Original Research Article

Comparison of intravaginal misoprostol alone and in combination with intracervical foley's catheter for termination of second trimester pregnancy at a tertiary care hospital

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Abstract

Background: Termination of pregnancy in the second trimerter is more dangerous than the first. Main concern is to provide more effective method of termination and to reduce time of induction as well **Objectives:** To assess the effectiveness, safety and acceptability of intracervical foley's catheter and vaginal misoprostol versus vaginal misoprostol for termination of second trimester pregnancy. **Methods:** This clinical study was conducted on 200 pregnant patients intended for termination of pregnancy between 13 -22 gestational weeks for any indication. Enrolled women were equally allocated into two groups: Group I (Misoprostol group): a standard regimen of moistened misoprostol tablets (400 µg) 4 hourly inserted vaginally to a max of 5 doses Group II (Combined group): intracervical Foley catheter inserted with a standard regimen of moistened misoprostol tablets (400 µg) 4 hourly intravaginally was used. Misoprostol was kept in posterior fornix and the dose was repeated every 4th hourly till the catheter got expelled out or till maximum five doses **Results:** The mean induction to abortion interval 15.75 ±1.5 h in the misoprostol group and 8.5±2.5h in combined group which was found to be statically significant($p<0.001$). The success rate with misoprostol group was 94% and in combined group was 97%. **Conclusions:** Combined use of intracervical foley's catheter and vaginal misoprostol is a novel safe, effective and acceptable method for termination of second trimester pregnancy.
Key Word: intracervical foley's catheter.

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Received Date: 16/08/2018 Revised Date: 10/09/2018 Accepted Date: 27/10/2018
DOI:

Access this article online	
Quick Response Code:	Website: www.medpulse.in
	Accessed Date: 30 October 2018

INTRODUCTION

Midtrimester termination of pregnancy (TOP) has a global incidence of 10-15[1,2,3]. Most of the time it is unavoidable. There is a gradual increase in incidence because of wide scale introduction of prenatal screening programme[4] Midtrimester abortions are associated with three to five times higher risk of maternal morbidity and mortality than termination of pregnancy during first trimester[5]. Surgical methods have more morbidity may be complicated by incomplete evacuations, uterine perforation and cervical trauma, therefore the medical methods of TOP seem to be better alternative to surgical methods[6,7] Surgical methods are gradually getting replaced by mifepristone, prostaglandins, oxytocin and mechanical methods. The most efficacious regimen for medical second trimester termination of pregnancy appears to be the use ofa combination of mifepristone, followed by misoprostol[8,9,10]. This regimen has had 97–99% rate of abortion within 24 hours[8,11]. Incountries where mifepristone is not available or affordable,

How to cite this article: Swarn Kanta, Pooja Sharma, Sandeep Sharma, Mandeep Sharma. Comparison of intravaginal misoprostol alone and in combination with intracervical foley's catheter for termination of second trimester pregnancy at a tertiary care hospital. *MedPulse – International Medical Journal.* October 2018; 5(10): 100-102. http://www.medpulse.in

gemeprostol or misoprostol alone have been shown to be effective, although a higher total dose is needed and is less effective than the combined regimens[12]. We conducted this study to compare the efficacy of misoprostol alone and its combination with Foley's catheter balloon for therapeutic termination of second trimester pregnancy.

