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PAPER OF A COMPARATIVE STUDY OF SUBLINGUAL VERSUS VAGINAL MISOPROSTOL FOR MANAGEMENT OF FIRST TRIMESTER MISSED ABORTION

Obstetrics & Gynaecology

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ABSTRACT

Introduction : Missed abortion is defined as death of conceptus without expulsion of its contents with closed cervix before fetal viability. Abortion occurs in approximately 10–20 % of all pregnancies. The risk of spontaneous abortion increases with old maternal age, high gravidity, and increased paternal age.[1] Successful pregnancy is dependent on the integration of complex genetic, hormonal, immunologic and cellular events, and must involve complete cooperation during the conception, implantation and evolution of the embryo.[2] Management of missed abortion includes the following: Surgical evacuation and Medical evacuation[5].

Aims & Objectives : To assess the efficacy and safety of sublingual and vaginal misoprostol for the management of first trimester missed abortion. To compare the safety and efficacy of both the regimesent[6,7].

Mathodology

- We include total 240 patients of missed abortion . Cases were divided into 2 groups-

Group-A: 400 µg of misoprostol sublingually every three hours for a maximum of 4 doses

Group-B : 400 µg of misoprostol vaginally every three hours for a maximum of 4 doses

CONCLUSION : sublingual misoprostol for the medical management of missed abortion in first trimester is more effective than the vaginal route. However, it showed more adverse effect.

KEYWORDS

INTRODUCTION

Missed abortion is defined as death of conceptus without expulsion of its contents with closed cervix before fetal viability. Abortion occurs in approximately 10–20 % of all pregnancies. The risk of spontaneous abortion increases with old maternal age, high gravidity, and increased paternal age.[1] Successful pregnancy is dependent on the integration of complex genetic, hormonal, immunologic and cellular events, and must involve complete cooperation during the conception, implantation and evolution of the embryo.[2] Most individual abortions occur due to intrinsic defects in pregnancy products, such as abnormal reproductive cells, incomplete implantation, deformities in the embryo, accidental injury to the embryo, and other possible causes previously unknown[3]. Today, with the advancement of knowledge and new technologies, it is possible to make accurate diagnoses of abnormal pregnancies and to terminate a pregnancy in the early stages[4].

Medical management of first trimester abortions have significant economic advantages over traditional surgical management[6]. Misoprostol a synthetic prostaglandin E1 analog, is cheap, stable at room temperature and effective in inducing cervical ripening and uterine contractions.[11] . These medical methods are an alternative to surgical abortions, requiring less training skills and expertise to perform, less risk of surgery and anaesthesia, need of operating room and is more natural. It permits greater privacy and is well tolerated physically and emotionally.[12]

Vaginal misoprostol like inconsistent absorption and incomplete absorption in addition to women finding vaginal administration uncomfortable.[10,13,14] Misoprostol given vaginally though took longer for onset and had a lower peak (peak concentration after 60 minutes it had a more sustained effect as compared to oral misoprostol). Subsequently a new route of giving misoprostol by sublingual administration has been developed.[15] The sublingual mucosa, being very vascular, serves the purpose of better absorption. Sublingual application also avoids the first pass effect through the liver. The misoprostol tablets, when placed under the tongue, dissolve within 10-15 min. Pharmacokinetics now shows that sublingual misoprostol has the shortest onset of action, the highest peak concentration and greatest bioavailability among the routes of administration.[16]This study was undertaken to compare the efficacy of 400 µg sublingual misoprostol with 400 µg of vaginal misoprostol, in repeated doses, for medical management of missed miscarriage.

AIMS

- To assess the efficacy and safety of sublingual and vaginal misoprostol for the management of first trimester missed abortion.
- To compare the safety and efficacy of both the regimes

OBJECTIVES

- To evaluate the induction-abortion interval, amount of vaginal bleeding, number of doses required, presence of retained product of conception and need for evacuation.
- To evaluate the side effect of both the route of administration in terms of nausea, diarrhea, fever and stomach cramps.

MATERIAL & METHODS

Our study is hospital based randomised control prospective study conducted in obs and gynaec department government medical college kota rajasthan.

- We include total 240 cases in my hospital selected randomized and devided in two groups

Group-A: 400 µg of misoprostol sublingually every three hours for a maximum of 4 doses

Group-B : 400 µg of misoprostol vaginally every three hours for a maximum of 4 doses.

