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

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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 various hospitals. It has replaced the necessity of extra-amniotic bougie use in many centers, with a high effectiveness reaching up to 95%. **OBJECTIVES:** This study aimed to evaluate the relative efficacy of extra amniotic bougie (EAB) and vaginal misoprostol in second trimester abortion, specifically in terms of the duration of induction abortion, the rate of complete abortion, and the overall success of these treatments. **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.

Keywords: 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)

There are different types of abortion, and one of them is spontaneous abortion while another type is induced abortion. Subtypes of the induced abortion are as follows:

• Threatened abortion • Inevitable abortion • Complete abortion • Incomplete abortion • Missed abortion • Recurrent abortion • Septic abortion

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.

Amendment to the MTP Act in 2021

1. A single certified medical practitioner's opinion is required for the termination of pregnancy within the first 20 weeks of gestation.
2. Requirement of two certified medical professionals' opinion for the termination of a pregnancy between 20-24 weeks.
3. Termination of pregnancy is permissible for rape survivors within a 24-week timeframe.
4. If contraception fails for a woman or her partner, it is possible to undergo a medical termination of pregnancy (MTP) within a timeframe of up to 20 weeks.
5. In cases where significant foetal abnormalities have been diagnosed by a medical board, MTP can still be performed even after 24 weeks.

Medical techniques for medical termination of pregnancy in second trimester (MTP7):

1. Intramniotic administration of medications: (i) A solution containing 20% hypertonic saline (ii) A solution containing hypertonic glucose (iii) Urea (iv) Prostaglandin
2. Administration of medications by the ovular route: (i) A solution containing 0.1% Ethacridine lactate, (ii) a solution of saline with a higher concentration than normal, (iii) naturally occurring substances called prostaglandins, and (iv) a combination of drugs called Mifepristone and Misoprostol.
3. Extra uterine methods: (i) Carboprost intramuscularly
4. Insertion of extra ovular devices, such as use of sterile catheters or Bougie.

Operable 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].

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 research conducted by Chaudhuri et al. in 2006 compared the effectiveness of inserting a 400-mcg tablet of vaginal misoprostol for every 12 hours up to a maximum of 4 doses, and also with the use of extraamniotic ethacridine lactate for MTP in second trimester. In microprostol group, the average time from induction to abortion was shorter, with a duration of 15.5 hours. The rate of effective abortion was 95% within 48 hours.[11]

Abbas Mitwaly AB, Abbas AM, and Abdellah MS (2016) conducted a clinical investigation involving 180 women who had missed miscarriages, with gestational ages ranging from 13 to 24 weeks. The trial was prospective, randomised, and open-labeled. The objective of the study was to evaluate and contrast the effectiveness and safety of two methods for terminating pregnancy in cases of second trimester miscarriage: intrauterine extra-amniotic misoprostol and vaginal misoprostol administered at a dose of 200 micrograms every 4 hours. The patients were randomly assigned via a computer generated numbers to receive successive doses of 200 µg misoprostol every 4 hours, either through intrauterine extra-amniotic administration using a Foley catheter or through vaginal administration. The average gestational age was 17.74 weeks. The average duration of miscarriage in the intrauterine extra-amniotic group was 5.27 hours, which was considerably shorter than the vaginal group (9.92 hours, p=0.001). The incidence of side effects was higher in the vaginal group. The researchers determined that administering 200 µg of intrauterine extra-amniotic misoprostol every 4 hours is a more successful and safer method for inducing second trimester miscarriage compared to using vaginal misoprostol.[12]

The current study examined the effectiveness of vaginal prostaglandins in comparison with the insertion of extra-amniotic bougie insertion in 50 patients seeking second trimester pregnancy termination at Vinayaka Missions Kirupanandavariyar Medical College and Hospitals in Salem.

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 they met the criteria of them being in second trimester (14-20 weeks) of pregnancy, who had indications for MTP and without any surgical/ medical complications. The exclusion criteria for the study were the patients with previous caesarean sections/myomectomy, Patients with

epilepsy/cardiopulmonary disorders/glaucoma/renal/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 hourly not exceeding more than 5 doses administered via vagina. The termination of pregnancy in the second group was carried out by use of extra amniotic bougie insertion.

Methods of induction of misoprostol: About 400 micrograms of misoprostol was inserted under aseptic conditions into the fornix posteriorly. Subsequent administrations were abstained from in the event of bleeding /contractions in the uterus. The sample were monitored in a semi-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 uterine contractions, membranes rupture, and occurrence of blood loss, time taken for 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 oxytocin(10 units) in 500 ml of RL and 0.2 mg of methyl ergometrine intravenously to in order avoid any bleeding manifestations. In instances of partial abortion, the residual products of conception were extracted either by curettage or via manual methods. Before patients were discharged, an USG was performed to eliminate the possibility of any remaining products of conception.

Method for insertion of extra-amniotic bougie: Following confirmation of the patient's empty bladder, the patient was positioned in lithotomy. Under sterile conditions, the extra-amniotic bougie was inserted. No anesthesia was required. Twenty-four hours later, oxytocin infusion was initiated. Patients were monitored in a semi-ICU setting, noting the onset of uterine contractions, pain, or vaginal bleeding, as well as the time of expulsion and the nature of abortion (complete or incomplete). To prevent excessive bleeding, all patients received 10 units of oxytocin in 500ml of Ringer's lactate and 0.2mg of intravenous methyl ergometrine. In cases of incomplete abortion, remnants were either manually extracted or removed with curettage. Patients unable to expel remnants within 48 hours received treatment with either intracervical PGE2 gel or laminaria tent, in conjunction with high-titer oxytocin. Before discharge, all patients underwent a comprehensive ultrasound examination to rule out any remaining fetal 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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Conflicts of interest: There are no conflicts of interest**.**

Ethical statement

Institutional ethical committee accepted this study. The study was approved by the institutional human ethics committee, Vinayaka mission's, Kirupananda Variyar medical college and hospitals, Salem, Tamilnadu. Informed written consent was obtained from all the study participants and only those participants willing to sign the informed consent were included in the study. The risks and benefits involved in the study and the voluntary nature of participation were explained to the participants before obtaining consent. The confidentiality of the study participants was maintained.

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Authors' Contributions

Dr. Swathi C Reddy - conceptualization, data curation, investigation, methodology, project administration, visualization, writing—original draft, writing—review and editing; ***Dr Jeyamani B*** - conceptualization, methodology, writing—original draft: ***Dr. Navya sree P-*** writing—review and editing, visualization, supervision, writing—original draft. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work. All authors have read and agreed to the published version of the manuscript**.**

Data Avaılabılıty

All datasets generated or analysed during this study are included in the manuscript.

Informed Consent

Written informed consent was obtained from the participants before enrolling in the study

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