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To compare the efficacy of manual vacuum aspiration verses misoprostol in first trimester incomplete miscarriage

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Abstract

Objective: To compare the efficacy of manual vacuum aspiration verses misoprostol in first trimester incomplete miscarriage

Material and Methods: All patients with first trimester miscarriage assessed by ultrasound, On bimanual pelvic examination uterine size less than or equal to 12 weeks size with open cervix , maternal age between 18-35 years, parity less than or equal to 4 and gravidity less than or equal to 5 were included in this study. Consenting women randomized to either description of the method picked by the lottery method. All participants regardless of treatment assigned given tablet Brufen 400mg and vibramycin 100mg for pain relief and infection prophylaxis. The patients are offered follow up visit after 1 week with an ultrasound report. The final outcome was measured after one week of the procedure.

Results: Mean age of the patients in MVA group was 28.2±5.68 years whereas in misoprostol group was 26.56±5.43 years. In MVA group, In contrast mean gestational age in MVA group was significantly lower 66.54±11.02 days whereas in misoprostol group was 65.75±10.93 days, gestational age of most of the patients in both groups was found < 70 days. Pain score-wise comparison revealed significantly lower scores in MVA groups (1.75±0.87) as compared to misoprostol group (I.99±1.32). Common side effects reported were mainly heavy bleeding (96.1% vs. 3.90%, P-value=0.001), normal bleeding(75.5% vs.24.5%, P-value=0.001*) fever (100% vs. 0%, P-value=0.001*), and chills (100% vs. 0%, P-value=0.001*). Efficacy rate in MVA group was significantly higher as compared to misoprostol group. In MVA group, efficacy was found in 269 (97.1%) patients whereas in misoprostol group efficacy was found in 260 (93.9%) patients.

Conclusion: Oral misoprostol is as safe and acceptable as manual vacuum aspiration.

Keywords: Manual vacuum aspiration, misoprostol, incomplete miscarriage, first trimester of pregnancy

Introduction:

Miscarriage is one of the common contributory factor of maternal morbidity especially in developing world. Nearly 20% of clinically recognized pregnancy ends up in miscarriage.[1] WHO estimate that 10- 20 million women risk their lives annually by subjecting themselves to termination of pregnancy.[2,3]

Pakistan is a developing country with limited resources in health sector. Pakistan has slow fertility rate decline as compared to other developing countries.[4] According to a recent survey, approximately 2.2 million abortions occur in Pakistan, signifying an annual abortion rate of 50 per 1,000 pregnancies.[5]

In Pakistan the annual estimated miscarriage rate elevated up to 29 per thousand aged between 15 to 49 years. Incomplete and missed miscarriages frequently occurs in approximately 15% of clinically recognized pregnancies and in 890, 000 women per year, out of which 15% encounter complications related to unsafe miscar-

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riage.[6]

Incomplete miscarriages can be managed expectantly, surgically and medically (using misoprostol with or without mifepristone). Surgical management has been the standard of care worldwide for many years, and its safety and effectiveness is well proven where there is high-quality medical care.[7]

Most common medical intervention used in Pakistan is misoprostol. This has been found to be safe, effective and acceptable among women who are not willing for invasive procedures.[8] Misoprostol indeed portrays an enduring alternative for first trimester miscarriages. It has been administrated as a vital drug in obstetrics and gynecology as it is utero tonics and cervical priming action. Its administration is conducted by a single dose of 600mcg misoprostol given to the patient even in the lower level vicinity where availability of post abortion care is currently limited or non-existent. It can also be a tremendous opportunity for the patient who desire minimal intervention. In model list of essential medicine WHO (2010), has added and prescribed Misoprostol for the treatment of incomplete miscarriage.[9]

While MVA is safe and effective procedure and in terms of surgical evacuation World health organization (WHO) recommends as the manual vacuum, aspiration preferred method for the first trimester abortion.[9]

Maternal deaths in relation to abortion have been observed throughout South Asia including Pakistan. Major step should be conducted in order to decrease maternal mortality and morbidity. High quality data is efficient to monitor these parameters in accordance with success of intervention aimed at improving and saving women's life.[10] This study explored the plausible efficacy of either misoprostol or manual vacuum aspiration. To indicate the feasibility and integrating methods and to attain the perspective result provided by the perspective and experience of patients of both the procedures.

Material and Methods:

This was a randomized controlled trial conducted in Obstetric & Gynecological department at Civil Hospital Karachi from July 2013 to December 2013. Total 554 patients were included in study, out of which 227 were in MVA group and same number in Misoprostol group.

