COMPARING THE EFFECTIVENESS OF MISOPROSTOL WITH MANUAL VACUUM ASPIRATION IN TREATING FIRST TRIMESTER MISCARRIAGES

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ABSTRACT

Background: Medical abortion is a widely accepted and extremely effective procedure of providing abortion services. The findings of this study will be disseminated among healthcare professionals to enhance treatment and suggestions. Additionally, they will be utilised for future research endeavors, such as presentations and article publications.

Objective: The objective is to assess the effectiveness of misoprostol compared to manual vacuum suction in patients experiencing first trimester miscarriages.

Material & Methods: The research was carried at the Department of Obstetrics and Gynaecology, Qazi Hussain Ahmed Medical Complex, Nowshera, between June 2021 and December 2021. The study participants were allocated to two groups by a random assignment process utilising a lottery approach. Participants in group A received Manual Vacuum Aspiration (MVA), whereas participants in group B were treated with misoprostol. The effectiveness of the procedure is determined by the lack of any remnants of pregnancy on the fifth day of treatment.

Results: Our results indicate that the mean age of patients in Group A was 30± 7.93 and that of Group B was 31± 7.11. 50 (94%) patients responded well to manual vacuum aspiration; 45 (85%) responded well to misoprostol.

Conclusion: Our research findings indicate that manual vacuum aspiration is more effective than misoprostol in treating miscarriage during the first trimester of pregnancy.

KEY WORDS: Manual vacuum aspiration, Misoprostol, First trimester miscarriages.

INTRODUCTION

Medical abortion is a viable and socially acceptable choice for abortion care.[1] Due to the minimal medical prerequisites for administering medical abortion drugs, and the fact that the woman can typically oversee the abortion process herself, an increasing number of induced abortions in the United States (US) and worldwide are being performed using medical methods.[2] Unsafe abortion continues to pose a substantial risk to the lives and well-being of women.[3] One technique to decrease unsafe abortion, especially in areas with limited trained surgical doctors, is to provide access to medical abortion by extending the gestational ages at which it can be safely performed.[4]

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The optimal medical abortion treatment is the combination of mifepristone and misoprostol. However, there are differences in the dosage, time, and method of administering these two medications.[4] The efficacy of all regimens is influenced by gestational age, with a decrease in effectiveness shown after nine weeks gestation.[5,6] Therefore, it is recommended to consistently repeat misoprostol dosages starting in the late first trimester. According to WHO recommendations, using misoprostol at home is considered safe and acceptable, and it is just as effective as administering it at a clinic for pregnancies up to 63 days gestation. Research on pregnancies in later stages would also have to show comparable effectiveness, acceptability, and rates of negative outcomes when using medical abortion medicines at home.[8]

Misoprostol is a type of prostaglandin that induces contractions in the muscles of the uterus, softens the cervix, and widens its opening. It is utilised by individuals to provoke abortion and labour, as well as to manage atonic postpartum haemorrhage and peptic ulcers. One advantage of this medication is that it is stable and reasonably priced, with a minimal incidence of adverse effects. As a result, it has been placed in the World Health Organisation's list of essential

pharmaceuticals.[9] Misoprostol alone, with a success rate ranging from 65 to 93%, can be used as a substitute for surgery in the medical treatment of miscarriage. It is most efficient during the initial phases of pregnancy, with the added benefits of cost-effectiveness, minimal invasiveness, and avoidance of surgical problems. In order to enhance the efficacy, doctors also employ a combination of Misoprostol with additional drugs such as mifepristone and methotrexate.[10] According to a study, MVA shown effectiveness in 269 patients, which accounts for 97.1% of the total. On the other hand, misoprostol was effective in 260 patients, representing 93.9% of the total.[11] In a separate trial, the efficacy of MVA was observed in 95.7% of patients, whereas misoprostol shown efficacy in 81.3% of patients.[12]

The aim of study is to evaluate the efficacy of manual vacuum aspiration in comparison to misoprostol for treating first-trimester miscarriages in patients. This study provides the latest and current data on the efficacy of manual vacuum aspiration compared to misoprostol in our particular population. even if there have been few studies completed in other populations. The results of this research will be shared with healthcare practitioners to improve treatment and recommendations. as well as to be utilised in future research endeavours, such as presentations and article publication.

