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Research Article

A PROSPECTIVE STUDY TO COMPARE COMBINED USE OF INTRAVAGINAL MISOPROSTOL AND INTRACERVICAL FOLEY CATHETER VERSUS INTRAVAGINAL MISOPROSTOL ALONE FOR TERMINATION OF MID-TRIMESTER PREGNANCY IN DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY SMS MEDICAL COLLEGE, JAIPUR

MONIKA YADAV, URMILA MAHALA*

Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur, Rajasthan, India. Email: urmilamahala4@gmail.com

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ABSTRACT

Objectives: The aims and objectives of the study are to compare the mean induction to abortion interval and efficacy of intra-vaginal misoprostol alone versus combined use of intravaginal misoprostol and intracervical Foley catheter in termination of mid-trimester pregnancy.

Methods: This was prospective, comparative study conducted during March 2021 to April 2022 at Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur. The study included sample size of 60 cases (30 cases in each group). 60 cases were randomly allocated to either intravaginal misoprostol alone (Group A) or combined use of intravaginal misoprostol and Foley catheter (Group B) for termination of mid-trimester pregnancy. The study included all pregnant females between 14 and 20 weeks of gestation who were admitted for termination of pregnancy.

Results: Mean induction to abortion interval±standard deviation for Group A was 20.79±2.01 h and for Group B, it was 17.29±3.58 h. Mean dose of tablet misoprostol required for Group A±standard deviation was 1453.3±267.47 mcg and for Group B, it was 1053.33±267.47 mcg.

Conclusion: In this study, we found that with the combined use of intravaginal misoprostol and intracervical Foley catheter, there was a significant reduction in duration of induction to abortion, total dose misoprostol required, and hospital stay than in intravagnial misoprostol alone in termination of mid-trimester pregnancy.

Keywords: Misoprostol, Foley catheter, Mid-trimester pregnancy.

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INTRODUCTION

Termination of pregnancy is defined as elective expulsion or extraction of products of conception from uterus instead of spontaneous onset of process irrespective of duration of pregnancy. Congenital abnormality and missed abortion are the most common cause for termination of second-trimester pregnancy [1].

Second-trimester abortions constitute 10–15% of all induced abortions [2].

Increase incidence of second-trimester abortion is because of introduction of prenatal screening programs by which serious fetal abnormalities such as cardiovascular and skeletal malformation can be detected earlier [3].

There are various methods of termination of pregnancy in mid-trimester, which are broadly classified into two groups medical and surgical methods [4].

Surgical methods

Dilation and evacuation and hysterotomy.

Medical methods

- Prostaglandins (misoprostol, mifepristone with misoprostol, gemeprost, dinoprostone, carboprost)
- High-dose oxytocin
- Intrauterine instillation of hypertonic solution (0.1% ethacridine lactate, hypertonic saline 20%).
- Termination of second-trimester pregnancy is more risky because surgical methods have more morbidity, therefore, the medical methods of termination of pregnancy seem to be better alternative to surgical methods [5].

Advantage of misoprostol

Inexpensive and stable at room temperature [6].

Active orally and vaginally

Vaginal route is more preferred due to less side effects [7].

Advantage of Foley's catheter

Economical, easily available, minimal complication. Catheter stimulates various unspecified regions of uterus which leads to increase its excitability and regular uterine contractions [8].

METHODS

This was prospective, comparative study conducted during March 2021–April 2022 at Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur. The study included sample size of 60 cases (30 cases in each group). 60 cases were randomly allocated to either intravaginal misoprostol alone (Group A) or combined use of intravaginal misoprostol and Foley catheter (Group B) for termination of mid-trimester pregnancy. The study included all pregnant females between 14 and 20 weeks of gestation who were admitted for termination of pregnancy.

Selection criteria

Inclusion criteria

All pregnant females between 14 and 20 weeks of gestation who were admitted for termination of pregnancy and have given written informed consent.

Exclusion criteria

1. Case of bleeding per vaginum
2. Associated systemic disease such as hypertension disorder and asthma

Table 1: Induction to abortion interval time in 2 groups (time in hours)

Time in hours	Number of patients (%)	
	Group A	Group B
14–17	3 (10)	21 (70)
18–21	22 (73.33)	1 (3.33)
22–25	5 (16.66)	8 (26.66)
Total	30 (100)	30 (100)
Mean±SD	20.79±2.01	17.29±3.58
p	<0.0001	

SD: Standard deviation

Table 2: Distribution of patients according to dose of tablet (misoprostol 400 µg)

Dose of misoprostol	Number of patients (%)	
	Group A	Group B
800 µg	13 (43.33)	0
1200 µg	16 (53.33)	14 (46.66)
1600 µg	0	13 (43.33)
2000 µg	1 (3.33)	3 (10)
Total	30 (100)	30 (100)
Mean (µg)	1453.3±267.47	1053.3±267.47
p	<0.0001	

3. Hypersensitivity to prostaglandin
4. Patient with infected vaginal discharge
5. Women who will be participating in any other study.

Methodology

All pregnant females between 14 and 20 weeks of gestation who will be admitted for termination of pregnancy fulfilling inclusion and exclusion criteria.

After taking consent (written and informed), detailed history including obstetric, menstrual, medical, and surgical history will be taken.

General physical examination and obstetric examination will be done.

Routine blood investigations will be done.

All cases will be divided into two groups on the basis of computer-generated randomized sequence:

Group 1 (misoprostol group)

A standard regimen of moistened misoprostol tablet (400 µg) four hourly intravaginally (max 5 doses) was given until termination.

