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COMPARISON OF INTRAVAGINAL MISOPROSTOL ALONE AND IN COMBINATION WITH INTRACERVICAL FOLEY'S CATHETER FOR TERMINATION OF SECOND TRIMESTER PREGNANCY AT A TERTIARY CARE HOSPITAL IN CENTRAL RURAL INDIA

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ABSTRACT

Introduction: Terminating a pregnancy in 2nd trimester is a bigger danger to both the mother and foetus as compared to a 1st trimester pregnancy. A majority of the abortions in 2nd trimester are carried out because of foetal abnormalities and sometimes maternal complications. Out of the different methods of termination, medical methods are believed to be safer and more effective as compared to the surgical approaches.Intravaginal misoprostol and intracervical Foley's catheter are the most preferred methods amongst which some researchers claim intravaginal misoprostol whereas others believe intracervical Foley's catheter to be more effective and few researches have speculated that the 2 methods combined give best results. **Materials & Methods:** The study was carried out in 40 patients of AVBRH, Sawangi(M) after taking consent from ethical committee. Subjects were divided into 2 groups according to the method used for termination of pregnancy either misoprostol alone(n=20) or combined method(n=20). Primary and secondary outcomes and side effects were compared amongst the 2 groups. P value of less than 0.05 was considered statistically significant. **Result:** The induction to abortion interval was 7.8±2.2 hours in combined group which is significantly shorter than misoprostol alone group (12.95±1.55 hours) ($p<0.05$). The success rate was higher in combined group (90%) as compared to misoprostol (80%). **Conclusion:** Use of intracervical

Foley's catheter improves the efficacy of intravaginal misoprostol for 2nd trimester abortions with shorter induction to abortion period with no significant side effects.

KEYWORDS: Efficacy, Foley's catheter, Intravaginal, misoprostol, pregnancy, 2nd trimester, termination.

INTRODUCTION

Despite the recent advances in prenatal diagnosis in first trimester, termination of pregnancy in second trimester due to foetal abnormalities and intrauterine foetal death still accounts for large number of abortions, and has increased the demand for rapid termination of pregnancy. The main concern of the obstetricians is to provide the most effective and safest method, which have shortest induction to expulsion time, ideally should be cost effective and with minimal side effects. Earlier gestations (typically 12 to 20 weeks) have shorter abortion times than later gestational ages, but differences in complication rates within the second trimester according to gestational age have not been demonstrated. Second-trimester pregnancy termination comprises 10 to 15 percent of the approximately 42 million abortions performed annually worldwide.[1] Second-trimester procedures can be performed either with medication or by inducing mini labour by induction of labour by mechanical methods (Foleys catheter) or surgically by dilation and evacuation (D&E).

It was 8th decade of the last century when McKenzie found vaginal prostaglandin preparations fruitful for ripening the cervix. Now-a-days prostaglandin (natural as well as synthetic) preparations in the form of pessaries, tablets, gels and solutions are in vogue for cervical ripening and induction of labour.

Misoprostol is the synthetic prostaglandin of choice for medical termination. Misoprostol can be used via oral, vaginal or rectal route but when used per vagina there are fewer chances of gastrointestinal side effects like abdominal pain, and vaginal bleeding. Misoprostol is more widely used also because it is inexpensive and stable at room temperature. Misoprostol alone is best used vaginally or sublingually and doses of 400 mcg are generally superior to 200 mcg or less. Dosing every 3 h is superior to less frequent dosing intervals of up to 12 h are effective when using higher doses (600 or 800 mcg) of misoprostol. Abortion rates at 24 h are approximately 80%–85%.

Use of the Foley's catheter for termination of pregnancy was first described by Krause in 1833. In 1967, Embrey and Mollison reported a 94% successful induction rate in 100 women with Foley's catheter. The direct mechanical dilatation and endogenous release of prostaglandin are the mechanism of cervical ripening by Foley's catheter which causes mini labour hence propelling the product of conception out. The combined use of Foley's catheter balloon and instillation of extra amniotic PGF2-alpha at regular interval has resulted in very short mean induction to expulsion interval and with minimal side effects.