MATERIAL AND METHODS

This research was undertaken by department of obstetrics & gynaecology, at Qazi Hussain Ahmed Medical Complex in Nowshera from June to December 2021. This was a randomised controlled trial comparing two different treatment methods for first-trimester miscarriage. The overall sample size consisted of 106 individuals, with an equal distribution of 53 members in individual group. WHO calculator was used to calculate sample size, assuming an MVA efficacy of 95.7%, misoprostol efficacy of 81.3%, a confidence level of 95%, and a test power of 80%.[12] We utilised a non-probability consecutive sampling method to choose 12 patients, whom we divided into two groups. One group was administered MVA, while the other group received Misoprostol. The study encompassed all women within the reproductive age range who had reached full-term pregnancy, defined as being at least 12 weeks into gestation, as well as those who needed medical intervention to terminate their pregnancy, regardless of the reasons. The researchers did not include women who had previously taken prostaglandins, received oxytocin infusions, experienced trauma during pregnancy, had unsuccessful abortions or bleeding disorders, septic abortions, recognised uterine malformations, or were hemodynamically unstable. All participants who satisfied the specified criteria were enrolled in the trial either through the outpatient department or the emergency department. Ethical approval was taken from hospital research evaluation board. An informed consent was taken as well from paritents. We conducted a comprehensive evaluation, including a thorough medical history, clinical examination, and radiological assessment, in accordance with the hospital's protocols. We employed the lottery approach to randomly assign all the eligible patients into two groups. My approach. In group A, we administered MVA to the patients, while in group B, we administered misoprostol. The trainee independently performed all the procedures while being supervised by a proficient obstetrician who is a fellow of the CPSP. We monitored all female patients until the fifth day after their surgery. The efficacy of the operation was determined based on the absence of any products of conception on the fifth day of therapy. All the personal data, such as name, address, contact number, age, parity, gravidity, and time of gestation, were documented on the prearranged Performa (attached). We adhered rigorously to exclusion criteria in order to mitigate the influence of confounding factors and other sources of bias. The data was analysed using SPSS version 23. We performed calculations to determine the average and variability of quantitative factors, such as age and gestation period. Additionally, we analysed categorical data, such as parity, gravidity, and efficacy, by calculating their frequencies and percentages. We employed a chi-square test to assess the effectiveness of two groups, keeping a significance level of $p < 0.05$. The efficacy was categorised based on age, parity, gravidity, and period of gestation in order to examine the factors that influence it. The chi-square test was used, keeping significance level of $P < 0.05$.

RESULTS

The results of study are shown in table 1, illustrating the age distribution and average age in groups A and B. Group B patients exhibited a greater average age. The gravity distribution was studied as follows: in Group A, 35 patients (66% of the total) were primigravida, while 18 patients

(34% of the total) were multigravida. By comparison, Group B consisted of 36 primigravida patients (68% of the total) and 17 multigravida patients (32% of the total). Table 2 Upon analysing the gestation period, we discovered that in Group A, 23 patients (accounting for 44% of the patients) had a period of gestation (POG) of less than 7 weeks, whereas 30 patients (accounting for 56% of the patients) had a POG longer than 7 weeks. Within Group B, 25 patients, accounting for 47% of the total patients, exhibited a POG (Period of Gestation) of less than 7 weeks. Conversely, 28 patients, constituting 53% of the total patients, had a POG of more than 7 weeks. Table 3.