Group 2 (misoprostol and Foleys combined group)

The patients were administered 400 µg misoprostol intravaginally along with inserting intracervical Foley's catheter (number 16 FrCh) inflated with 50 mL normal saline. Then, 400 µg misoprostol (maximum 5 doses) was repeated four hourly until termination of pregnancy.

All the women were followed up till expulsion of fetus.

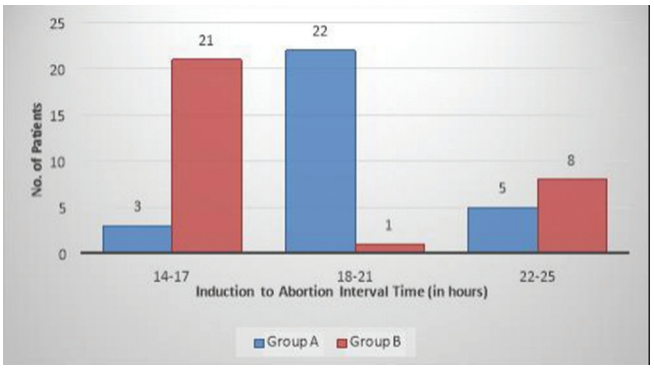
Procedure efficacy (induction to abortion interval, total dose of misoprostol, and success rate), safety acceptability, side effects (nausea, vomiting, diarrhea, and temperature), and amount of blood loss will be assessed. All the data will be collected, compiled, and entered in the pro forma.

Patient consent statement

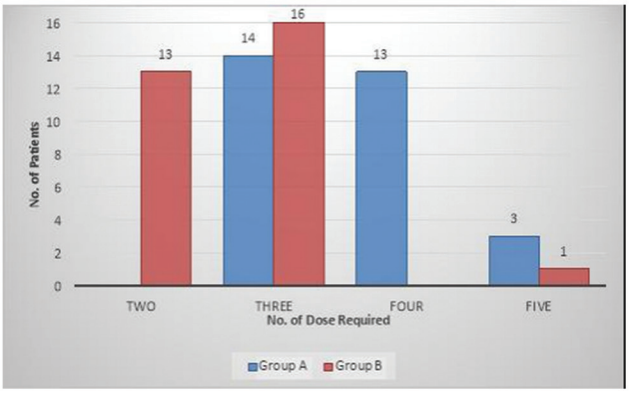
I voluntary agree to participate in study "a prospective study to compare combined use of intravaginal misoprostol and intracervical Foley catheter versus intravaginal misoprostol alone for termination of mid-trimester pregnancy in Department of Obstetrics and Gynaecology SMS Medical College, Jaipur."

RESULTS

In the above table, we found that mean induction to abortion time for Group A was 20.79 h and for Group B, it was 17.29 h. The p-value was <0.0001. We found significant difference between these groups as p<0.05 (Table 1).



Here, we found that mean dose required for Group A patients was 1453.3 mcg and for Group B, it was 1053.3 mcg. There was significant difference found between these groups as p<0.05 (Table 2).



DISCUSSION

Misoprostol is widely used in combination with mifepristone for second-trimester terminations. Since mifepristone is comparatively costly so in low-resource settings such as our country to reduce the cost, to shorten the induction to abortion interval, and to minimize the side effects of repeated doses of misoprostol, authors used intra-cervical Foley catheter in combination with vaginal misoprostol for mid-trimester TOP.

The most efficacious regimen for medical termination of second-trimester pregnancy appears to be use of mifepristone followed by misoprostol [9]. This regimen has an abortion rate of 97–99% in first 24 h [10].

In this study, we included 60 patients and divided them into two equal groups. In Group A, we used misoprostol only and in Group B, we used misoprostol and intracervical Foley combined.

We found that mean gestational age for Group A was 16.23 weeks. In Group B, mean gestational age was 16.5 weeks.

We found that mean induction to abortion time for Group A was 20.79 h and for Group B, it was 17.29 h. The p value was <0.0001. We found significant difference between these groups as p<0.05.

Mahajan *et al*. [11] found that the mean induction to abortion interval was 18.31±1.95 h in the combined group (Group A) and 21.90±2.62 h in the misoprostol group (Group B). In this study, authors found a significant reduction in induction to delivery time in combined group as compared to misoprostol alone group.

Kanta *et al*. [12] found that the mean induction to abortion interval 15.75±1.5 h in the misoprostol group and 8.5±2.5 h in combined group which was found to be statistically significant ($p<0.001$). 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±1.63 h in the misoprostol group and 19.76±1.52 h in the catheter group ($p<0.001$).

We found that mean duration of hospital stay was 2.93 days in Group A. In Group B, mean hospital stay was 2.1 days. The p value was 0.0003.

From the above discussion, we can conclude that the combined use of intracervical Foley catheter and vaginal misoprostol is a safe, effective, and acceptable method for termination of second-trimester pregnancy. The use of Foley catheter with misoprostol for termination of pregnancy was cheaper and very convenient methodology for both patients and obstetricians. This study supports the use of misoprostol combine with Foley catheter.

CONCLUSION

In this study, we found that with the combined use of intravaginal misoprostol and intracervical Foley catheter, there was a significant reduction in duration of induction to abortion, total dose misoprostol required, and hospital stay than in intravagnial misoprostol alone in termination of mid-trimester pregnancy.

AUTHORS CONTRIBUTION

All the authors contributed to the preparation of the final manuscript.

CONFLICT OF INTEREST

None.

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Nil.

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