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Efficacy of Oral Misoprostol in First Trimester Incomplete Miscarriage vs Manual Vacuum Aspiration: Randomized Control Trial

Dr. RUQIA HAMEED
OBS & Gynae Department Bolan Medical College, /SPH Quetta
Dr. ERUM BASHIR KHAN
General Surgery Department, Federal Govt. Polyclinic Hospital Islamabad
Dr. FAIZA ROHAIL
DOW Medical College Karachi
Prof. Dr. AISHA SIDDIQA
OBS & Gynae Department Bolan Medical College, /SPH Quetta

Abstract

Introduction: - *Miscarriage is generally defined as the spontaneous loss of a pregnancy prior to 24 weeks 'gestation, that is, before the fetus is usually viable outside the uterus. Bleeding in early pregnancy is the most common reason for women to present to the gynecology emergency department and in many of these women miscarriage will be diagnosed.[1]*

Objective: *To determine the efficacy of Oral Misoprostol in 1st trimester incomplete miscarriage versus Manual Vacuum Aspiration.*

Study Design*: Randomized control trial.*

Study Settings*: Department of Obstetrics & Gynecology Bolan Medical College/Hospital Quetta.*

Duration of Study: *1st January 2021 to 31st January 2022*

Methodology: *The current study was conducted on 204 pregnant women aged between 20-40 years, patients had presented at the Gynecological Emergency ward with clinical features of incomplete miscarriage at a gestational age of ≤12 weeks. Patients were separated in two groups, Oral Misoprostol and Mannual Vacuum Aspiration. Efficacy in both groups was evaluated. Pregnant women patients with incomplete miscarriage however have had other intrauterine device in signs of standard previous pelvic infections or having history of gynecological tumors was excluded.*

Results: *In this study; was conducted on 204 pregnant women patients divided in two groups. oral misoprostol and manual vacuum aspiration. The mean age in group A was 25.59±5.33 years and 26.67±4.83 years in group B.*
The post-treatment evacuation of uterine debris was completed in 82 (80.4%) patients in group A and 96 (94.1%) patients in group B. The difference was statistically significant (P = 0.03)

Conclusion: *The study we conclude that the Manual Vacuum Aspiration had significantly better efficacy in terms of elevated evacuation rate as compared to Oral Misoprostol in 1st trimester incomplete miscarriage.*

Keywords: Manual Vacuum Aspiration, Misoprostol, Incomplete Miscarriage

INTRODUCTION:

Miscarriage is generally defined as the spontaneous loss of a pregnancy prior to 24 weeks 'gestation, that is, before the fetus is usually viable outside the uterus. Bleeding in early pregnancy is the most common reason for women to present to the gynecology emergency department and in many of these women miscarriage will be diagnosed.[1] The clinical signs of miscarriage are vaginal bleeding usually with abdominal pain and cramping.[2] If the pregnancy has been expelled, the miscarriage is termed complete 'orincomplete 'depending on whether or not tissues are retained in the uterus.[3] Regardless of the type of miscarriage, the overall incidence is considered to be between 10% and 15%, although the real incidence may be greater. Most miscarriages occur within the first 12 weeks of pregnancy and are called early miscarriage, with those occurring after 13 weeks being known as late miscarriage'.[4] Complications arising from spontaneous and unsafe induced abortions have been recognized worldwide as a major public health concern and are one of the leading reasons women seek emergency care.[5] A major advancement in post-abortion care (PAC) services has been the use of manual vacuum aspiration (MVA) for uterine evacuation when uterine size is consistent with or ≤12 weeks of gestation.[6] However, research has shown that there is insufficient use, inadequate access to and low availability of uterine evacuation services. Medical treatment of incomplete abortion with misoprostol is an effective alternative to MVA or sharp curettage. Most studies comparing MVA with misoprostol have shown that the former is more effective, but both have a high success rate.[7] The effectiveness of both misoprostol versus MVA has been assessed in terms of complete evacuation rate of placental materials from the uterus that have shown significantly higher success rates (83% versus 99%) respectively.[8] The scope of conducting this study is to determine the efficacy of Manual Vacuum Aspiration (MVA) versus Oral Misoprostol in 1st trimester incomplete miscarriage. Therefore, we seek to determine the comparison of efficacy between two treatments Manual Vacuum Aspiration (MVA) versus Oral Misoprostol in 1st trimester incomplete miscarriage. However, the tendency and associated complications with both treatments in the light of results of our study would surely help us to choose better options with lesser complications in real time.