We conducted an analysis to evaluate the efficacy of two groups. Our findings indicate that Group A, which utilised Manual Vacuum Aspiration, demonstrated effectiveness in 50 patients (94% of the total), while it was deemed ineffective in 3 patients (6% of the total). By contrast, 85% of the 45 patients in Group B reported that Misoprostol was effective, whilst 15% found it to be useless. The information is presented in table 4. Tables 5-8 provide information on the differentiation of effectiveness based on age, number of pregnancies, stage of pregnancy, and number of previous births.

TABLE NO 1. AGE DISTRIBUTION
(n=106)

AGE	GROUP A	GROUP B	P Value
18-28 years	32(60%)	34(64%)	0.4958
29-40 years	21(40%)	19(36%)	
Total	53(100%)	53(100%)	
Mean and SD	30 ± 7.93	31 ± 7.11	

TABLE NO 2. GRAVIDITY DISTRIBUTION
(n=106)

GRAVIDITY	GROUP A	GROUP B	P value
Primigravida	35(66%)	36(68%)	0.836
Multigravida	18(34%)	17(32%)	
Total	53(100%)	53(100%)	

TABLE NO 3. PERIOD OF GESTATION
(n=106)

POG	GROUP A	GROUP B	P value
≤ 7weeks	23(44%)	25(47%)	1.0000
>7 weeks	30(56%)	28(53%)	
Total	53(100%)	53(100%)	
Mean and SD	7 ± 2.83	7 ± 2.91	

TABLE NO 4. EFFICACY
(n=106)

EFFICACY	GROUP A	GROUP B	P value
Effective	**50(94%)**	**45(85%)**	**0.111**
Not effective	**3(6%)**	**8(15%)**	
Total	**53(100%)**	**53(100%)**	

TABLE NO 5. STRATIFICATION OF EFFICACY WITH RESPECT TO AGE DISTRIBUTION

AGE	EFFICACY	GROUP A	GROUP B	P value
18-28 years	**Effective**	**30(94%)**	**29(85%)**	**0.265**
	Not effective	**2(6%)**	**5(15%)**	
Total		**32(100%)**	**34(100%)**	
29-40 years	**Effective**	**20(95%)**	**16(84%)**	**0.246**
	Not effective	**1(5%)**	**3(16%)**	
Total		**21(100%)**	**19(100%)**	

TABLE NO 6. STRATIFICATION OF EFFICACY WITH RESPECT TO GRAVIDITY DISTRIBUTION

GRAVIDITY	EFFICACY	GROUP A	GROUP B	P value
Primigravida	Effective	33(94%)	31(86%)	0.248
	Not effective	2(6%)	5(14%)	
Total		35(100%)	36(100%)	
Multigravida	Effective	17(94%)	14(82%)	0.261
	Not effective	1(6%)	3(18%)	
Total		18(100%)	17(100%)	

TABLE NO 7. STRATIFICATION OF EFFICACY WITH RESPECT TO PERIOD OF GESTATION

POG	EFFICACY	GROUP A	GROUP B	P value
≤ 7 weeks	Effective	22(96%)	21(84%)	0.186
	Not effective	1(4%)	4(16%)	
Total		23(100%)	25(100%)	
>7 weeks	Effective	28(93%)	24(86%)	0.341
	Not effective	2(7%)	4(14%)	
Total		30(100%)	28(100%)	

TABLE NO 8. STRATIFICATION OF EFFICACY WITH RESPECT TO PARITY DISTRIBUTION

PARITY	EFFICACY	GROUP A	GROUP B	P value
Primi Para	Effective	32(94%)	29(88%)	0.371
	Not effective	2(6%)	4(12%)	
Total		34(100%)	33(100%)	
Multi Para	Effective	18(95%)	16(80%)	0.169
	Not effective	1(5%)	4(20%)	
Total		19(100%)	20(100%)	

DISCUSSION

The aim of our study is to evaluate how effective misoprostol is in comparison to manual vacuum aspiration for the managing first trimester miscarriages. In Pakistan, misoprostol is used for medical treatment with different doses and schedules. Since 1970, manual vacuum aspiration has been widely used worldwide for the outpatient treatment of first-trimester pregnancy loss.

