

Research Paper—Obstetrics & Gynecology



Feb, 2010

Comparison of Efficacy of Misoprostol and Ethacredine Lactate in Mid Trimester Abortion

*Dr. Uday Patel ** Dr. Kavita Chandani

** Dr. H.B. Saini ****Dr. B.R. Leuva



*****Dr. Kishor Chauhan

***** Dr. Deepak Desai

*_*****Department of Obstetrics & Gynecology, SBKS MIRC, Piparia, Baroda

OBJECTIVE(S): To compare safety & effectiveness of vaginal misoprostol for midtrimester termination of abortion as compared with ethacredine lactate.

METHODS(S): Effect of tablet misoprostol 400 µg six hourly versus extraamniotic ethacredine lactate in second trimester abortion were studied in 100 cases in a prospective, randomized controlled study. Results were analyzed by applying Chi – Square test.

RESULTS: Mean induction – abortion interval in misoprostol group was significantly less than the ethacredine lactate group. (8.52 hours & 26.31 hours respectively). Mean induction-abortion interval was not influenced by cervical length & parity. Complication of incomplete abortion was significantly less in case group (4%) compared to control group (28%). 96% clients of control group required oxytocin augmentation for completing the abortion process compared to none of the clients of case group. This was statistically highly significant. One failure was recorded in the case group compared to 2 failures in control group. Hospital stay in case group was less compared to control group which was statistically highly significant. Cost of the drugs in case group was less as compared to control group. No use of oxytocin, less hospital stay & less daily wages loss of their husbands, makes the case group method more cost effective.

CONCLUSION: Vaginal misoprostol is far

superior as abortifacient than Ethacredine lactate.

KEY WORDS: Misoprostol, Ethacredine lactate, Induction abortion interval.

INTRODUCTION: Unwanted & unplanned pregnancies have a deleterious effect on the women's physical & mental health & social background. Abortion is a method of preventing unwanted pregnancies. The subject of pregnancy termination or induced abortion is charged with emotion, superstition and religious beliefs. It involves social, political and economical issues in every country. From historical times, termination of pregnancy was practiced with or without legal and social sanctions. Because of its greater safety nowadays and its great impact on population control, abortion has gained tremendous popularity in the last few years to get rid of unwanted child in the family. In India, most of the women, who are multipara, residing in rural areas, belonging to a low socio economic group, are anemic & malnourished & illiterate. The termination of pregnancy in such illiterate population would remain the only option to limit their family on one side & to preserve health status on the other side. These abortions are to be judged by different standards: medical, ethical, social, religious & eugenic. With present knowledge no country in the world can reduce its population growth without recourse to pregnancy termination. That is why more and more countries are liberalizing their abortion laws. These abortions many times are carried by quacks,

dais and unqualified persons, with resultant high morbidity and mortality rates. So as to have a better health of a woman and reduce the number of illegal abortions the medical termination of pregnancy act was passed in Indian Parliament in August 1971 & came into force from April 1972. Implementary rules & regulations were revised in 1975. Tendency of unmarried & widows to hide pregnancy, social taboos & customs, low socio-economic status, illiteracy, conception occurring in lactation amenorrhoea, tendency & curiosity of couple to know about the sex of the conceptus, irregularity of menstruation at both ends of reproductive life, trying to terminate the pregnancy by the drugs available across the counter e.g. estrogen progesterone tablet or injection - are some of the factors which force the client to visit a gynaecologist during second trimester. In second trimester diagnosis of pregnancy is not a difficult problem.

Though various methods are available which administer the drugs by various routes for mid trimester abortion, but the search for the safest, most effective, cheapest, easiest, non surgical method for termination of pregnancy continues. Ethacredine lactate by both extra amniotic & intra amniotic routes was the gold standard for the mid trimester pregnancy termination till recent time.³ Though it was less effective, (85% success rate compared to 95% success rate with intra amniotic hypertonic saline), the maternal mortality was unknown, as the margin of safety with ethacredine lactate is very high.² Vaginal misoprostol has been used for termination of pregnancy in recent years.

American Journal of Obstetrics and Gynaecology 2003 states, vaginal misoprostol is convenient and safe alternative method for midtrimester termination of pregnancy.⁸ To see the efficacy of this wonder drug I took this study where midtrimester abortion by conventional extraamniotic ethacredine lactate method was compared with intravaginal insertion of tab misoprostol. The very encouraging results of my small study of 50 cases with vaginal misoprostol

seems to have ended for the time being the search for ideal cost effective, safe, convenient, non surgical method of mid trimester termination of pregnancy.

