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**Original Article**

# Comparison of Misoprostol and Manual Vacuum Aspirator for Managing Early Pregnancy Miscarriage

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## ABSTRACT

Manual vacuum aspiration is a safe and effective technology for the treatment of incomplete miscarriage but it is not widely available and affordable in rural areas particularly in low-resource countries. **Objective:** To compare efficacy, safety and acceptability of misoprostol and manual vacuum aspirator in management of early pregnancy miscarriage **Methods:** Prospective quasi experimental study Department of gynecology and obstetrics, Sheikh Khalifa Bin Zayed Al Nahyan (CMH).Muzaffar Abad. Study duration was 6 months. A sample of 90 women was calculated using WHO calculator. Patients were approached through non probability consecutive sampling. After following inclusion and exclusion criteria, Patients were randomly divide into two groups; Group A was given misoprostol while group B was patients underwent manual vacuum aspiration. Data were analyzed with SPSS version 25.0. Chi-square and fissure exact test was applied. **Results:** Total 90 patients were included in study. Mean age of patients was 35.4 ± 3.2SD. Treatment failure/incomplete uterine evacuation was significantly lower in manual vacuum aspiration group as compared to misoprostol group (45.6% vs 36.7%, p=0.05). Misoprostol showed less adverse events (p=0.03) and high satisfaction rate (p=0.00) as compared to manual vacuum aspirator. **Conclusions**: Manual vacuum aspirator is more effective in complete uterine evacuation as compared to misoprostol. However, misoprostol is found as more safe with limited side effects and highly acceptable drug as compared to manual vacuum aspirator. It is recommended to use misoprostol as a better choice for management of early pregnancy loss in resource limited areas.

## INTRODUCTION

Miscarriage is a common complication of early pregnancy of first trimester. European society of Human Reproduction and Embryology (ESHRE) in 2005 revised early pregnancy events terminologies [1]. Pregnancy loss without ultrasound verification but positive human chorionic gonadotropin (before 6 weeks of gestation) is referred as biochemical loss. Pregnancy loss after confirmation of intrauterine pregnancy with ultrasound or histological evidence is termed as clinical miscarriage. Clinical miscarriage is divided into two main categories; early clinical pregnancy loss and late clinical pregnancy loss (before 12 weeks of gestation and 12-21 weeks of gestation respectively) [2]. It is estimated that approximately 46 million induced abortions take place annually worldwide. A significant number of these procedures are carried out unlawfully in unsafe conditions, leading to roughly 78,000 annual fatalities across the globe. The primary causes of these deaths are septicemia and hemorrhaging [3]. Literature reported that incidence of early pregnancy loss varies from 20-24 years women to 40-44 years (10% to 51% respectively) [4]. Over the years Maternal Mortality Ratio (MMR) worldwide has decreased by 38% from 2000 to 2017 [5]. Early pregnancy loss (before an embryo developed) is physiological phenomenon associated with chromosomal abnormalities. Several clinical studies reported vaginal bleeding as serious sign of early miscarriage while nausea and vomiting was reported a protective sign against pregnancy loss. Several drugs are used for early pregnancy loss management. Misoprostol is most common one. Misoprostol is an effective

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prostaglandin E1 analogue [6]. Success rate of misoprostol in managing early pregnancy loss depend upon on its dose and route of administration. It can be administrated orally, vaginally or sublingually with dose ranging from 100-800 micrograms. National institute for health and care excellence recommended single dose of 800 micrograms of misoprostol (orally or vaginally) [7]. Manual vacuum aspirator is cheap and safe method for early pregnancy loss without use of anesthesia. World Health The treatment of first-trimester missed miscarriages has been a topic of debate and discussion in the medical community. Patients have a variety of options, including expectant care, medicinal treatment, or surgical intervention [8]. Ibiyemi *et al.*, reported manual vacuum aspirator is associated with high evacuation rate as compared to misoprostol while both methods showed high acceptability and satisfaction [9]. Khaniya *et al.*, reported that misoprostol and manual vacuum aspirator both are effective in 1st trimester incomplete miscarriages [10].