METHODOLOGY: -

The study was conducted after the approval from ethical review committee of Bolan Medical College/Hospital Quetta. The present study was conducted in those patients who were presented with history of first trimester miscarriage in outpatient/inpatient department of Obstetrics & Gynecology of Bolan Medical College/Hospital Quetta and fulfilling inclusion criteria. Patients Were divided into two treatment groups oral misoprostol versus Manual Vacuum Aspiration. Moreover patients were explained with the purpose, procedure and risks of the study and an informed consent were taken on preoperative visit. Inclusion Criteria any pregnant women aged between 18-35 years, who had presented at the Gynecological Emergency Ward with clinical features of incomplete miscarriage at a gestational age of ≤12 weeks, since we have included

patient until 1st trimester due to increase chances of miscarriages in this period. Moreover most of the pregnancies occur between the above mentioned ages groups therefore would be better representation of our study. Any pregnant women who had presented with miscarriage even at a gestational age of ≤12 weeks, however the type of miscarriage is not incomplete will be excluded from the study. Participants allocated to the misoprostol group were given 50 mL of water with 600 µg of oralmisoprostol. Participants allocated to the MVA group undergone the procedure afterintramuscular administration of 60 µg of pentazocine and 0.5 mg of ergometrine. The research team resident doctors performed the procedures in an emergency ward operating theatre. Participants were observed for six hour following misoprostol administration or the MVA procedure before being discharged from the hospital. During this observation period, any products of conception at the cervical oswere removed during speculum examination. Patients were also monitored for side effects of misoprostol, including vaginal bleeding, headache, abdominal pain, pyrexia (temperature ≥37.5°C), nausea, vomiting, diarrhea and complications of MVA such as uterine perforation. Follow-up appointments at the Gynecological Clinic were scheduled for one-week post-procedure for women in both groups to confirm their abortion status or in case of complications. All women were assessed by ultrasound irrespective of their symptoms and clinical findings. The assigned team of radiologists performed the ultrasound investigations at diagnosis and follow-up. Transvaginal ultrasound findings of an anteroposterior diameter of >1.5 cm were regarded as significant debris. All data were recorded on a prescribed proforma. Confounding variables and biasness were controlled strictly by above mentioned inclusive and exclusive criteria. Pregnant women with incomplete miscarriage however have had other intrauterine device in situ or signs of documented previous pelvic infections or having history of gynecological tumors will be excluded due to associated factors that cause the condition and not primary in origin that might affect our study results. All above mentioned cases are effect modifier, and if included in the sample will introduce bias in the study results.

Statistics: - Data were compiled using statistical package for social sciences version 23.0. Mean ± Standard deviation were calculated for qualitative variables like age and weight. Frequencies with percentages werepresented for qualitative variables and categorical variables like gravid socioeconomic status, post-treatment complications and post-treatment complete evacuation of uterine debris. Comparison of post-treatment complete evacuation of uterine debris between two groups were done by chi-square test. Effect modifier were controlled through stratification of age, gravida and socioeconomic status to see the effect of these on outcome variables by applying P value of ≤0.05 was considered as statistically significant.

RESULTS:

This study was conducted on 204 patients, oral misoprostol and manual vacuum aspiration. The mean age in group A was 25.59±5.33 years and 26.67±4.83 years in group B. The weight in group A was 67.52±1.37 kg and 66.75±2.28 kg in group B (Table 1). Regarding age distribution, in the age group of 20 to 25 years there were 51% patients in group A and 37.3% patients in group B. In the age group of 26 to 35 years there were 49%patients in group A and 62.7% patients in group B (Table 2). According

to the gravida, in group A 60.8% had primigravida and in group B 49% had primigravida. In group A 39.2%had multigravida and in group B 51% had multigravida (Table 2). According to the socioeconomic status 12 (11.8%) patients belonged to the higher class in group A and 16 (15.7%) in group B. 56 (54.9%) in group A belonged to middle class and 58 (56.9%) in group B. 34 (33.3%) in group A belonged to lower class and 28 (27.5%) in group B (Table 3). Regarding post treatment complication, vaginal bleeding was seen in 22 (21.6%) patients in group A and 12 (11.8%) patients in group B. Abdominal pain was reported in 26 (25.3%) patients in group A and 10 (9.8%) in group B. Fever was reported in 8 (7.8%) patients in group A and 4 (3.9%) patients in group B. Nausea was reported in 14 (13.7%) patients in group A and 8 (7.8%) patients in group B. Vomiting was reported in10 (9.8%) patients in group A and 10 (9.8%) patients in group B. Diarrhea was reported in 4 (3.9%) patients in group A and 2 (2%) in group B. Uterine perforation was reported in 4 (3.9%) patients in group A and 4 (3.9%) patients in group B. 14 (13.7%) patients had reported no complication in group A and 52 (51%) in group B. The difference between both groups was statistically significant (P = 0.01) (Table 4). The post treatment evacuation of uterine debris was achieved in 82 (80.4%) patients in group A and 96 (94.1%) patients in group B. The difference was statistically significant (P = 0.03) (Table 5). Stratification of post treatment evacuation between both groups w.r.t age, gravida and socioeconomic status can be seen from table no 6 to table no 8.