MATERIAL AND METHODS

This study was conducted in SMGS hospital from Sept 2017 to May 2018. We studied women admitted for second trimester of pregnancy. Pregnant women needing termination between 13to 22 weeks were enrolled. Gestational age was calculated from the date of the first day of last menstrual period and confirmed by ultrasonography. Women having history of two or more previous caesarean section, contraindication to misoprostol, low lying placenta, multiple pregnancy, grand multipara, coagulation disorder, disseminated intravascular coagulopathy, chorioamnionitis, and vaginal infections were excluded from the study. we included 200 patients in our study. Enrolled patients were divided into 2 groups. 100 in each group. Group 1 (misoprostol group) Received a standard dose of 400ug 4hourly in the posterior fornix till 5 doses. Group 2(combined group) under all aseptic measures Foley's catheter (14-16 Fr) was introduced through cervix to the extra amniotic space and balloon was inflated with 30 ml normal saline. Catheter was firmly attached to patient's thigh. At the same sitting 400µg misoprostol was kept in posterior fornix and the dose was repeated every 4th hourly till the catheter got expelled out or till maximum five doses. Cervical reassessment was done and if needed oxytocin infusion was started in both groups. Maternal vitals were monitored and side effects like chills, nausea, vomiting, diarrhea, headache, severe pain abdomen, excessive bleeding p/v were observed. Failure of this method was considered if there were serious side effects or no delivery of the fetus after 48 hours. Effectiveness was determined by complete expulsion of fetus and placenta, need for surgical intervention (D/E, hysterotomy, hysterectomy) and rate of complications, excessive bleeding p/v. The data was collected on a structured questionnaire. The groups were compared with respect to the patient's characteristics, gestational age, indication for termination of pregnancy, rate of complications, etc.

RESULTS

A total number of 200 patients were included in the study. Average age, parity, and gestational age were comparable in both groups undergoing abortion as shown in Table 1. Most common indication for termination of pregnancy was IUFD followed by congenital anomaly and PPROM as depicted in table 2 .The mean induction to abortion interval 15.75 ±1.5 h in the misoprostol group and 8.5±2.5h in combined group which was found to be statically significant.($p<0.001$). 6 patients in the misoprostol group and 3 in the combined group did not deliver and underwent surgical evacuations. Table 3 reveals the maternal complications. There was no significant difference between the two groups regarding the frequency of maternal uterine rupture, cervical lacerations, nausea and vomiting, blood transfusion and venous thromboembolism.

Table 1: Maternal characteristics

	Misoprostol group	Combined group	P-value
Maternal age (years)	25.4 ± 3.2	26.2 ±2.2	>0.05
Parity	1.2 ± 1.1	1.5 ± 1.3	>0.05
Gestational age	17.2 ± 1.8	18.4 ± 3.81	>0.05

Table 2: Indications of termination of pregnancy and induction to abortion interval

	Misoprostol group	Combined group	P-value
IUFD	62	58	>0.05
Congenital anomalies	34	36	>0.05
PPROM	4	6	>0.05
IAI	15.75 ± 1.5	8.5 ± 1.25	<0.001

Table 3: Complications of intervention

	Misoprostol group	Combined group	P-value
Nausea and vomiting	5	6	>0.05
Diarrhea	4	5	>0.05
Fever	10	11	>0.05
Shivering	11	10	>0.05
Headache	6	4	>0.05
Excessive bleeding	6	4	>0.05
Retained placenta	5	6	>0.05

DISCUSSION

Second trimester abortions are painful procedures. Various agents have been used and compared with misoprostol in second trimester pregnancy terminations[13,14,15] Misoprostol is widely used for second trimester terminations. However, there is still a need to find out the best route and dose with minimum IAI along with minimal side effects and complications (16) In low resource settings like our country mifepristone is non-affordable and non-available. In order to shorten the induction to abortion interval and to minimize the side effects of repeated doses of misoprostol, we used

intracervical foley's catheter in combination with vaginal misoprostol. In this study, the mean induction to abortion interval 15.75 ±1.5 h in the misoprostol group and 8.5±2.5h in combined group. The success rate with misoprostol group was 94% and in combined group was 97%. Our study is consistent with a comparative study conducted including 90 pregnant women intended for termination of pregnancy between 13 and 24 gestational weeks for any indication. Enrolled women were equally allocated into three groups the first received vaginal misoprostol (n=30), the second received intracervical Foley catheter alone (n=30) and the third received both (n=30). The induction to abortion interval was 7.5± 1.25 h in the combined group, compared to 11.76 ± 1.63hin the misoprostol group and 19.76 ± 1.52 h in the catheter group (pvalue<0.001) with a success rate of 100% and no major complications reported[17]

CONCLUSION

we concluded in our study combined use of foley's and misoprostol is safe and significantly reduces the induction to abortion time as compares to misoprostol alone with no additional risk

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Source of Support: None Declared
Conflict of Interest: None Declared