There have been continuing efforts to improve abortion technology in terms of effectiveness, safety (lower complication risk), technical ease of performance and acceptability. The optimal method for second-trimester abortion continues to be debated. There are no evidence-based data from developing countries such as India about the preferred method by obstetricians in low socioeconomic patients.

AIM AND OBJECTIVES

1. To study the efficacy and safety of mechanical method of induction of 2nd trimester abortion.
2. To compare the outcome of mechanical method of 2nd trimester abortion with intravaginal misoprostol.

MATERIALS AND METHODS

This randomized controlled study was carried out in the AVBRH, DMIMSU, Sawangi(M), Wardha. Ethical committee approval was obtained. Pregnant women needing termination between 14 to 28 weeks were enrolled.

The cases were randomized into two groups-

Group A: misoprostol alone

Group B: Intracervical Foley's catheter combined with intravaginal misoprostol.

Pregnant ladies attending the OPD of AVBRH for II trimester MTP who fulfil inclusion and exclusion criteria were selected for the study. Ultrasound examination was used for the date confirmation and their eligibility to enter into the study.

Selected patients were admitted to obstetrics ward and procedure will be planned. Complete evaluation of each patient was done at admission. Detailed history as well as clinical findings of medical and obstetric examination was recorded. Informed consent was taken, thorough

detailed counselling the patient about the different procedures and methods for the termination were done.

Statistical methodology

Patients were assigned into 2 groups on admission.

In GROUP A, Induction was carried out using Intravaginal Misoprostol 400 microgram, and repeated every four hours up to a maximum of 4 doses.

In GROUP B, Induction was done by Foley's catheter induction. The patient was placed in lithotomy position, the cervix was visualized taking all aseptic precautions, the anterior lip of the cervix was grasped with a ring forceps. No 14 F Foley's catheter was held with another ring forceps and introduced into the cervix beyond internal os. The balloon was then inflated with 30 ml saline and the catheter was pulled back snugly against the internal os and taped to the inner aspect of thigh. Intravaginal Misoprostol 200 microgram was used every 6 hours upto a maximum of 6 doses.

P value of less than 0.05 was considered statistically significant.

Inclusion criteria

Singleton pregnancy at 14-20 gestational weeks that fulfil the indications defined in The MTP Act of India 1971 and have given informed written consent to participate in the stud,. Congenital Anomaly detected.

Exclusion criteria

Patient in the process of abortion, Multiple gestation, Underlying medical conditions of hepatic, renal & cardiac disease, diabetes mellitus, asthma were excluded from the study, Cervical Incompetence, Scarred uterus, Pregnancy with cervical lesions, Patients with placenta previa, Known maternal allergy to prostaglandins or previous adverse reaction, Patients with genital infections.

The outcomes were studied as:

Primary outcome: Time lapsed until the expulsion of the conceptus will be noted to calculate the induction to delivery time.

Secondary outcomes: Febrile morbidity, Excessive bleeding, Need for instrumental evacuation or other additional procedures, Pain.

RESULTS

Table 1 – Age of Study women

Age in years	Group A (misoprostol group) N=20		Group B (combined group) N=20	
	No(n)	%	No (n)	%
<20	1	5	0	0
21-25	13	65	14	70
26-30	5	25	4	20
31-35	1	5	2	10
Mean Age	(22.65 ± 3.65 years)		(23.00 ± 2.00 years)	
⧢2-value	7.40,p-value=0.06,NS,p>0.05			

Amongst the 40 antenatal women who underwent termination of pregnancy in the second trimester, 20 were selected for induction by misoprostol alone and 20 by combination of Foley's catheter with misoprostol. The mean age of the women was 22.65 ± 3.65 years in group A and 23.00 ± 2.00 years in group B, thus showing no significance as a variable associated to the outcome of use of either method of termination of pregnancy in this study. The mean weight of patients 56.9±1.9kgs in group A and 57.35±2.35kgs in group B) was also insignificantly associated to the outcomes of this study. The mean gestational age in our study group was 17± 7 weeks and 17.8± 6.2 weeks in group A and B respectively.

These results similar to other studies[2,3] indicated that the 2 groups were comparable with respect to maternal age, weight of the mother, parity and gestational age in weeks.