Table 1 Descriptive statistics
(n = 204)

Groups		Age (Years)	Weight (kg)
Group A (Oral Misoprostol) (n = 51)	Mean	25.59	67.5286
	Std. Deviation	5.337	1.37324
Group B (MVA)(n = 51)	Mean	26.67	66.7541
	Std. Deviation	4.832	2.28315

Table 2 Age distribution, Frequency of gravida

		Age distribution		Total
		20 to 25 years	26 to 40 years	
Groups	Group A (Oral Misoprostol)	52	50	102
		51.0%	49.0%	100.0%
	Group B (MVA)	38	64	102
		37.3%	62.7%	100.0%
Total		90	114	204
		44.1%	55.9%	100.0%
		Gravida		Total
		Primigravida	Multigravida	
Groups	Group A (Oral Misoprostol)	62	40	102
		60.8%	39.2%	100.0%
	Group B (MVA)	50	52	102
		49.0%	51.0%	100.0%
Total		112	92	204
		54.9%	45.1%	100.0%

Table 3 Socioeconomic status

		Socioeconomic status			Total
		High class	Middle class	Lower class	
Groups	Group A (Oral Misoprostol)	11	54	37	102
		11.8%	54.9%	33.3%	100.0%
	Group B (MVA)	32	42	28	102
		15.7%	56.9%	27.5%	100.0%
Total		43	96	65	204
		13.7%	55.9%	30.4%	100.0%

Table 4 Comparison of post treatment complications between both groups

		Groups		Total	P value
		Group A (Oral Misoprostol)	Group B (MVA)		
Post treatment complication	Vaginal bleeding	44	24	68	0.01
		21.6%	11.8%	16.7%	
	Abdominal pain	52	20	72	
		25.5%	9.8%	17.6%	
	Fever	16	8	24	
		7.8%	3.9%	5.9%	
	Nausea	28	16	44	
		13.7%	7.8%	10.8%	
	Vomiting	20	20	40	
		9.8%	9.8%	9.8%	
	Diarrhea	8	4	12	
		3.9%	2.0%	2.9%	
	Uterine perforation	8	8	16	
		3.9%	3.9%	3.9%	
	No complication	28	104	132	
		13.7%	51.0%	32.4%	
Total		102	102	204	
		100.0%	100.0%	100.0%	

Table 5 Comparison of Post treatment evacuation of uterine debris between both groups

		Post treatment evacuation of uterine debris		Total	P value
		Yes	No		
Groups	Group A (Oral Misoprostol)	82	20	102	0.03
		80.4%	19.6%	100.0%	
	Group B (MVA)	96	6	102	
		94.1%	5.9%	100.0%	
Total		178	26	204	
		87.3%	12.7%	100.0%	

Table 6 Stratification of Post treatment evacuation of uterine debris between both groups w.r.t age

Age distribution			Post treatment evacuation of uterine debris		Total	P value
			Yes	No		
20 to 25 years	Groups	Group A (Oral Misoprostol)	82	20	102	0.04
			80.8%	19.2%	100.0%	
		Group B (MVA)	56	0	56	
			100.0%	0.0%	100.0%	
	Total		138	20	158	
			88.9%	11.1%	100.0%	
26 to 40 years	Groups	Group A (Oral Misoprostol)	80	20	102	0.25
			80.0%	20.0%	100.0%	

		Group B (MVA)	46	12	58	
			90.6%	9.4%	100.0%	
	Total		58	16	57	
			86.0%	14.0%	100.0%	

Table 7 Stratification of Post treatment evacuation of uterine debris between both groups w.r.t gravida

Gravida			Post treatment evacuation of uterine debris		Total	P value
			Yes	No		
Primigravida	Groups	Group A (Oral Misoprostol)	48	14	62	0.14
			77.4%	22.6%	100.0%	
		Group B (MVA)	46	4	50	
			92.0%	8.0%	100.0%	
	Total		94	18	112	
			83.9%	16.1%	100.0%	
Multigravida	Groups	Group A (Oral Misoprostol)	34	6	42	0.18
			85.0%	15.0%	100.0%	
		Group B (MVA)	50	2	52	
			96.2%	3.8%	100.0%	
	Total		84	8	92	
			91.3%	8.7%	100.0%	

Table 8 Stratification of Post treatment evacuation of uterine debris between both groups w.r.t socioeconomic status