Inclusion criteria: All patients with first trimester miscarriage were assessed by ultrasound, open cervical os and symphyiso fundal height of uterus is less than or equal to 12 weeks by bi manual and physical examinatio the women of the age is 18- 35 years included in the study. Parity <= to 4, gravidity less than or equal to 5, included in the study.

Exclusion criteria: Miscarriage with gestational age more than 12 weeks of gestation. Septic Abortion. Gestational trophoblstic disease. Ectopic pregnancy. Post delivery retained products of conception. Missed miscarriage.

Data collection: The whole procedure has been explained to women who fulfilling the inclusion criteria either coming through the outpatient department or emergency were included in the study. Consenting women randomized to either description of method and picked by the lottery method. Procedure was explained to all participants' analgesics and antibiotics were given as pain killer & infection prophylaxis respectively. Manual vacuum aspiration was performed under local anesthesia in the procedure room by 60ml syringe its canula was inserted to cervix by creating vacuum all the products of conception were removed.

The subjects that included in Misoprostol group are given an introduction to the use misoprostol for incomplete miscarriage. The dose of 600mcg misoprostol recommended only once for first trimester incomplete miscarriages. All the patients who were stable were discharged 1-2 hours after the procedure. The patients were offered follow-up visit after 1 week with ultrasound report. The final outcome was measured after one week of the procedure.

Table-1: Descriptive Statistics n=554

	MVA	Misoprostol	MVA	Misoprostol	MVA	Misoprostol
	Age		**Gestational Age**		**Pain Score**	
Mean	28.2	26.56	66.54	65.75	1.75	1.99
S.D	5.68	5.43	11.02	10.93	0.87	1.32
Minimum	18	22	55	56	1	1
Maximum	35	31	78	78	7	8

Table-2: Proportion of Age, Gestational Age, Gravidity, Parity and Efficacy (n=554)

		MVA		Misoprostol	
		N	**%**	**N**	**%**
Age (in years)	≤25	117	42.2	162	58.5
	>25	160	57.8	115	41.5
Gestational Age (in days)	≤70	144	52	154	55.6
	>70	133	48	123	44.4
Gravidity	Primagravidity	121	43.7	120	43.3
	Multigravidity	156	56.3	157	56.7
Parity	Nulliparous	92	33.2	73	26.4
	Primiparous	136	49.1	144	52
	Multiparous	49	17.7	60	21.7
Efficacy	Positive	269	97.1	260	93.9
	Negative	8	2.9	17	6.1

Table-3: Clinical outcome

	Misoprostol [n=283]	MVA [n=289]	P-value
Lost to follow-up	2.12(6)	4.15(12)	
Returned to follow-up	97.88(277)	95.8 (277)	0.1621
Participant Characteristics of side effects reported			
Side effects	Misoprostol [n=277]	MVA [n=277]	P-value
Heavy Bleeding	99(96.1%)	4(3.9%)	0.001*
Normal Bleeding	262(75.5%)	85(24.5%)	0.001*
Spotting	104(54.7%)	86(45.3%)	0.107
Vomiting	14(73.7%)	5(26.3%)	0.036*
Fever	40(100%)	0(0%)	0.001*
Chills	49(100%)	0(0%)	0.001*
Previous Induced abortion	49(60.5%)	32(39.5%)	0.041*
Previous Spontaneous	54(75%)	18(25%)	0.001*
Nausea	14(77.8%)	4(22.2%)	0.017*

Results:

Descriptive statistics showed that mean age of the patients in MVA group was 28.2±5.68 years whereas in misoprostol group was 26.56±5.43 years. Mean gestational age in MVA group was 66.54±11.02 days whereas in misoprostol group was 65.75±10.93 days. Mean pain score in MVA group was 1.75±0.87 whereas in misoprostol group was 1.99±1.32 (table 1).

Most of the patients in MVA group was presented with >25 years, i.e. 160 (57.8%) whereas in misoprostol group most of the patients were of age <25 years 162 (58.5%). Gestational age of most of the patients in both MVA and misoprostol group was ≤70 days, i.e. 144 (52%) and 154 (55.6%) respectively. (table 2)

In MVA group prim gravidity was found in 121 (43.7%) patients and mulligravidity was found in 156 (56.3%) patients whereas in misoprostol group, primigravidity was found in 120 (43.3%) patients and multigravidity was found in 157 (56.7%) patients.

