RESEARCH
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A COMPARATIVE STUDY OF THE EFFICACY OF VAGINAL PROSTAGLANDIN WITH EXTRAAMNIOTIC BOUGIE IN SECOND TRIMESTER MEDICAL TERMINATION OF PREGNANCY

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Abstract
BACKGROUND: Abortion refers to the deliberate ending of a pregnancy prior to the point where the foetus is capable of surviving outside the womb. Due to its simplicity, safety, and effectiveness, medical abortion is increasingly preferred over invasive procedures and anaesthesia in many centres. It has successfully replaced the use of bougie in most regions, with a high effectiveness reaching up to 95%.
OBJECTIVES: The objective of this study was to assess the comparative effectiveness of vaginal misoprostol and extra amniotic bougie (EAB) in the second trimester abortion in the areas of induction abortion interval, complete abortion rate as well as the success of outcome in these methods.
METHODOLOGY: The study was carried out on a sample of 50 female patients who were undergoing second trimester abortions and receiving outpatient care in the Obstetrics and Gynaecology department at Vinayaka Mission's Kirupanandavariyar Medical College and Hospital in Salem. The patients were randomly assigned into two groups. The first group had 25 patients who were given an initial dosage of 400 mcg of misoprostol, followed by 200 mcg every 4 hours for a maximum of 5 doses administered vaginally. The second group of 25 patients underwent termination via extra amniotic bougie insertion.
RESULTS: The majority of cases who received misoprostol had an induction abortion duration of less than 12 hours. On the other hand, the majority of cases who received EAB had a mean duration of more than 48 hours. The likelihood of a successful abortion was markedly greater in the group that took misoprostol compared to the group that received EAB. The incidence of complications was reduced in the group of patients who received EAB as compared to those who took misoprostol.
CONCLUSION: Of the cases that were administered misoprostol, 64% experienced complete abortion, while 36% experienced incomplete abortion. Conversely, among the cases that received EAB, only 36% achieved complete abortion, while 64% experienced incomplete abortion. It was noted that the likelihood of incomplete abortion was significantly higher in cases that received EAB alone.
KEY WORDS: Vaginal misoprostol , Extra amniotic bougie , Induction abortion interval, Complete Abortion.

INTRODUCTION

Abortion is the deliberate or natural ending of a pregnancy before the foetus has reached the stage of being able to survive outside the womb, typically estimated to be 28 weeks of gestation or when the foetus weighs around 1000 grammes. Recent advancements in newborn care have reduced the period of viability to 20 weeks of gestation, which is equivalent to a foetal weight of 500gm in affluent countries.

Abortion can occur naturally or be deliberately caused. Induced abortion refers to the intentional termination of a pregnancy, which can occur within the boundaries of the law or outside of it. The global annual incidence of abortions is estimated to be between 40 and 60 million.(1)

Despite the availability of safe and efficient contraceptive treatments, couples still experience contraceptive failure and appear before the specialist during their second trimester. Second trimester abortions carry an elevated risk of infection due to surgical interventions. Unmarried and unplanned pregnancies are the leading cause for second trimester abortions. The conventional approach for performing a second trimester abortion was the insertion of a bougie through the amniotic sac. A bougie is a cylindrical, flexible tube made of rubber. In recent times, medical abortive procedures have become increasingly popular because to their convenient administration, high level of safety, and effectiveness. They were preferred due to lack of

invasiveness as well as anaesthetic requirement, with the success rates being as high as 95% (2)

Medical termination of pregnancy (MTP) refers to the intentional termination of a pregnancy. Terminating a pregnancy prior to the stage of foetal viability can be achieved through the administration of drugs or through surgical intervention.

Medical techniques for second trimester medical termination of pregnancy (MTP):

1. Administration of medicines directly into intraamniotic: (i) 20% hypertonic saline (ii) Hypertonic glucose (iii) Urea (iv) Prostaglandin
2. Additional administration of medicines into extraamniotic route: (i) 0.1% Ethacridine lactate (ii) Hypertonic saline (iii) Prostaglandins (iv) Mifepristone and Misoprostol
3. Intramuscular: (i) Carboprost intramuscularly
4. Extra ovular insertion of devices, such as sterile catheters or Bougie.