METHODS: This is a prospective, randomized controlled study. It was conducted on randomly selected 100 clients in second trimester. Written informed consent was obtained from all subjects after explaining the nature & purpose of the study. Prenatal sex determination was not done in any clients.

They were subjected to detailed history taking, complete general, physical & systemic examinations and vaginal examination. Subjects with past history of classical cesarean section, previous one or two lower segment caesarean section and past history of hysterotomy/perforation of uterus were excluded from the study.^{1,6} Clients in case group received 400 microgram misoprostol vaginally every 6 hrly till abortion was completed. Clients in control group received extraamniotic ethacredine lactate.

All these clients received inj. oxytocin in pints whenever they were referred to labour room. In case group *client* was given dorsal position. Under all aseptic & antiseptic precautions parts were cleaned with savlon, tab Misoprostol 400 µg was kept in posterior fornix every 6 hrly till abortion process was completed. In control group after evacuating the bladder, injection atropine 0.5 mg IM was given ½ hour before the procedure. Client was given lithotomy position. Under all aseptic & antiseptic precautions, parts were cleaned with savlon & draped with sterile towel. With the help of Sims speculum & anterior vaginal wall retractor, cervix was visualized. Anterior lip of cervix was held with vulsellum. No. 16/18 French Foley's catheter was introduced through the cervical os upto the bifurcation of catheter. Thus, catheter was allowed to pass between membrane & uterine decidua. Catheter bulb was inflated with 30 ml of normal saline. Catheter was then pulled out to facilitate separation of the membranes & to occlude the internal os by balloon to prevent leakage of dye. 150 CC of ethacredine lactate

was instilled through the catheter. The mouth of the catheter was occluded with cotton thread & catheter was fixed to the thigh of the client. In both groups – sterile pad with T bandage was given. Client was transferred to the ward with instructions to report to labour room if she had – C/o abdominal pain, bleeding per vaginum, leaking per vaginum, or spontaneous expulsion of catheter in control group. In Ward, in the study group Tab misoprostol 400 microgram was kept in posterior fornix after 6 hours of procedure and repeated thereafter 6 hrly till the desired effect of 2 finger cervical dilatation was achieved.

RESULTS:

Table – 1 : Induction - Abortion Interval In CASE & CONTROL

IA I in hours	CASE (N -50)				CONTROL (N -50)			
	Primigravida (N -8)		Multigravida (N -42)		Primigravida (N -10)		Multigravida (N -40)	
	No.	%	No.	%	No.	%	No.	%
0 – 12	06	75	20	47.6	02	20	09	22.5
> 12 -18	00	--	07	16.6	00	--	07	17.5
≥ 18 – 24	02	25	11	26.1	04	40	04	10
≥ 24 – 30	00	--	02	4.7	03	30	05	12.5
≥ 30 – 36	00	--	00	--	00	--	07	17.5
≥ 36 – 48	00	--	00	--	01	10	03	7.5
≥ 48 – 60	00	--	01	2.38	00	--	02	05
≥ 60 – 72	00	--	00	--	00	--	00	--
≥ 72	00	--	01	2.38	00	--	03	7.5

(Chi-square Test) (p=0.0004)

Mean Induction – Abortion Interval

	CASE (N-50)	CONTROL (N-50)
Duration (in hours)	8.52	26.31

Then clients were given misoprostol 400µg orally & were referred to labour room for completion of abortion process. In the control group the clients were observed in the ward for complaints of abdominal pain, bleeding per vaginum, leaking per vaginum or spontaneous expulsion of catheter. With any of the above complaints the client was referred to labour room after assessment. In the labour room, clients of case group were watched for process of abortion as they were sent to labour room only after giving 400 µg misoprostol orally. In control group, all clients were started with 10 unit oxytocin drip in ringer lactate.