In MVA group, nulliparity was found in 92 (33.2%) patients, primiparity in 136 (49.1%) patients and multiparity was found in 49 (17.7%) patients whereas in misoprostol group nulliparity was found in 73 (26.4%) patients, Primiparity was found in 144 (52%) patients and multiparity was found in 60 (21.7%) patients. Manual vacuum aspiration found more efficacious than misoprostol group. in 260 (In MVA group, efficacy was found in 269 (97.1%) patients whereas in misoprostol group efficacy was found in (93.9%) patients. (table 2)

The association of side effect in women among both groups were less in MVA group common side effects which reported were mainly heavy bleeding (96.1% vs. 3.90%, P-value=0.001), normal bleeding (75.5% vs.24.5%, P-value=0.001*) fever (100% vs. 0%, P-value=0.001*), and fever with chills (100% vs. 0%, P-value=0.001*). In addition side effect like spotting and vomiting are probable impacts of misoprostol and women should be counseled before practicing the method to increase the compliance. So the women in the misoprostol group experienced a more side effects than the MVA group (Table 3).

Discussion:

The objective of the study was to determine the effectiveness of manual vacuum aspiration in first trimester incomplete miscarriage as compared to misoprostol. So in Pakistan, however, medical management to compare the efficacy of manual vacuum aspiration verses misoprostol in miscarriage using misoprostol with varying

dosage regimens and routes of administration (sublingual, oral or vaginal) are currently in use. Manual vacuum aspiration has been used successfully as an outpatient procedure for the treatment of first trimester pregnancy loss in the USA since early 1970's.

In present study total 554 patients underwent intervention, 227 patients in each group. Mean age of patients which observed in MVA group was 28.2±5.68 years, whereas in Misoprostol group was 26.56± 5.43 years. Slightly higher age group 31.8± 5 years were reported by Gazvani et al.[11] Mean gestational age in both groups were 70 days (9 weeks) which was also comparable to above study.[11] It was noted in current study that MVA group has slightly higher efficacy (97%) as compared to misoprostol group (93.9%) which is also observed by study conducted by Madhu Das.[12] Bique C et al in 2007[13] have compared the efficacy of misoprostol and MVA treatment in incomplete miscarriages also reported that MVA has higher efficacy as compared to misoprostol (98.0%) VS (92.1%) p-value of 0.0001 on the other hand results reported from study conducted in Uganda[14] in which misoprostol (96%) was more effective than MVA(92 %). According to Bano and Bique[9] MVA was 100% effective while misoprostol was (92%) and (91%) respectively.

For instance medical treatment was equally effective, perhaps increasing waiting period from one to two weeks or repeating dose may have improved the outcome with misoprostol in first trimester miscarriages between 9 and 12 weeks gestation also. Tang OS in his review on the use of misoprostol for early pregnancy failure has reported a high acceptability and a success rate ranged from 84% - 93% depending on the regimen of misoprostol, the duration of waiting period and the types of miscarriage.[15] Study conducted in Burkina West Africa showed success of both the regimes in numerous trials. The overall success rate for the two treatments was high. Misoprostol 94.5%, MVA 99.1% (RR 0.95) (95% CI 0.92-0.99).[16] Regarding side effects profile in our study population more side effects were observed in misoprostol group as compared to manual vacuum aspiration, which was also comparable to study conducted by Madhu Das C et al.[12] Specific side effects which noticed were fever with chills with p- value of (0.001) which were also noticed by Gabika Bray in his study.[17] Symptoms severity was less and transient so patients got relief with symptomatic treatment. It was found in our study that heavy bleeding with a p-value (0.001) followed by spotting p-value (0.107) which is statistically significant that was also noticed by Madhu Das et al,[12] but Shwekerela found heavy bleeding in MVA group than misoprostol group[18] it was observed that misoprostol as well as manual vacuum aspiration both are equally effective which was also reported by Ahmed SK et al in his study.[19]

In this study both treatment groups were successful but MVA group has slightly higher efficacy in terms of time, as all the products of conception removed at one sitting , less bleeding after procedure with short hospital stay , patient can be discharged at same day which was agreed by other studies.[20-23] While misoprostol group also has good results but In terms of effectiveness it is not always effective with 1st dose but may require repeat dose and bleeding or spotting may remain continues for one to two weeks.

Conclusion:
We conclude in this study that manual vacuum aspiration is more effective than misoprostol and it has less side effects profile, but both options are cheap as there is no need of General anesthesia and no long hospital stay. Misoprostol is good alternative option for low resource setting.

All women and men of reproductive age should be informed about effective methods of contraception, including emergency contraception. Community-based distribution of appropriate methods should be available to avoid induced miscarriages. Community health workers should be trained to recognize and treat minor complications of medical miscarriage and to arrange referral when necessary.

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Role and contribution of authors:

Dr Adeela Tahir, collected the data, references and did he initial writeup

Dr Farzana Aamir, critically review the article and made the final changes.

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