Surgical procedures:

1. Dilation and Evacuation (3,4,5)

Hysterotomy is a surgical procedure.

Complications that arise from medical termination of pregnancy may be incomplete abortions (6), infection (7), uterine rupture (8), and live birth (9).

This study examined the effectiveness of misoprostol compared to bougie insertion in 50 patients seeking second trimester pregnancy termination at Vinayaka Missions Kirupanandavariyar Medical College and Hospitals in Salem.

AIM AND OBJECTIVES OF THE STUDY

To assess the comparative effectiveness of vaginal misoprostol and extra amniotic bougie in inducing second trimester abortion and to compare the

i. Induction abortion interval ii. Complete abortion rate and iii. Success rate between the two methods.

REVIEW OF LITERATURE

According to a comparative study which examined the effectiveness of second trimester abortions using oral and vaginal misoprostol and conducted by K.S. Wong, C.S.W. Ngai, E.L.W. Yeo, L.C.H. Tang, and P.C. Ho in 1997. The study found that 90% of abortions were completed within 48 hours in the vaginal group, whereas the oral group had a lower rate of 69% during the same time frame. (10)

The study conducted by Snehamay Chaudhuri et al. in 2006 compared the effectiveness of inserting a 400mcg tablet of misoprostol into the vagina every 12 hours for a maximum of 4 doses, with the use of extraamniotic ethacridine lactate for second trimester medical termination of pregnancy (MTP). In the microprostol group, the average time from induction to abortion was shorter, with a duration of 15.5 hours. Additionally, the rate of effective abortion within 48 hours was 95%. (11)

Anitha Singh and Shanthi Roy conducted a clinical trial in 1985 with 75 patients who underwent second trimester MTP. These patients were administered a rubber catheter as part of the procedure. The study documented a success rate of 92%. (12)

MATERIALS AND METHODS:

After obtaining clearance from Institutional Ethical Committee, a comparative study was carried out among 50 patients attending the Department of Obstetrics and Gynaecology on OPD basis at Vinayaka Mission's Kirupanandavariyar Medical College and Hospital in Salem, during the period of June 2021 to June 2022. These patients were included in the study when the met the criteria of them being in 14-20 weeks of pregnancy, fulfilling indications for MTP according to MTP Act and without any medical/surgical complications.

Exclusion criteria:

1)Patients with any prior history of uterine surgery like myomectomy or C-section

2)Those with any uncontrolled seizure disorder/cardiovascular disease/glaucoma/pulmonary, renal or hepatic diseases as well as those prone towards allergic reactions towards misoprostol or other prostaglandins.

These 50 enrolled subjects were randomly divided into two groups of 25 each. One group was given 400 mcg of misoprostol to start with and then 200 mcg every 4 hours up to a maximum of 5 doses administered via vagina. The termination of pregnancy in the second group was carried out by use of extra amniotic bougie insertion.

Method of misoprostol induction: About 400 mcg of misoprostol was inserted into the posterior fornix under aseptic conditions. Subsequent administrations were abstained from in the event of uterine contractions or bleeding. Patients were monitored in a intensive care unit (ICU) and the following observations were made - Induction time, Temperature, pulse rate, and blood pressure measured every 4 hours, Timing of the initiation of contractions, rupture of membranes, and occurrence of bleeding, Duration of expulsion, Timing of subsequent dosages. Also the nature of abortion – whether complete/incomplete, need for oxytocin, requirement for dilatation and curettage and any signs of maternal complications like fever, pain & vomiting. After the evacuation, all patients are administered 10 units of oxytocin in 500 ml of RL and 0.2 mg of methyl ergometrine intravenously to prevent severe bleeding. In instances of partial abortion, the residual products are removed either manually or by curettage. Before patients were discharged, an USG was performed to eliminate the possibility of any remaining products of conception.