Table 2- Weight of Study Subjects

Weight in kgs	Group A N=20		Group B N=20	
	No(n)	%	No (n)	%
<55	2	10	3	15
56-60	15	75	13	65
61-65	2	10	2	10
66-70	1	5	2	10
Mean Weight	(56.9±1.9 kgs)		(57.35±2.35kgs)	
⧢2-value	3.38,p=0.33,NS,p>0.05			

Table 3- Parity of Subjects

Parity	Group A N=20		Group B N=20		P value
	No(n)	%	No (n)	%	
Primigravida	6	30	7	35	0.56,p=0.45,NS
Multigravida	14	70	13	65	

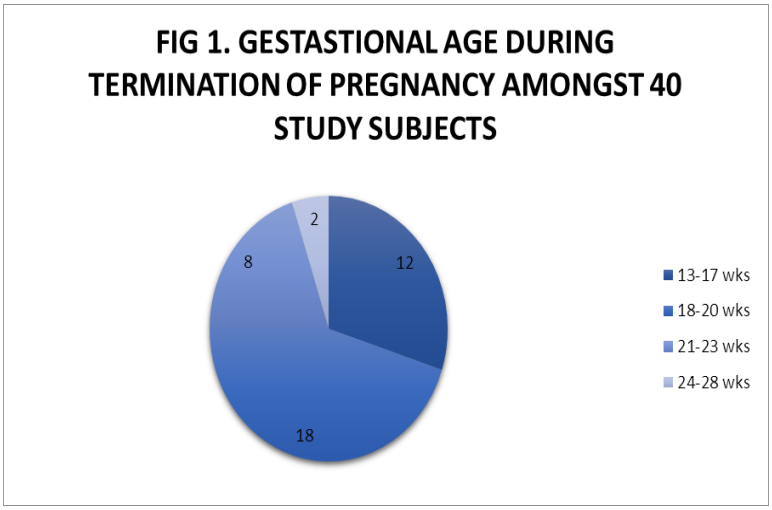

Table 4- Distribution of the 2 Groups According To Gestational Age in Weeks

Gestational age	Group A (n=20)	Group B (n=20)	P value
13–17 weeks	7(35%)	5(25%)	2.38,p=0.12,NS
18–20 weeks	9(45%)	9(45%)	0.00,p=1.00,NS,p>0.05
21–23 weeks	3(15%)	5(25%)	3.12,p=0.17,NS,p>0.05
24-28 weeks	1(5%)	1(5%)	0.00,p=1.00,NS,p>0.05
Mean Gestational Age	(17 ± 7 weeks)	(17.8 ± 6.2 weeks)	

Table 5- Indications for Termination Of Pregnancy

Indications	Group A N=20	Group B N=20	P value
Foetal anomaly	7	6	0.09,p=0.75,NS
Foetal demise	11	13	0.41,p=0.51,NS
Maternal indications	2	1	0.36,0.54,NS

Table 5 shows that the most common indication was foetal demise, which accounts for 55% and 65% in groups A and B respectively. Second common indication was congenital anomaly incompatible with life, like anencephaly, hydrops foetalis, and hydrocephalus. (35% and 30%).

Table 6- Primary Outcomes of Misoprostol Vs. Combined Group

Gestational age	Misoprostol group	Combined group	P
13–17 weeks	**(n=7)**	**(n=5)**	
Induction to abortion interval	11.8 ± 2.0 hours	6.8 ± 2.4hours	
Expulsion of foetus			
-At 4 hours	0	0	0.00,p=1.00,NS
-At 8 hours	0	3/5	120,p=0.0001,S
-At 12 hours	1/7	4/5	87.43,p=0.0001,S
-At 16 hours	3/7	5/5	28.57,p=0.0001,S
-At 20 hours	7/7	0	200,p=0.0001,S

