluded that Addition of a 0.5 mg of crushed tablet of Dinoprostone in extra-amniotically instilled ethacridine lactate reduced the instillation-abortion interval significantly, increased the chances of complete abortion and increased the success rate. In Kruti Deliwala et al[10] study, Dr V B Bangal et al study [11], concluded that use of vaginal misoprostol for second trimester termination of pregnancy is effective ,safe, better , and convenient in comparison to ethacridine lactate.

Conclusion:

This study concluded that combined extraamniotic instillation of ethacridine lactate followed by vaginal misoprostol is more effective than vaginal misoprostol alone for second trimester termination of pregnancy, resulted in shorter induction to abortion intervals compared to vaginal misoprostol alone, did not affect mode of delivery and adverse effects were less. Thus combined ethacridine lactate followed by vaginal misoprostol can be considered as safe and efficacious method for second trimester termination of pregnancy.

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