The drip continued till the process of abortion was completed. After expulsion of abortus, in all clients of both case and control group we noted time of expulsion of abortus, weight, length & congenital malformation of abortus, induction abortion interval & weight of placenta. In case group, Check curettage was not done when the pregnancy was beyond 14 wks but was selectively done in those with pregnancy less than 14 weeks. In control group, Check curettage was done in all cases irrespective of weeks of gestation. All check curettages were done under atropine, sedation and antibiotics. The clients were discharged with advice to come for follow up after 2 weeks in O.P.D & further follow up was planned according to the findings of the first visit. Table 1 shows the induction-abortion interval in both case and control group. Induction-abortion interval is defined as a period between instillation of drug / dye to expulsion of placenta. It is seen from table 1 that 46 out of 50 (92%) clients in case group aborted within 24 hours compared to 26 out of 50 (52%) in control group.⁵

When we compared the induction-abortion interval of primigravidas in both case and control groups, it was found that 100% of primis in case group aborted within 24 hours, compared to just 60% in control group. 48 out of 50 clients (96%) of case group aborted within 30 hours and 1 in the next 24 hours. 1 Client was labeled as method failure in case group. In control group 34 out of 50 (68%) clients aborted within 30 hours, 11 cli-

ents aborted in 48 hours, 3 clients in next 24 hours.¹¹ 2 Clients were labeled as method failure. One failure in case group & 2 in control group were multiparous clients. Subsequently, they had the I.A.I. of 120, 130 and 133 hrs respectively. The reason for all failures in multiparous clients of both groups could be due to increased proportion of fibrosis in the cervical tissue as a result of repeated deliveries. The difference of induction abortion interval between case & control group is statistically highly significant. In the present study, the mean induction abortion interval in the case group was 8.52 hours compared to 26.31 hours in control group. Hence, the difference of induction - abortion interval in two groups was 17.79 hours, which was statistically highly significant. What is important for the abortion process to get completed is its uterotonic activity.

Table 2 shows the influence of parity on mean induction abortion interval. In case and control group, nulliparous clients had mean induction abortion interval slightly more than their parous counterparts. When the mean induction - abortion interval amongst nulliparous clients of case & control groups were compared, the difference was statistically highly significant (p=0.832). Similar was the conclusion when parous clients were compared (p=0.652).⁹ When the mean induction - abortion interval between nulliparous and parous clients within either case or control groups were compared; the difference was statistically not significant.

Table - 2 Mean Induction-Abortion Interval & Parity

Parity	CASE (N-50)			CONTROL (N-50)		
	No.	%	Mean hours	No.	%	Mean hours
Nulliparous	8	16.32	9	10	20.83	28.20
Parous	41	83.67	7.42	38	79.16	25.11

Nulliparous (p = 0.832)

Parous (p = 0.652)

Table - 3 : Comparison Of Complications In Case & Control Groups

Complications	CASE (N-50)		CONTROL (N-50)	
	No.	%	No.	%
I. Morbidity				
a. Complication requiring operative management				
1. Cervical tear	00	--	00	--
2. Retained products	02	04	14	28
3. Uterine perforation	00	--	00	--
4. Uterine rupture	00	--	00	--
5. Failure of procedure	01	02	02	04
b. Complications requiring conservative management				
1. Excessive blood loss	00	--	02	04
2. Fever	10	20	15	30
II. Mortality				
Maternal mortality	00	--	00	--

I (a): ($p = 0.363$)
0.259)

I (b): ($p =$

Complications were divided into 2 groups as shown in the Table 3. In case group only 2 (4%) clients had evidence of retained products.¹⁰ In the control group, as a policy, check curettage was done in all cases.¹⁰ In 14 out of 50 clients check curettage showed material ³ 100 gms and hence, they were labeled as incomplete abortion.¹² Excessive blood loss was reported in 2 clients in control group, but the necessity of blood transfusion did not arise. 10 clients in the case group had reported fever which was less than 100°F, persisted for < 2 hours and was relieved by paracetamol.

Technical failure : It is defined as failure to perform the procedure. As a result of accidental rupture of membranes or blood tap vaginally in extra-amniotic procedures for which the procedure had to be abandoned.

Method failure: It is defined as failure to initiate the process of abortion (i.e. uterine contraction or cervical dilatation) within 72 hours after performing the procedure successfully. Table 3 shows that in case group there was 1 method failure. This client was multiparous and had gestational age of 16 weeks. In control group there were 2 method failures. Both were multiparous,

having 3 cms long tubular cervix and gestational age of 16 and 18 weeks. The study shows that 44 out of 50 (88%) controls required less than 20 units of oxytocin, for completing the abortion process, while 4 controls (8%) required more than 20 units of oxytocin. Only 2 controls aborted without the help of oxytocin. None of the client in case group required any oxytocin for completion of abortion process. This makes the case group methodology of abortion with misoprostol a cost effective one.