Method for Bougie insertion: After ensuring the patient's bladder is empty, the patient is kept in lithotomy position. Under aseptic precautions, Bougie is introduced extra amniotically. No anaesthesia is required. It is followed 24 hrs later by oxytocin infusion. The patients were observed in semi-ICU & the following are noted: - The onset of uterine contractions, pain or vaginal bleeding. - Time of expulsion. - Nature of abortion/complete or incomplete. About 10 U Oxytocin in 500ml of RL and 0.2mg iv methyl ergometrine are given to all patients to prevent excessive bleeding. In instances of incomplete abortion, the remnants are extracted either manually or with curettage. Patients who were unable to expel the remnants within 48 hours were treated with either intracervical PGE2 gel or laminaria tent in tandem with high titre oxytocin. A complete ultrasound examination is performed on all patients before to discharge in order to exclude the presence of any remaining foetal tissue.

RESULTS

Table 1 Showing the age distribution in relation to misoprostol and EAB groups

	Misoprostol		EAB		Total	
	Frequency	**Percentage**	**Frequency**	**Percentage**	**Frequency**	**Percentage**
19 – 22	5	20%	5	20%	10	20%
23 – 25	4	16%	5	20%	9	18%
26 – 30	16	64%	15	60%	31	62%
Total	25	100%	25	100%	50	100%
Mean ±SD	26.32 ± 3.40		25.20 ± 3.66		25.76 ± 3.54	
Chi square test=0.14, p=0.93, Not statistically significant						

The average age of the participants who received misoprostol was 26.32 ± 3.40 years, while the mean age of those who received EAB was 25.20 ± 3.66 years. The overall average age was 25.76 ± 3.54 years. There was no statistically significant difference in the average age between the groups, indicating that both groups are comparable.

Table 2: Displaying the distribution of gestational age in weeks in both groups.

Gestational Age in Weeks	Misoprostol		EAB		Total	
	Frequency	**Percentage**	**Frequency**	**Percentage**	**Frequency**	**Percentage**
14 – 16	20	80%	4	16%	24	48%
16 – 18	2	8%	17	68%	19	38%
18 – 20	3	12%	4	16%	7	14%
Total	25	100%	25	100%	50	100%
Mean ±SD	15.84 ± 1.74		17.24 ± 1.42		16.54 ± 1.72	
Chi square test=22.65, p=<0.0001*, Statistically significant						

The current study found that the average gestational age of the participants was 16.54 ± 1.72 weeks. The participants who took misoprostol had an average age of 15.84 ± 1.74 weeks, whereas those who received EAB had a mean age of 17.24 ± 1.42 weeks.

Table 3 Listing the indications for MTP in the study subjects.

	Misoprostol		EAB		Total	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
Eugenic	10	40%	2	8%	12	24%
Failure of Contraceptive	1	4%	0	0%	1	2%
Medical	6	24%	7	28%	13	26%
Unwanted	8	32%	16	64%	24	48%
Total	25	100%	25	100%	50	100%
Chi square test=9.07, p=0.02*, Statistically significant						

In this study, 40% of the individuals who got misoprostol underwent MTP due to eugenic reasons, 4% experienced contraceptive failures, 24% had medical reasons for the MTP, and 32% had unwanted pregnancies.

Of the women who received EAB, 8% experienced it owing to eugenic reasons, 2% had contraceptive failure, 26% underwent abortions for medical reasons, and 48% had unwanted pregnancies.

A notable statistical difference was found in the use of misoprostol for the indication of medical termination of pregnancy (MTP). Misoprostol was more commonly utilised in situations involving eugenic reasons and unwanted pregnancies. EAB was more prevalent among those who experienced unintended pregnancies.

Table 4: Presenting the total dose of prostaglandins used in both groups.

