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ORIGINAL ARTICLE

Role of Manual Vacuum Aspiration Versus Sublingual Misoprotol in First Trimester Miscarriage in a Tertiary Care Hospital PMC, Nawabshah

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ABSTRACT

Objective: To compare the efficacy of manual vacuum aspiration versus sublingual misoprostol in first trimester miscarriage at people's medical college hospital Nawabshah.
Study Design: Randomized Controlled Trial.
Settings: Department of Gynaecology and Obstetrics, Peoples Medical University & Hospital Nawabshah.
Duration of Study: 7th April 2021 to 6th October 2021.
Materials & Methods: A total of 100women with first trimester incomplete abortion, 18 to 45 years of age were included. Patients having allergy to misoprostol or other prostaglandins, contraindication to prostaglandin therapy (asthma, hypertension, glaucoma) and suspected ectopic pregnancy assess on ultrasound were excluded. Group A received a single dose of 600 microgram of sublingual misoprostol every three hours and group B who underwent MVA for evacuation of retained products of conception. Efficacy was noted.
Results: The mean age of women in group B was 30.14 ± 4.12 years and in group A was 30.20 ± 3.69 years. Majority of the patients 51 (51.0%) were between 18 to 30 years of age. The mean gestational age in group B was 7.92 ± 2.42 weeks and in group A was 7.48 ± 2.32 weeks. In this study, success was seen in 46 (92.0%) women in group B (manual vacuum aspiration) and 37 (74.0%) women in group A (sublingual misoprostol) with p-value of 0.017.
Conclusion: This studyconcluded that manual vacuum aspiration (MVA) is effective and safe procedure as compared to sublingual misoprostol in first trimester incomplete abortion.
Keywords: first trimester incomplete abortion, manual vacuum aspiration, misoprostol

INTODUCTION

Miscarriage is one of the common contributory factor in maternal morbidity especially in developing world. Nearly 15% 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.[1]

Pakistan is a developing country with limited health resources. Pakistan has slow fertility rate decline as compared to other developing countries.[2] According to a recent survey, approximately 2.2 million miscarriage occur in Pakistan, signifying an annual abortion rate of 50 per 1,000 pregnancies.[3] Although miscarriage is the biggest cause of pregnancy loss in the UK, it cause remains poorly understood and there is a great deal of research focused on improving management and services for this condition.[4] Many different surgical procedures for first trimester miscarriage are performed under local anaesthesia (LA) all over the world to avoid the use of general anesthesia or because general anaesthesia is not available. Surgical abortion below 7 weeks is rare in France, because the French Ministery of Health suggests performing abortions medically up to 7 weeks' gestational age that can be performed without any hospitalization.[5]

Most common medical termination performed in Pakistan is misoprostol. This has been found to be safe, effective and acceptable among women who are not willing for invasive procedures.[6] Manual vacuum aspiration (MVA) is a safe and cheap method that can be performed by authorized nurses without the use of general anaesthesia or access to electricity.[7,8] The World Health Organization (WHO) guidelines and a Cochrane Library review concluded that vacuum aspiration is the preferred surgical method for uterine evacuation after an incomplete abortion in the first trimester.[8,9]

Studies investigating the safety and efficacy of misoprostol only abortion in the first trimester are limited, and there is no common consensus on the best Protocol. Routes of administration include per oral buccal, sublingual, and vaginal.[10] Across the various protocols, demonstrated efficacy has ranged significantly, from under 80%[11,12] to more than 90%.[13,14] The majority of the existing studies report efficacy around 85%.[15] Efficacy rates are higher with earlier gestational ages, more doses and greater follow-up intervals.[16] Study of Adeela Tahir[1] reported 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), moderate bleeding (75.5% vs.24.5%, P-value=0.001) fever (100% vs. 0%, P-value=0.001). In addition side effect, like per vaginal 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.[1]In the study of AdeelaTahir 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'. Another study reported the efficacy of MVA and misoprostol in first trimester miscarriage was 99% vs 83% respectively.[17]

The aim of our study was to compare the efficacy of manual vacuum aspiration versus sublingual misoprostol in first trimester miscarriage. As literature regarding comparison of misoprostol and manual vacuum aspiration in terms of complete evacuation among women with incomplete abortion is very limited locally as well as internationally. Moreover available literature use variation in efficacy of both treatment. So it becomes very important to understand the efficacy of both treatments in order to develop a strategy for future on maternal health. This study will help the obstetrician to choose appropriate method for evacuation in order to improve maternal outcomes.

MATERIALS AND METHODS

This randomized controlled trial was conducted at Department of Gynaecology and Obstetrics, Peoples Medical University & Hospital Nawabshah, during from the period 7th April 2021 to 6th October 2021. Total 100 women having ages 18 to 45 years with first trimester miscarriage diagnosed by ultrasound and clinical examination finding open cervical os and symphyiso fundal height of uterus is less than or equal

to 12 weeks by manual and physical examination. Parity < to 4, gravidity less than or equal to 5 were included in the study. Patients having known allergy to misoprostol or other prostaglandins, contraindication to prostaglandin therapy (asthma, hypertension, glaucoma) and suspected ectopic pregnancy assess on ultrasound. Pelvic infection or sepsis, hemodynamically unstable patients diagnosed clinically on abnormal heart rate (arrhythmias) Cold periphery, confusion, decreased urine output, low blood pressure (hypotension) and restlessness, and patients with previous scarred uterus and history of surgical evacuation of previous miscarriages were excluded.