Total patients included in trial were 106, with an equal distribution of 53 patients in each group. The average age in Group A was 30± 7.93, while in Group B it was 31± 7.11. Within Group A, 35 patients (66% of the total) were primigravida, while 18 patients (34% of the total) were multigravida. In Group B, 36 patients (68%) were primigravida and 17 patients (32%) were multigravida. Within Group A, there were 34 primiparous patients, making 64% of the total, and 19 multiparous patients, making 36% of the whole. In Group B, 33 patients (63% of the total) were primipara, meaning they were giving birth for the first time, while 20 patients (37% of the total) were multipara, meaning they had given birth before. Group A, which utilised manual vacuum aspiration, attained a success rate of 94% in 50 patients. On the other hand, Group B, which employed misoprostol, attained a success rate of 85% in 45 patients.

A study carried by Tahir A et al.[11] similar results were found. The mean age of subject in the MVA group was 28.2±5.68 years, while in the group B it was 26.56±5.43 years. On the other hand, the average length of pregnancy in the MVA group was considerably shorter (66.54±11.02 days), while in the group B it was 65.75±10.93 days. In majority cases both groups had a gestational age of less than 70 days. A comparison of pain assessments showed considerably fewer scores in the MVA groups (1.75±0.87) compared to the misoprostol group (1.99±1.32). 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*) were the most commonly reported side effects. The effectiveness rate in the group A was meaningfully higher compared to the misoprostol group. The MVA group demonstrated efficacy in 269 patients, accounting for 97.1% of the total, whereas the misoprostol group achieved efficacy in 260 patients, accounting for 93.9% of the total.

In a separate trial, Nwafor JI et al.[12] reported comparable results, showing a greater rate of failure in the group B compared to the group A. The rate of uterine evacuation did not significantly differ between the two groups (81.3% vs. 95.7%, RR = 4.3, 95% CI 0.98–18.9, P value = 0.05). However, a greater number of women in the misoprostol group expressed a preference for that approach compared to women in the MVA group (47 vs. 30, X[2] = 16.95, P < 0.001). Women in the misoprostol arm had a considerably higher mean client satisfaction score (13.2 (2.1) versus 7.3 (4.6), P < 0.001) than women in the MVA group. Group A experienced a significantly higher average cost of primary treatment ($67.8 (8.9) versus 14.4 (4.0), P < 0.001) compared to group B. The mean cost of repeated uterine evacuation did not differ statistically significantly between the two experimental groups. With a p-value of 0.86, the mean cost for the misoprostol group was $65.76 (6.6) while the mean cost for the MVA group was $64.9 (6.3).

The observed higher successful rate in the group B is comparable to the success rate stated by Ibiyemi et al.[13] The significant success rate found in the misoprostol group indicates that using medication to manage partial abortions in carefully chosen patients is a highly effective substitute to manual vacuum aspiration.

In this study, problems didn't happen very often in either of the treatment groups. After taking misoprostol, four women had a lot of vaginal bleeding, which meant that the leftover foetal tissue had to be removed quickly by manual vacuum aspiration (MVA). In addition, women who received misoprostol in the trial reported a higher occurrence of severe vaginal bleeding compared to those who were treated with MVA. Still, there wasn't a big difference between the two treatment groups in the levels of blood before and after evacuation.

The results of this research were consistent with the findings of investigations conducted by Ibiyemi et al. in Ilorin,[13] Fawole et al. in Ibadan,[14] and Adisso in Benin.[15] None of the patients in this research experienced genital tract sepsis. Weeks[19] and his colleagues did study in Uganda and found that genital tract sepsis happened in one woman who was given misoprostol and in three women who were given manual vacuum aspiration. Not a single pelvic infection happened during this study, which is likely because antibiotics were given to everyone.