INCLUSION CRITERIA

- Gestational sac with mean sac diameter of >25 mm, without fetal pole (blighted ovum).
- The presence of fetal pole >7 mm, with no cardiac pulsations.
- Gestational sac mean diameter <18 mm, with no interval growth being observed on rescanning 10 days later.
- The absence of embryo with heartbeat at least 2 weeks after an ultrasound scan that showed a gestational sac without a yolk sac.
- Women giving informed consent

EXCLUSION CRITERIA

- Incomplete abortion
- RPOC
- Hb <8 g/dl
- Coagulopathy or anticoagulant therapy
- Inherited porphyria
- Hypersensitivity to these drugs
- Bronchial asthma

METHODOLOGY

- All the cases were subjected to full history taking, including age, gravity, parity, last menstrual period (LMP), and present complaint (e.g., amenorrhea, regression of symptoms of pregnancy, pain, bleeding), complete general examination, obstetric examination, and transvaginal ultrasound examination to confirm the diagnosis. Cases were divided into 2 groups-
- **Group-A:** 400 µg of misoprostol sublingually every three hours

for a maximum of 4 doses

- **Group-B :** 400 µg of misoprostol vaginally every three hours for a maximum of 4 doses.

OBSERVATIONS

Table – 1 Distribution of Cases According to Age Group

Age Group (in yrs)	Group-A		Group-B	
	No.	%	No.	%
<20	3	2.50	4	3.33
20 – 24	43	35.83	42	35.00
25 – 29	56	46.67	52	43.34
30 – 34	11	9.17	16	13.33
35 – 39	7	5.83	6	5.00
Total	120	100.00	120	100.00
Mean ± SD (in yrs)	25.86 ± 4.19		26.09 ± 4.19	

p = 0.6666 Both groups were comparable (p-value >0.05).

Table – 2 Distribution of Cases According to Ultrasonography Findings

Ultrasonography Findings	Group-A		Group-B	
	No.	%	No.	%
Blighted Ovum	14	11.67	10	8.33
Fetal Heart Pulsation Absent or Fetal Pole Absent	106	88.33	110	91.67
Total	120	100.00	120	100.00

p = 0.3894

Table – 3 Distribution of Cases According to Time Since Last Delivery

Time Since Last Delivery (in yrs)	Group-A		Group-B	
	No.	%	No.	%
Primigravida	56	46.67	61	50.83
<1	5	4.17	5	4.17
1 – 2	27	22.50	17	14.17
2 – 3	32	26.66	37	30.83
Total	120	100.00	120	100.00
Mean ± SD	0.92 ± 0.97		0.92 ± 1.05	

p = 0.9873

Table – 4 Distribution of Cases According to Induction-Abortion Interval

Induction-Abortion Interval (in hrs)	Group-A		Group-B	
	No.	%	No.	%
6 – 12	83	69.17	12	10.00
12 – 18	11	9.17	60	50.00
Total	94	78.33	72	60.00
Mean ± SD (in hrs)	11.01 ± 2.10		13.78 ± 2.20	

p = 0.0000

The difference between both groups were statistically significant (p=0.000).

Table – 5 Distribution of Cases According to Side-effects

Side-effects	Group-A		Group-B		p-value
	No.	%	No.	%	
Nausea / Vomiting	24	20.00	6	5.00	0.0004
Diarrhoea	20	16.67	6	5.00	0.0036
Fever / Chills	18	15.00	9	7.50	0.0660
Excessive Bleeding	8	6.67	5	4.17	0.3923

Table – 6 Distribution of Cases According to Level of Satisfaction

Level of Satisfaction	Group-A		Group-B	
	No.	%	No.	%
Highly Satisfied	45	37.50	21	17.50
Satisfied	49	40.83	51	42.50
Unsatisfied	26	21.67	48	40.00
Total	120	100.00	120	100.00

p = 0.0005

DISCUSSION

Our randomized Prospective comparative study show that womens of reproductive age group have maximaum fertility and sexual drive so these female are prone to pregnancy .our study Group-A, out of 120 cases diagnosed missed abortion , 56 (46.67%) women were in the age group of 25-29 yrs, 43 (35.83%) women were in the age group of 20-24 yrs, 11 (9.17%) women were in the age group of 30-34 yrs, 7 (5.83%) women were in the age group of 35-39 yrs and 3 (2.50%) women were in the age group of <20 yrs. In Group-B, out of 120 cases diagnosed missed abortion, 52 (43.34%) cases were in the age group of 25-29 yrs, 42 (35.00%) cases were in the age group of 20-24 yrs, 16 (13.33%) cases were in the age group of 30-34 yrs, 6 (5.00%) cases were in the age group of 35-39 yrs and 4 (3.33%) cases were in the age group of <20 yrs. Both groups were comparable (p-value >0.05).