Written informed consent obtained from the patient for procedure and its complications were explained to the patients. After fulfilling the inclusion criteria either coming through the outpatient department or emergency were included in the study. Consenting women randomized to either group picked by the lottery method. Patients divided into two groups. Group A received a single dose of 600 microgram of sublingual misoprostol every three hours and group B who underwent MVA for evacuation of retained products of conception. Procedure was explained to all participants. Manual vacuum aspiration was performed under local anesthesia in the procedure room by 60m1 syringe its cannula was inserted in cervix than by creating vacuum all the products of conception were removed and confirm after 24 hours assessment was done by ultrasound whether cavity is evacuated completely or not.

After collection of data, the analysis was conducted by using Statistical Package for Social Science (SPSS) software, Version 21. Mean±SD/median (IQR) were calculated for quantitative variable like age, height, weight, BMI, parity, gravida and gestational age. Frequency and percentage were calculated for place of residence, previous history of abortion and efficacy. Comparison of efficacy between both groups was done using chi square test.

RESULTS

Age range in this study was from 18 to 45 years with mean age of 30.15 ± 3.87 years.The mean age of women in group B was 30.14 ± 4.12 years and in group A was 30.20 ± 3.69 years. Majority of the patients 51 (51.0%) were between 18 to 30 years of age as shown in Table I. Gestational age was from ≤12 weeks with mean gestational age of 7.63 ± 2.35 weeks. The mean gestational age in group B was 7.92 ± 2.42 weeks and in group A was 7.48 ± 2.32 weeks as shown in Table II. Mean parity was 3.29 ± 1.15 (Table III). Mean BMI was 33.62 ± 3.76 kg/m^2 (Table IV). Distribution of patients according to previous h/o abortion is shown in Table V.

In this study, efficacy was seen in 46 (92.0%) women in group B (manual vacuum aspiration) and 37 (74.0%) women in group A (sublingual misoprostol) with p-value of 0.017 (Table VIII).

Table 1: Age distribution for both groups (n=100).

	Group B (n=50)		Group A (n=50)		Total (n=100)	
Age (years)	No. of patients	%age	No. of patients	%age	No. of patients	%age
18-30	27	54.0	24	48.0	51	51.0
31-40	23	46.0	26	52.0	49	49.0
Mean ± SD	30.14 ± 4.12		30.20 ± 3.69		30.15 ± 3.87	

Table 2: Distribution of patients according to Gestational age in both groups.

Gestational Age	Group B (n=50)		Group A (n=50)		Total (n=100)	
(weeks)	No. of patients	%age	No. of patients	%age	No. of patients	%age
1-6 weeks	18	36.0	22	44.0	40	40.0
7-12 weeks	32	64.0	28	56.0	60	60.0
Mean ± SD	7.92 ± 2.42		7.48 ± 2.32		7.63 ± 2.35	

Table 3: Distribution of patients according to parity in both groups.

Parity	Group B (n=50)		Group A (n=50)		Total (n=100)	
	No. of patients	%age	No. of patients	%age	No. of patients	%age
1-3	35	70.0	27	54.0	62	62.0
4-5	15	30.0	23	46.0	38	38.0
Mean ± SD	1.94 ± 1.50		1.38 ± 1.14		1.29 ± 1.15	

Table 4: Distribution of patients according to BMI.

BMI (kg/m^2)	Group B (n=50)		Group A (n=50)		Total (n=100)	
	No. of patients	%age	No. of patients	%age	No. of patients	%age
≤30	15	30.0	14	28.0	29	29.0
>30	35	70.0	36	72.0	71	71.0

Table 5: Distribution of patients according to previous h/o abortion.

Previous h/o	Group B (n=50)		Group A (n=50)		Total (n=100)	
abortion	No. of patients	%age	No. of patients	%age	No. of patients	%age
Yes	30	60.0	30	60.0	60	60.0
No	20	20.0	20	20.0	40	40.0

Table 6: Comparison of efficacy between both Groups (n=100).