-At 24 hours	0	0	0.00,p=1.00,NS
-At > 24 hours	0	0	
18–20 weeks	**(n=5)**	**(n=5)**	0.00,p=1.00,NS
Induction to abortion interval	12.5 ± 1.8hours	7.7 ± 2.31hours	
Expulsion of foetus			
-At 4 hours	0	0	0.00,p=1.00,NS
-At 8 hours	0	3/5	85.71,p=0.0001,S
-At 12 hours	0	4/5	85.71,p=0.0001,S
-At 16 hours	1/5	5/5	133.3,p=0.0001,S
-At 20 hours	2/5	0	50,p=0.0001,S
-At 24 hours	3/5	0	85.71,p=0.0001,S
-At > 24 hours	5/5	0	
21–23 weeks	**(n=7)**	**(n=9)**	
Induction to abortion interval	13.1 ± 1.3hours	7.8 ± 2.1hours	
Expulsion of foetus			
-At 4 hours	0	0	0.00,p=1.00,NS
-At 8 hours	0	2/9	24.72,p=0.0001,S
-At 12 hours	0	5/9	75.86,p=0.0001,S
-At 16 hours	0	7/9	125.2,p=0.0001,S
-At 20 hours	0	8/9	157.1,p=0.0001,S
-At 24 hours	0	9/9	200,p=0.0001,S
-At > 24 hours	7/7	0	200,p=0.0001,S
24–28 weeks	**(n=1)**	**(n=1)**	
Induction to abortion interval	14.4 ± 1.1	8.9 ± 2.0	
-At 4 hours	0	0	0.00,p=1.00,NS
-At 8 hours	0	0	0.00,p=1.00,NS
-At 12 hours	0	1/1	200,p=0.0001,S
-At 16 hours	0	0	0.00,p=1.00,NS
-At 20 hours	0	0	0.00,p=1.00,NS
-At 24 hours	1/1	0	200,p=0.0001,S
-At > 24 hours	0	0	0.00,p=1.00,NS

Table 7- Secondary Outcomes of Misoprostol vs. Combined Group

Gestational age	Misoprostol group	Combined group	P
13–17 weeks	**(n=3)**		
Manual separation of placenta	0	0	200,p=0.0001,S
Surgical evacuation	0	0	200,p=0.0001,S
Blood loss (<200 ml)	2/3	3/5	0.77,p=0.37,NS,p>0.05
Blood loss (>200 ml)	1/3	2/5	1.05,p=0.30,NS,p>0.05
18–20 weeks	**(n=4)**	**(n=5)**	
Manual separation of placenta	¼	1/5	0.00,p=1.00,NS,p>0.05
Surgical evacuation	0	0	200,p=0.0001,S
Blood loss (<200 ml)	4/4	5/5	0.00,p=1.00,NS,p>0.05
Blood loss (>200 ml)	0	0	200,p=0.0001,S
21–23 weeks	**(n=7)**	**(n=9)**	
Manual separation of placenta	4/7	2/9	25.63,p=0.0001,S
Surgical evacuation	3/7	1/9	25.98,p=0.0001,S

Blood loss (<200 ml)	5/7	7/9	0.93,p=0.33,NS,p>0.05
Blood loss (>200 ml)	2/7	2/9	0.96,p=0.32,NS,p>0.05
24–28 weeks	**(n=1)**	**(n=1)**	
Manual separation of placenta	1/1	1/1	0.00,p=1.00,NS,p>0.05
Surgical evacuation	1/1	1/1	0.00,p=1.00,NS,p>0.05
Blood loss (<200 ml)	0	0	200,p=0.0001,S
Blood loss (>200 ml)	1/1	1/1	0.00,p=1.00,NS,p>0.05

Table 8- Side Effects of Misoprostol Vs Combined Group

Gestational age	Misoprostol group	Combined group	P value
13–17 weeks	**(n=3)**	**(n=5)**	
Nausea	1/3	1/5	4.33,p=0.03,S,p<0.05
Vomiting	0/3	1/5	22.22,p=0.0001,S
Abdominal pain	2/3	4/5	4.33,p=0.03,S
Infection	0/3	2/5	50,p=0.0001,S
18–20 weeks	**(n=4)**	**(n=5)**	
Nausea	3/4	1/5	60.65,p=0.0001,S
Vomiting	1/4	2/5	9.52,p=0.002,S
Abdominal pain	2/4	3/5	2.02,p=0.15,Ns,p>0.05
Infection	0/4	1/5	22.22,p=0.0001,S,p<0.05
21–23 weeks	**(n=7)**	**(n=9)**	
Nausea	2/7	4/9	5.55,p=0.018,S
Vomiting	2/7	3/9	0.58,p=0.44,NS,p>0.05
Abdominal pain	2/7	4/9	5.55,p=0.018,S
Infection	1/7	1/9	0.70,p=0.40,NS,p>0.05
24–28 weeks	**(n=1)**	**(n=1)**	
Nausea	1/1	1/1	0.000,p=1.00,NS,p>0.05
Vomiting	1/1	1/1	0.000,p=1.00,NS,p>0.05
Abdominal pain	1/1	1/1	0.000,p=1.00,NS,p>0.05
Infection	1/1	1/1	0.000,p=1.00,NS,p>0.05