Women who got misoprostol treatment had a better average client satisfaction score at a follow-up visit (13.2 (2.1)) than women who got MVA treatment (7.3 (4.6)). In contrast to the women in group A (65.2%), a greater number of women in the misoprostol group (97.9%) indicated a desire to repeat the same procedure. The rationale for selecting misoprostol included its high efficacy rate of 95.8%, its rapid and uncomplicated treatment process with a success rate of 83.3%, and its capacity to circumvent the need for uterine instrumentation, which was preferred by 85.4% of participants. Similarly, compared to women in the MVA group, more misoprostol group members will suggest the treatment to a friend for the same reasons. The outcomes matched those of Ibadan, Dim in Enugu,[17] Chigbu in Abia,[18] and Fawole et al.[14] Nevertheless, the disparity in customer satisfaction shown in this trial diverged with the results of a study conducted in Ilorin by Ibiyemi[13] and another study carried out in Uganda by Weeks[19] both of which indicated that there was no discernible distinction in mother satisfaction between the medical and surgical groups. Furthermore, the study conducted in Finland revealed a notable distinction: women who underwent manual hoover aspiration expressed higher levels of satisfaction with their therapy in comparison to individuals who received misoprostol.[20] This study differs in terms of maternal satisfaction as it exclusively covered women with incomplete losses, unlike the aforementioned studies that encompassed various types of miscarriage. The MVA group experienced discomfort and dread throughout the procedure, while women who took 3 tablets of misoprostol found it easier. This difference in experience may have made it harder for women who had MVA to be accepted by clients and make them happy.

According to a study, the group of women who received misoprostol had reduced initial treatment expenditures for those who experienced an incomplete miscarriage and had a smooth recovery ($14.36 compared to $4.02) compared to the group who received MVA ($67.84 compared to 8.9%). The study found that the first treatment for a partial miscarriage with MVA cost four times as much as the first treatment with misoprostol. Even though more women in the misoprostol group failed treatment,

there was no disparity in the average cost of subsequent care between the two groups.

A study done in Finland found that the main costs of surgery were lower, but our results show that they were higher. The general costs were the same, though, even when extra costs from problems in the medical group were taken into account. [21] The disparity in cost-effectiveness across the studies can be attributed to the broader scope of miscarriage types examined in the Finnish study, leading to divergent outcomes.

According to the results of this study, medical therapy should be considered the most effective approach to assist determined women who have experienced a simple incomplete miscarriage in the first trimester of pregnancy, particularly in tertiary and other healthcare facilities. The many benefits it offers are the reason for this. Manual vacuum aspiration, on the other hand, should only be done on women who have problems or who are not likely to show up for their follow-up appointments to make sure that all of the uterine fluid is removed.

The primary advantage of this investigation was the implementation of a randomised controlled trial design. Blinding was not feasible due to the study's design, nevertheless, it is expected that the impact on outcome variables was insignificant. Moreover, the utilisation of a dependable and accurate tool, such as PPSQ, was a notable advantage of this research. This test is commonly utilised to assess the level of client satisfaction with medical care. We conducted an exit interview to evaluate the level of acceptance and satisfaction among clients with the treatment. This approach was effective in reducing or eliminating any bias that may have been influenced by the clients themselves. In addition to these qualities, the present study had a constraint. The study, being conducted at a single location, enables the extrapolation of study results to the specific area of investigation. The inclusion of many centres in the experiment would have enhanced the generalizability of the study findings. To evaluate the suitability, contentment, and cost-efficiency of therapy groups in low-resource settings, the authors propose conducting an extra multicenter randomised controlled study that replicates the treatment protocol.

CONCLUSION

There was no statistically significant difference in the two therapies' efficacy, despite the higher failure rate of medical therapy. On the other hand, medical care was linked to better levels of patient acceptability and satisfaction and proven to be more cost-effective than surgery.

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