



COMPARATIVE STUDY OF MIFEPRISTONE PLUS MISOPROSTOL VS DINOPROSTONE GEL AND FOLEY'S TRACTION FOR SECOND TRIMESTER MTP

Obstetrics & Gynaecology

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ABSTRACT

Background: Abortion is an integral part of women health care. Maternal morbidity, mortality and psychological impact are much greater in midtrimester abortion than first trimester.

Objective: To study and compare efficacy of combination of Mifepristone and misoprostol with Dinoprostone gel and foley's traction for induction of 2nd trimester MTP.

Method : A retrospective study conducted at tertiary hospital from 1st July 18 to 31st Dec 19 to find out effective method of second trimester MTP with less complication. A total of 100 pregnant women of 14-20 wks GA were studied to compare combination of Mifepristone plus Misoprostol (GrA) Vs Dinoprostone gel and foley's traction (Gr B).

Results : Gr A has shorter IAI and lesser side-effects as compared with Gr B. The mean IAI is 10 hr 44 mn in Gr A while 16 hr 30 mn in Gr B.

Conclusion : Among two methods, Mifepristone plus Misoprostol is found to be more effective, has shorter IAI and lesser side effects for second trimester MTP as compared to Dinoprostone gel and foley's traction.

KEYWORDS

INTRODUCTION

Abortion is an integral part of women health care. 25% of all pregnancy ended in an induced abortion.¹ On average 56 million induced abortions were reported world-wide each year between 2010 to 2014. Rate of termination of pregnancy is persistently increasing due to wide spread use of antenatal screening techniques to detect pregnancies complicated by fetal anomalies. Maternal morbidity, mortality and psychological impact are much greater in midtrimester abortion than first trimester. There is urgent pressing need for safest and most effective method for mid trimester abortion with minimum risk & side effects to mother.

Majority of second trimester MTP are carried out by medical methods using dinoprostone gel or combination of mifepristone plus misoprostol tablets. Prostaglandin E2 (PGE2) or Dinoprostone gel used intra-cervically causes softening & dilatation of cervix followed by uterine contraction. PGE2 is expensive and requires refrigeration for storage with warming before use which is widely used traditionally over past few decades. Recently use of mifepristone along with misoprostol as effective agent for mid trimester abortion is well established. Mifepristone is anti progesterin, it binds with progesterone receptor on endometrium. It causes trophoblast to separate from decidua and increases uterine contractility. Misoprostol is synthetic PGE1 analogue which is cheap and stable at room temperature. It is available as 100 & 200 µg.

We conducted a study with objective to compare efficacy of mifepristone followed by misoprostol with dinoprostone gel plus Foley's traction for second trimester MTP.

Aims & Objectives—1.To study and compare efficacy of routine protocol of combination of Mifepristone plus Misoprostol (Group A) Vs Dinoprostone gel and foley's traction (Group B) for induction of 2nd trimester MTP. 2. Comparison of Induction to abortion interval (time calculated from first dose of misoprostol or dinoprostone gel till abortion) 3. Comparison of side effects between both groups.

MATERIAL & METHODS:

A retrospective study conducted at B.J. Govt. Medical college & Sassoon General Hospital, Pune during period of 1st July 2018 to 31st Dec 2019 to find out effective method of second trimester MTP with less complication. A total of 100 pregnant women seeking 2nd trimester MTP of 14-20 weeks of gestation with legal valid indication of MTP were included in study. Data was collected from medical records of patients, which included demographic characteristics, obstetric, medical history, blood investigation report, US report and detailed

information of maternal complications. Most common cause for second trimester MTP in our study was congenital anomaly followed by sexual assault.

Group A (50 Cases) were induced by giving tab mifepristone 200 mg orally followed by tab misoprostol 600 µg. (200 µg sublingually + 400 µg in posterior vaginal fornix) given after 48 Hrs and then tab misoprostol 200 µg SL was repeated every 4 hrly till abortion. Group B (50 Cases) were induced by dinoprostone gel 0.5mg plus Foley's traction and reassessment every 6 Hrly and reinduction by dinoprostone gel. The Foley's catheter was inserted intra cervically and bulb was inflated with 40-50 cc normal saline. Foley's traction was given by strapping catheter on medial aspect of thigh of patient. Women with bronchial asthma, hepatic and renal disease were excluded from study. In both groups, before re-induction patients were examined for uterine contraction, vaginal bleeding or any side effects and vaginal examination was done to assess cervical dilatation. After expulsion of products of conception, examination of products expelled and vaginal examination was done for completeness & check ultrasound was done in both groups.

Statistical Analysis:

Descriptive statistics such as mean, frequencies and percentage was used. For comparison of categorical variables chi-square test was used.

RESULTS:

The outcome variables studied were induction to abortion interval (IAI), misoprostol dose required for abortion, complications of second trimester MTP like incomplete abortion, hemorrhage due to atonic or rupture of uterus and failure of induction. Failure of procedure was defined as IAI >40 hrs from first dose of misoprostol or dinoprostone gel.