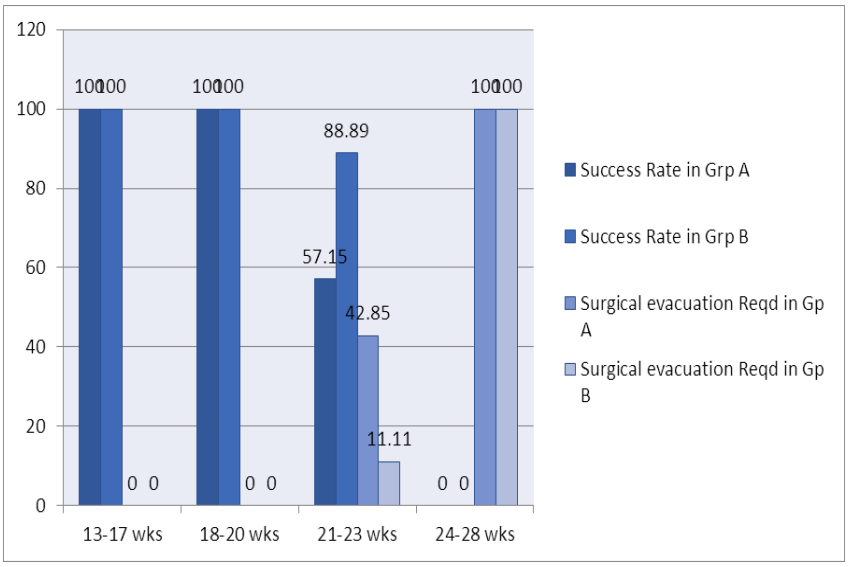

Fig 2. Comparison of Success Rate In Group A and B

DISCUSSION

When the risk of continuation of pregnancy is more than the benefits of delivering, induction of labour by various methods of cervical ripening in a short period of time plays an important role. In our country, there is very scanty literature available on second trimester abortions. India is believed, by many, to have the highest number of second trimester terminations in worldwide, but no conclusive data is available, resulting in absence of any such claim. In most of the previous studies, the estimates of number of abortions in this developing nation have unfortunately not been distinguished between the first 2 trimesters. Many recent studies have looked into abortions according to the period of gestation in weeks. Estimates from the Government of India data for 2003 were that 11% of all abortions had taken place in second trimester.

Different studies discuss various methods for induction of labour in the second trimester, but there is still no agreement on the which is the most proper and safest way to induce labour in such cases having an unripe cervix. It carries a higher financial cost to individuals, medical institutions and society. Second trimester abortion remains a necessary procedure despite higher risks and costs compared to first trimester procedures due to advances in antenatal diagnosis; decreases access to timely, early abortion care; and medical complications of pregnancy in second trimester. Amongst the many methods, two popular methods used by modern obstetricians are vaginal misoprostol alone or use of cervical Foley's catheter combined with misoprostol.

Shabana et al[3] observed that the induction to abortion interval was 15.6±5.4 hours in the combined group as compared to 21.9 $\pm$ 4.9 hours in misoprostol group($p<0.05$). The success rate was initially 100% but decreased with increase in gestational age. They speculated that since the dose of misoprostol was same in both groups, the decrease in induction to abortion interval was obtained due to the use of intracervical Foley's catheter because of the disruption of the integrity of amnion-chorion and myometrium and the release of prostaglandin and cytokines, which alters the collagen and extracellular matrix rendering the uterus susceptible.
The study carried by Rezk et al[4], compared the outcome between 3 different groups. The first received vaginal misoprostol, the second received intracervical Foley's catheter alone and the third received both. The induction to abortion interval was 7.5±1.25 h in the combined group, compared to 11.76 $\pm$1.63 h in the misoprostol group and 19.76 $\pm$ 1.52 h in

the catheter alone group (p value<0.001) with a success rate of 100% and no major complications reported.