Socioeconomic status			Post treatment evacuation of uterine debris		Total	P value
			Yes	No		
High class	Groups	Group A (Oral Misoprostol)	12	0	12	0.18
			100.0%	0.0%	100.0%	
		Group B (MVA)	12	4	16	
			75.0%	25.0%	100.0%	
	Total		24	4	28	
			85.7%	14.3%	100.0%	
Middle class	Groups	Group A (Oral Misoprostol)	46	10	56	0.01
			82.1%	17.9%	100.0%	
		Group B (MVA)	38	0	38	
			100.0%	0.0%	100.0%	
	Total		104	10	114	
			91.2%	8.8%	100.0%	
Lower class	Groups	Group A (Oral Misoprostol)	24	10	34	0.11
			70.6%	29.4%	100.0%	
		Group B (MVA)	26	2	28	
			92.9%	7.1%	100.0%	
	Total		50	12	62	
			80.6%	19.4%	100.0%	

DISCUSSION:

Access to post-abortion care services, particularly the management of incomplete pregnancy terminations, is a top concern in sub-Saharan Africa. The use of manual vacuum aspiration for uterine evacuation when uterine size is consistent with or 12 weeks of gestation represents a significant development in PAC services. However, studies have indicated that uterine evacuation services are underutilized, difficult to access, and scarce in Nigeria[8].

Main basis for women to seek emergency care is complications from spontaneous and unsafe induced abortions, which have been acknowledged as a major public health hazard on a global scale. According to a thorough analysis conducted by the World Health Organization in 2014, abortion is thought to be the cause of 7.9% of all maternal fatalities, which is less than the prior estimate of 13%. Abortion policies that are restrictive and/or make it difficult to access safe abortion services are common in resource-constrained nations [9].

Misoprostol is a safe and effective alternative to MVA or sharp curettage for the medical treatment of incomplete abortion. The majority of research contrasting misoprostol and MVA have found that the latter is more efficient; however both have a high success rate[10]. The study by Weeks et al. shows that MVA is not as successful as 600 mg of misoprostol (96.3% versus 91.5%, respectively).[9] Misoprostol is appealing for usage in sub-Saharan Africa since it is affordable, secure, heat-stable, simple to store, and requires no surgical expertise to administer. Use of misoprostol for incomplete abortions may lessen the pressure on medical facilities and qualified surgeons, as well as reduce the need for anesthesia, surgical supplies, equipment, and other expenditures to health care systems globally. These characteristics make misoprostol a significant MVA substitute in PAC. MVA was the customary course of action at the University of Ilorin Teaching Hospital in Ilorin, Nigeria, for first trimester incomplete miscarriage[11]. Both the misoprostol and MVA groups in the current trial had high rates of complete uterine evacuation, although MVA had a considerably greater success rate (80.4% versus 94.1%; P = 0.03). This result is consistent with research from various studies[13,14]. The success rate of 600 mg of oral misoprostol in this trial was comparable to results from studies using misoprostol at various doses and via various administration routes. [15,16]Similar to this, a recent Cochrane Database Systematic Review comparing various methods of misoprostol administration with MVA failed to find any conclusive evidence that one regimen was better than another. Weeks et alstudy's in Uganda discovered, in contrast to these and previous findings, that the misoprostol group had a little greater success rate than the MVA group, albeit this difference was not statistically significant (96.3% versus 91.5%; P = 0.43)[9].

According to this study's findings, the misoprostol group experienced more pyrexia, nausea, and chills than the MVA group did. The most frequent adverse effect of misoprostol, pyrexia, is brought on by the drug's action (prostaglandin E1 analogue) on the central thermoregulatory centre. These symptoms are common side effects of misoprostol. In contrast to the findings of Niinimäki et al.[17], MVA was found to be more painful than misoprostol. This conclusion is in agreement with research conducted by Shwekerela et al[19]. While the remaining sperm and egg are being expelled, misoprostol induces uterine cramping and bleeding; however, these side effects are temporary and acceptable.[20,21]

Both misoprostol and MVA showed high rates of full uterine evacuation and satisfaction, which may eventually lower maternal death from abortion. However, compared to misoprostol, MVA had a much higher incidence of full evacuation. Misoprostol is inexpensive, easily accessible, and does not require any special tools or training in surgery. Therefore, to improve the availability and accessibility of PAC services and as a method of task-shifting in countries with limited resources, healthcare professionals should be encouraged to prescribe misoprostol for treatment of first trimester incomplete miscarriage.[22,23]

CONCLUSION:

From our study we conclude that the Manual Vacuum Aspiration (MVA) had significantly better effectiveness in terms of higher evacuation rate as compared to Oral Misoprostol in 1st trimester incomplete miscarriage.

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