In both, case & control groups, most of the clients were admitted on the day of procedure. Duration of hospital stay is a very important factor especially for clients coming from rural areas who are working on daily wages. Considering this factor, clients were kept for minimum of 12 hours after abortion. In case group 43 (86%) clients were discharged within 2 days as compared to 14 (28%) clients in control group. In control group, 32 out of 50 (64%) had to stay in hospital for 3 – 4 days as compared to 5 (10%) clients in case group. In case group only 2 (4%) clients stayed for 5-6 days, one of them was failure case & the other had to wait for Lap TL, as uterus was comparatively larger in size. In control group 4 (8%) clients stayed for 5-6 days & the reason for delay was either method failure or some delay in offering permanent contraceptive coverage. Comparative less hospital stay in majority of clients of case group makes the method of misoprostol more cost effective. The difference in hospital stays in both case & control group is statistically highly significant. The cost of the drugs in case group was Rs. 35 compared to Rs.255 in control group. Comparatively less oxytocin use, less intravenous pints use, less hospital stay, less failure rate & therefore, less daily wages loss of their husbands, ultimately make the case group method more cost effective.

DISCUSSION: Case group and control group were comparable in relation to age, parity, gravidity, education, socio-economic status, religion, gestational age, haemoglobin status & indication. Mean induction – abortion interval in case

group was significantly less than the control group (8.52 hours & 26.31 hours respectively). Induction-abortion interval was inversely proportional to gestational age. Mean induction-abortion interval was not influenced by cervical length & parity. Complication of incomplete abortion was significantly less in case group (4%) compared to control group (28%). 96% clients of control group required oxytocin augmentation for completing the abortion process compared to none of the clients of case group. This was statistically highly sig-

nificant. One failure was recorded in the case group compared to 2 failures in control group. Hospital stay in case group was less compared to control group which was statistically highly significant. Cost of the drugs in case group was less as compared to control group.⁴ No use of oxytocin, less hospital stay & less daily wages loss of their husbands, makes the case group method more cost effective.

CONCLUSION: Vaginal misoprostol is far superior as abortifacient than Ethacredine lactate.^{7,8}

REFERENCE

1. Akoury et al: Randomized controlled trial of misoprostol for second trimester pregnancy termination associated with fetal malformations. American Journal of Obst. & Gynec. 2004, 190 (3): 755-762.
2. Allahbadia G: Comparative study of midtrimester termination of pregnancy using hypertonic saline, ethacredine lactate, prostaglandin analogue and Iodine – saline. : Journal of Indian Medical Association. 1992, 90 (9), 237-39.
3. Bhatena R. K. et al: Second trimester pregnancy termination using extra amniotic ethacredine lactate : Journal of Obst & Gynec of India 1990 (11) 1026-29.
4. Carbonell JL et al: Vaginal misoprostol for early 2nd trimester abortion: European journal contraception reproduction Health Care, 1998, 3 (2) : 93-8.
5. Dickinson J. E. et al: Efficacy of intravaginal misoprostol in 2nd trimester pregnancy termination: a randomized controlled trial. Journal of Maternal fetal medicine, 1998, 7 (3), 115-9.
6. Dickinson JE, Evans SF: The optimization of intravaginal misoprostol dosing schedules in 2nd trimester pregnancy termination. American journal of Obst & Gynec, 2002: 186 (3) 5 470-4.
7. Elsheikh A et al: Use of misoprostol for the termination of 2nd trimester pregnancies: Arch Gynecol Obstetrics, 2001, 265 (4): 204-6.
8. Feldman DM et al: A randomized comparison of two regimens of misoprostol for 2nd trimester pregnancy termination: American journal of Obst & Gynecol, 2003, 189 (3), 710-3.
9. Nagi SW et al: Randomized comparison of vaginal & oral misoprostol when combined with mifepristone of second trimester pregnancy. Human reproduction, 2000, 15 (10), 2205-8.
10. Lalitkumar, M. Bygdeman and K. Gemzell-Danielsson: Mid-trimester induced abortion: a review. Oxford journal Human Reproduction Update 2007 13(1):37-52