Subha et al[5] observed that the induction to abortion interval was 22.68±4.82 hours vs 13.84±5.3 hours in misoprostol vs. combined group. The success rate of misoprost alone was 82%, which is lesser compared to 90% in combined group. The success rate was similar to our study.

Fekratetal[6] studied three methods of cervical ripening and labor induction with vaginal misoprostol and Foley catheter and a combination of these two methods. The duration between induction of labor and delivery was significantly lower in misoprostol group. They resulted that the combination of these two methods didn't have more efficacy on cervical ripening.

Kashanianet al[7] andLevy R et al[8] concluded that Foley's catheter is a safe and suitable method for patients with an unfavourable cervix, and might reduce the duration of labor, moreover, the larger balloon volume may or may not improve these effects.

Fatemah et al, Fekrat et al,Hofmeyr et al, Chung JH et al, Culver J et al, Greybush M et al, Rust OA et al. show that the rate of success in misoprostol group was more than Foley catheter group[5, 8-14]

In Fatemah et al[5], the mean time to delivery was significantly shorter in misoprostol group rather than the Foley catheter group. Results in Fatemah et al indicated that vaginal misoprostol improves the process of delivery and increases the rate of vaginal delivery in the cases of unripe cervix. However, more studies with higher volume samples can be led to justify these results.

Hill et al[15] 2008 reported that the duration between induction and delivery in Foley catheter plus oral misoprostol group was significantly shorter than that of vaginal misoprostol group. Dalui et al[16] reported that the duration of cervical ripening was shorter in misoprostol group which is in consistent with the result of the study carried out by Fatemah et al[5] The number of the studied patients in their study was similar to ours. Daluiet al. compared the Foley catheter and prostaglandin gel E2 for cervical ripening and the results of misoprostol group were more successful.

In the study by Bani-Irshaid et al[17], the failure rate of termination and the total insertion-to-termination time was higher with Foley catheter without traction (16.5%, 16.5 hours) than with traction (10.0%, 14.2 hours) or prostaglandin (8.0%, 11.5 hours). However, Foley catheter as a method of termination of pregnancy in second and early third trimester is safe and inexpensive and its efficacy can be enhanced with the use of traction to give similar results to prostaglandin E2.

In Sciscione AC et al[18], no differences were found between Foley catheter and misoprostol for cervical ripening and induction of labor, against the results of the other studies. The most important cause for this result may be lower repeated doses of misoprostol that was used in their study compared with Fatemah al study.

The purpose of our study was to compare the efficacy and outcome of misoprostol alone and in combination with intracervical Foley's catheter for medical termination of second trimester pregnancy. In this study the induction to abortion interval was 7.8±2.2 hours in combined group which is significantly shorter than misoprostol alone group (12.95±1.55 hours) ($p<0.05$). The success rate was higher in combined group (90%) as compared to misoprostol (80%). Surgical evacuation was needed in 10% of the cases in combined as compared to 20% in the misoprostol group (table 6 and 7). The high incidence of surgical evacuation in this study may be a result of inadequate experience delaying with second trimester abortions. The cases which required surgical evacuation in both groups were between 21 – 28 weeks (6/18). The relatively higher risk of incomplete abortion should hence be informed to the women undergoing pregnancy termination in the latter half of second trimester. Difference in the amount of blood loss between both groups was statistically significant($p=0.0001$) in 18-20 and 24-28 weeks. Combined group showed less side effects than misoprostol alone in the first few weeks of 2nd trimester but then showed no statistically significant difference in the last 4 weeks of this trimester(Table 8).

CONCLUSIONS

Inspite of increased morbidity and complications associated with second trimester abortions these are inevitable. Obstetricians are aiming to furtherreduce induction to abortion interval and blood loss to make it much safer, to reduce the adverse outcomes and improve services. In present study, the use of Foley's catheter combined with misoprostol showed statistically more significant and better outcomes than use of misoprostol alone. Our study and many others have given great information needed on these abortions in order to motivate and

inform change. There is hope for a final claim on the use of the combined group over misoprostol alone after a close look is taken at all the analysed data and evidence available regarding the same.

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