	Misoprostol		EAB		Total	
	Frequency	**Percentage**	**Frequency**	**Percentage**	**Frequency**	**Percentage**
400 – 600	7	28%	8	32%	15	30%
600 – 800	12	48%	12	48%	24	48%
800 – 1200	6	24%	5	20%	11	22%
Total	25	100%	25	100%	50	100%
Mean ± SD	784 ± 293.93		752 ± 290.28		768 ± 289.57	
Chi square test=0.15, p=0.92, Not Statistically significant						

In this study, 28% of the participants who were administered misoprostol received a dosage of 400-600 mcg, whereas 48% received a dosage of 600-800, and 24% received a dosage of 800-1200 mcg. The average dosage needed in the misoprostol group was 784 ± 29, whereas in the EAB group, 32% received a dosage of 400-600mcg, 48% received a dosage of 600-800, and 20% received a dosage of 800-1200 mcg. The average dosage necessary in the EAB group was 752 ± 29. There was no

statistically significant disparity in the average dosage needed among the groups.

Table 5: Showing the induction-abortion interval among both groups.

	Misoprostol		EAB		Total	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
<12	12	48%	2	8%	14	28%
12 – 24	9	36%	9	36%	18	36%
24 – 48	4	16%	11	44%	15	30%
>48	0	0%	3	12%	3	6%
Total	25	100%	25	100%	50	100%
Chi square test=13.41, p=0.003*, Statistically significant						

In this study, it was found that 36% of the cases who got misoprostol had an Induction-Abortion interval of less than 12 hours, while 36% had an interval of 12-24 hours, and 16% had an interval of 24-48 hours.

Of the cases that got EAB, 8% had an induction-abortion ratio of less than 12 hours, 36% had a ratio of 12-24 hours, 44% had a ratio of 24-48 hours, and 12% had a ratio of more than 48 hours.

A significant disparity was noted in the average duration of induction and abortion among the groups. The majority of cases that were administered misoprostol experienced an abortion duration of less than 12 hours, while the majority of cases that underwent EAB had an average duration exceeding 48 hours.

DISCUSSION

Midtrimester abortion is a highly contested aspect of gynaecological medicine. Currently, the majority of mid-trimester abortions are performed using medical methods.

Socio-demographic details:

The average age of patients who received misoprostol in the trial was 26.32 ± 3.40 years, while the average age of participants who received EAB was 25.20 ± 3.66 years. The overall average age was 25.76 ± 3.54 years.

The study conducted by Jain JK et al. (13) found that the participants had a mean age of 28.4 years. Their observed mean age closely aligned with the current study.

Gestation age:

In this study, the mean gestational age was 16.54 ± 1.72 weeks. The average age of patients who received misoprostol was 15.84 ± 1.74 weeks, while the average age of those subjects who received EAB was 17.24 ± 1.42 weeks.

Total dosage of prostaglandins used:

STUDY	DOSE AND INTERVAL
Present study	Varied doses from 400-1200 mcg was tried
Chaudari S et al. (11)	400 mg 12 hrly
Wong et al.,(10)	400 mg 6 hrly
Jain JK et al., (13)	200 mg 6hrly/12 hrly

Induction – Abortion (IA) Interval:

In this study, the group of patients who were administered misoprostol experienced an Induction-Abortion gap of less than 12 hours in 36% of cases, 12-24 hours in 36% of cases, and 24-48 hours in 16% of cases.

Of the sample who got EAB, 8% had an induction-abortion ratio of less than 12 hours, 36% had a ratio of 12-24 hours, 44% had a ratio of 24-48 hours, and 12% had a ratio of more than 48 hours.

In the study conducted by Chaudari S et al.,(11) the average gap between IA was found to be 15.5 hours. Similarly, in the investigations conducted by Jain KS and Mishell R et al., (13) the IA interval was approximately 14 hours. These findings align closely with the results of the present study.

In the present investigation, the highest dose administered was 1200 mcg. However, a previous study conducted by Wong KS, Ngai CSW and Yeo ELK (10) found that the greatest dose needed for expulsion was approximately 2000 mcg. Additionally, it was demonstrated that the maximum dose required over a 48-hour period was 4000 mcg.

CONCLUSION

The sample enrolled in the present study had an overall mean age of 25.76 ± 3.54 years. While eugenic and unwanted pregnancies were primary choices for use of misoprostol in termination, unwanted pregnancies were the predominant cause in the EAB group. Among both the groups, successful outcome of abortion was observed in those who received misoprostol. Nevertheless, bougies are not the favoured option for termination when alternative methods are accessible.

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