Table 1 : Demographic Characteristics & Obstetric details of Study Group

Sr. No.		Group A (N=50)		Group B (N=50)		P value
			Percentage		Percentage	
1	Age in years					
	<20	12	24	10	20	0.5
	20-30	34	68	34	68	
	>30	4	8	6	12	
2	GA in Wks					
	14-16	10	20	6	12	0.27
	17-20	40	80	44	88	
3	Parity					
	Nullipara	28	56	30	60	0.68
	Multipara	22	44	20	40	

4	Marital Status					
	Married	38	76	34	68	0.37
5	Unmarried	12	24	16	32	
	Scarred uterus					
	Yes	12	24	14	28	0.21
	No	38	76	36	72	

Table 1. shows most of women were in age group of <30 yrs and nulliparous. 84% cases were between gestational age of 17-20 wks. In this study previous LSCS patients were 24% and 28% in group A & group B respectively.

Table 2 : Comparison of Induction abortion interval (IAI) between both groups.

Sr. No.	IAI in Hrs	Group A (N=50)		Group B (N=50)		P value
		Percentage		Percentage		
1	0 – 6 hr	4	8	2	4	.007
2	7 – 12 hr	42	84	18	36	
3	13 – 24 hr	4	8	26	52	
4	>24 hr	-	-	34	68	

Table 2 shows 84% women from Gr A aborted within range of 7-12 hrs compared to 36% women from Gr B. Gr A has shorter IAI compared to Gr B which was statistically significant ($p < 0.05$).

Table 3 : Comparison of average IAI between both groups

Sr.No.	IAI	Number	Minimum(min)	Maximum(Min)	P value
1	Group A	50	240	1520	0.007
2	Group B	50	350	2190	

Table 3 shows average IAI in Gr A was 10 hr 44 min and Gr B was 16 hr 30 min. Mifepristone group has shorter IAI compared to dinoprostone group which was statistically significant ($p < 0.05$). The mean total dose of Misoprostol required in Gr A was 800 µg.

Table 4 : Comparison of type of abortion (Complete / Incomplete) between both groups

Sr. No.	Type of abortion	Group A (N=50)		Group B (N=50)		P value
		Percentage		Percentage		
1	Complete Abortion	46	92	42	84	0.31
2	Incomplete Abortion	4	8	7	14	

In present study 8% women from Gr A and 14% from Gr B required dilatation & evacuation (D&E) for retain placental tissue.

Table 5 : Comparison of side effects & complications between both groups

Sr. No.	Adverse Effects	Group A (N=50)		Group B (N=50)		P value
		Percentage		Percentage		
1	Nausea	1	2	1	2	0.31
2	Vomiting	2	4	3	6	
3	Fever / Rigors	4	8	6	12	
4	Diarhea	1	2	-	-	
5	Need for BT	-	-	1	2	
6	Failure (IAI >40 hrs)	-	-	1 (IAI =50 Hrs, Hysterotomy)	2	

In present study 16% women from Gr A & 20% from Gr B experienced some side effects. In Gr A 8% women had fever / Rigors compared to 12% in Gr B. 1 woman (2%) from Grp B required hysterotomy for abortion due to failure to abort within 40 Hrs of induction.

DISCUSSION:

In past, many studies have evaluated various methods of 2nd trimester termination in terms of effectiveness, its complications, acceptability of methods and ease of performance. We studied effective abortifacient in terms of safety, efficacy and side effects. In present study we compared combination of mifepristone and misoprostol in 50 cases of group A with intravaginal dinoprostone gel in 50 cases from group B. Success rate of group A was 100% which is similar to study by Suneeta Singh et al⁷ whereas as a study by Indira et al¹ showed 94% success rate with dinoprostone.

In this study minimum dose of misoprostol required was 600 µg while maximum dose was 1600 µg. Average dose of misoprostol required

was 800 µg. These findings are comparable with studies by Kaur et al⁴ and Akkenapally et al.⁵ Majority of patient in this study were in age group of 20-30 years and with unscarred uterus.

The mean IAI in Gr A and Gr B was 10 hrs 44 min and 16 hrs 30 min respectively. Mean IAI in mifepristone with misoprostol group was consistent with finding by previous studies. Mean IAI in dinoprostone gel group was comparable with study of Indira et al³ and Dickinson et al.⁶ In this study one patient from Gr B failed to abort in 40 hrs quired hysterotomy. In this study total 4 patients from group A and group B required D&E for retained placental tissue. Thus mifepristone with misoprostol was found to be effective regimen for 2nd trimester abortion because of shorter IAI, less side effects lesser chance of incomplete abortions as compared to dinoprostone gel use.

CONCLUSIONS:

Mifepristone followed by misoprostol is effective method with shorter induction-abortion interval and lesser side effects for 2nd trimester MTP as compared to use of dinoprostone gel.

Conflict of interest- NIL

Funding source – NIL.

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