		Group B (n=50)		Group A (n=50)	
		No. of Patients	%age	No. of Patients	%age
EFFICACY	Yes	46	92.0	37	74.0
	No	04	8.0	13	26.0

P value is 0.017 which is statistically significant

DISCUSSION

Miscarriage is known to be the most common complication of early pregnancy one which can have serious medical consequences should it not be managed appropriately. In situations where medical intervention is indicated, a number of methods have been offered traditionally; these are surgical management of miscarriage (suction curettage under general anaesthesia) and medical management, using misoprostol. Manual vacuum aspiration (MVA) was described first in the 1970s as a possible method for managing incomplete miscarriage.[18]

Since this time, it has been adopted for other uses, including but not exclusively, termination of pregnancy and missed

miscarriage. Although a popular method of management throughout much of the rest of the world, it has only recently begun to be offered routinely in early pregnancy assessment units (EPAU's) throughout the UK. MVA is carried out in an out-patient setting and thus does not require hospital admission or a theatre team for management. The procedure is straightforward and can be carried out by doctors and appropriately trained EPAU advanced nurse practitioners. The procedure is performed under local anaesthesia using a self-locking syringe that creates a defined amount of vacuum in order to evacuate the products of conception.[19]

I have conducted this study to compare the success of oral misoprostol versus manual vacuum aspiration of first trimester incomplete abortion. The mean age of women in group B was 30.14 ± 4.12 years and in group A was 30.20 ± 3.69 years. Majority of the patients 51 (51.0%) were between 18 to 30 years of age. The mean gestational age in group B was 7.92 ± 2.42 weeks and in group A was 7.48 ± 2.32 weeks. In this study, success was seen in 46 (92.0%) women in group B (manual vacuum aspiration) and 37 (74.0%) women in group A (sublingual misoprostol) with p-value of 0.017. In the study of Adeela Tahir 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'. Another study reported the efficacy of MVA and misoprostol in first trimester miscarriage was 99% vs 83% respectively.[17]

Biqueet al[20] have compared the efficacy of MVA with that of the misoprostol for treatment of incomplete abortion. Follow-up at seven days' posttreatment reported success rate of 100% for MVA and 91% for misoprostol (100% vs. 91%; p 0.002). The results of the study favor manual vacuum aspiration as the preferred method for uterine evacuation during first trimester of pregnancy. This method is faster and more efficacious than medical termination with misoprostol especially at 9-12 weeks of gestation.[21]

Several studies have shown MVA to be a safe, effective and acceptable alternative to electric vacuum aspiration with very high success rates.[22-24] In 1997 Creinen and Edwards[96] reported their experience of early surgical termination of pregnancy using MVA under local anaesthesia in 2399 women, with complete uterine evacuation reported in 99.2%. A pilot study in the UK involving 56 women investigated the feasibility and acceptability of MVA and showed that 98% of women had a successful procedure without the need for any further surgical or medical intervention. Also, 98% of women were satisfied with the procedure and 86% said they would recommend it to a friend. Eighty percent said they would undergo the same procedure again, if required in the future.[25] Another study in the UK involving 246 women undergoing MVA under local anaesthesia for first-trimester, early fetal demise and mid-trimester incomplete miscarriage reported complete uterine evacuation in 95%, with the remaining 5% requiring additional treatment.[22]

In a study by Hemlin J et al[21] success rate with manual vacuum aspiration was 95.2%. Edwards S et al[27] also reported success rate with manual vacuum aspiration as 98%. Ansari R et al[103] found success rate with manual vacuum aspiration as 97.7%.Results of a study revealed that MVA is better treatment modality as compared to medical management (misoprostol intravaginally).The American College of Obstetrics and Gynecology (ACOG) endorses a protocol for medical management of women with an incomplete pregnancy loss and a uterus less than 12 weeks in size that utilizes misoprostol, 600 µg orally or 400 µg sublingually.[28]For delayed pregnancy losses, misoprostol can be increased to 800 µg vaginally or 600 µg sublingually. Doses can be repeated every 3 hours for up to three total doses.[29] Alternative regimens have also been studied. Overall, misoprostol, 800 µg, produces the highest expulsion rate, with little additional benefit noted after the third dose.[30] In women with gestations at 7 to 17 weeks, the 800-µg vaginal misoprostol regimen resulted in an 80% success rate when measured by complete expulsion within 3 days of treatment.[31] The efficacy is similar among all modes of administration, although gastrointestinal (GI) side effects (nausea, diarrhea) are more common when misoprostol is administered orally or sublingually.[32]

Fonseca et al conducted a study comparing conventional D&C with MVA, their study concluded that patients treated with MVA needed 77% less hospital stay and consumed 4% less hospital resources than patients treated with D&C.[33] Hence MVA has virtually eliminated some of the risks associated with traditional D&C such as infection and uterine perforation. As manual vaccum aspiration is an effective and safe procedure so midwives and nurses can easily be trained and this can be very useful for developing countries like Pakistan where majority of the population is in rural areas. In rural areas access to medical facilities are limited, high tech equipment are not available, power supply is erratic and maintenance of instruments is not up to the mark. Despite the proven benefits, MVA under local anaesthetic is still under used.

CONCLUSION

This study concluded that manual vacuum aspiration (MVA) is effective and safe procedure as compared to sublingual misoprostol in first trimester incomplete abortion. So, we recommend that manual vacuum aspiration should be used as a first line surgical method in the treatment of first trimester incomplete abortion to reduce the complications of the incomplete miscarriage as well as morbidity and mortality of these patients.

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