Similarly mean age of women in a study done by Souza ASR et al (2008)[65] was ranged from 24-30 yrs. study conducted by Park JY et al (2018)[70] the mean age was 32 yrs. As in developed country, marriage in advance age is common.

The present study show that majority of women in both groups were primi and second gravida. Primigravida in Group-A were 56 (46.67%) and 61 (50.83%) in Group-B. Second gravida in Group-A were 39 (32.50%) and 37 (30.83%) in Group-B. Third gravida in Group-A were 17 (14.17%) and 19 (15.83%) in Group-B. Fourth gravida in Group-A were 7 (5.83%) and 1 (0.83%) in Group-B. Fifth gravida in Group-A were 1 (0.83%) and 2 (1.67%) in Group-B. Mean gravida in Group-A was 1.80 ± 0.93 and in Group-B was 1.71 ± 0.87. Kushwah DS et al (2011)[74] in their study found mean parity to be 2.12 in sublingual group and 2.08 in oral group.Kaur P et al (2013)[68] studied where mean parity in Group-A (sublingual) was 2.36 ± 0.80 in Group-B (vaginal) mean was 2.32 ± 0.68.

The present study suggested that sublingual misoprostol was more effective than vaginal misoprostol . It required Mean induction-abortion interval in Group-A was 11.01 hours and 13.78 hours in Group-B which was statistically significant (p-value=0.0000).Similar to our study Sharma P et al (2018)[71] ,Tanha FD et al (2010)[76] , Rabiei S et al (2019)[2] found that by giving 600 g misoprostol sublingually and vaginally every 6 hrs, the mean induction-abortion interval in sublingual group was 7.10 ± 1.90 hrs and 9.38 ± 2.53 hrs in vaginal group. In this study also, mean induction-abortion interval in sublingual group was less than vaginal group. However due to use of high dose of misoprostol, the induction-abortion interval was less compared to our study.

Aly HH et al (2016)[8] and Dehbashi Z et al (2016)[69] noted different result compare this study after giving 100 g misoprostol sublingually and vaginally the mean induction-abortion interval was 12.6 ± 3.1 hrs in sublingual group and that in vaginal group was 9.0 ± 1.6 hrs.

Pathak BL et al (2019)[73] reported in their study that after giving mifepristone 200 mg followed by giving 800 g misoprostol vaginally and sublingually after 48 hrs. They found that mean induction-abortion interval in sublingual group was 4.14 ± 1.03 hrs and 4.34 ± 0.66 hrs in vaginal group. The time was less because they had given mifepristone prior and the dose of misoprostol was also more.

The present study in Group-A (sublingual) nausea and vomiting reported in 24 (20.00%) cases and require treatment whereas in vaginal (Group-B) only 6 (5.00%) reported, diarrhoea (more than 4 episodes) in 20 (16.67%) in Group-A and 6 (5.00%) in Group-B. Fever / chills treatment required in 18 (15.00%) in Group-A and 9 (7.50%) in Group-B. 8 (6.67%) women reported excessive bleeding in Group-A and 5 (4.17%) in Group-B.

This may be explained by the high bioavailability of sublingual misoprostol. Most patients considered the side-effect to be tolerant and transient and found that they decreased gradually after the first dose of treatment.

Similar observation was made by Tanha FD et al (2010)[76] and Shah N et al (2010)[67] , Kaur P et al (2013)[68] , Aly HH et al (2016)[8] ,Dehbashi Z et al (2016)[69] , Pathak BL et al (2019)[73] ,Sharma P et al (2018)[71] reported that regarding the route of administration, sublingual is an effective alternative in their study that, those women in sublingual group experienced more complications including diarrhea,bleeding, nausea , fever and shivering .

The present study in Group-A 45 (37.50%) women and and 21 (17.50%) women in Group-B were highly satisfied. 49 (40.83%) women in Group-A and 51 (42.50%) women in Group-B were satisfied. 26 (21.67%) women were unsatisfied in Group-A and 48

(40.00%) in Group-B were unsatisfied because of failure of treatment or side effects of misoprostol. The difference between both groups was statistically significant (p-value=0.0005).

Tanha FD et al (2010)[76] ,Saxena P et al (2004)[77] found that women in sublingual group were highly satisfied with this method.

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