Data available on comparison of two methods did not provide evidence of treatment choice in resource limited areas. Present study will contribute knowledge in choice of treatment. Present study was planned to compare efficacy, safety and acceptability of misoprostol and manual vacuum aspirator in management of early pregnancy miscarriage.

## METHODS

A prospective study Quasi Experimental Interventional pre and Post Design was conducted at department of gynecology and obstetrics, Sheikh Khalifa Bin Zayed Al Nahyan, CMH, Muzaffar Abad. Study duration was 6 months (18th September 2019-March 2020). A sample size of 90 women was calculated with P1=99%, P2=93% [9]. 95% confidence interval, 80% power of study using WHO calculator (45 patients in each group). Non Probability consecutive sampling was used for participant's selection in study. All participating women signed consent forms. Research approval was taken from ethical committee of respective institute. Inclusion criteria were based upon age 20-42 years and ultrasound based diagnosis of incomplete miscarriage (defined as patients with present history of vaginal bleeding, history of passing tissue or positive pregnancy urinary test with transvaginal ultrasound showing evidence of substantial debris) of ≤13 weeks of gestation (gestational age was determined from last period date in each patient). Exclusion criteria was based upon uterine scar, excessive bleeding, induced or septic miscarriage, hemodynamically unstable, patients with hemoglobin level <8gm%, patients with other metabolic disorders and patients who had allergy to E1 prostaglandin. Patients were randomly divided into two categories using random number table (computer generated). Group A patients were given 50 ml water with 600µg of misoprostol (orally). However patients in group B were give 60µg intramuscular administration of pentazocine, ergometrine (0.5mg) and undergone manual vacuum aspiration by resident doctors. Patients were observed for 6 hours after intervention for any side effect. They were followed 1 week after discharge from hospital. Patients were undergone transvaginal ultrasound after 1 week. Efficacy of treatment was measurement in terms of treatment failure. Treatment failure was defined as ultrasound findings of diameter >1.5 (anteroposterior), persistent vaginal bleeding and incomplete uterine evacuation. Safety was measured in terms of adverse effects while acceptability was measured in terms of satisfaction using Satisfaction with Life Scale (SWLS). The Satisfaction with Life Scale (SWLS) is a widely used instrument designed to measure an individual's global cognitive judgments of their life satisfaction. It consists of five statements that respondents rate on a scale from 1 (strongly disagree) to 7 (strongly agree), resulting in a total score that can range from 5 to 35. The SWLS has been demonstrated to possess favorable psychometric properties. High internal consistency means that the items on the scale are highly correlated with one another, indicating that they reliably measure the same underlying concept of life satisfaction. This is often quantified using Cronbach's alpha, which for the SWLS typically exceeds 0.80, suggesting excellent consistency. High temporal reliability, or test-retest reliability, refers to the stability of scores over time; in other words, individuals tend to receive similar scores when they retake the scale after a period, reflecting its reliability [11]. The study was approved by the ethical committee of H.H. Sheikh Khalifa Bin Zayed Al Nahyan Hospital / CMH, Muzaffar Abad, Azad Kashmir (Ref No. Ethical Committee / DME-391 dated: 18th-Sep-2019). Data were analyzed using SPSS version 25.0. Numerical data were presented in terms of mean ad standard deviation. Categorical and nominal data were presented in terms of percentage ad frequency. Post stratification chi-square and fissure exact test was applied to avoid selection bias. P value ≤ 0.05 was considered significant in our study results.

## RESULTS

Total 90 patients were included in study. Mean age of patients was 35.4 ± 3.2 S.D. There were 51 (56.7%) women in 20-30 years' age group and 39 (43.3%) in 31-42 years' age group. Among all, 56 (62.2%) women were house wife while 34 (37.8%) were working women. Marital status was single in 8 (8.9%) and married in 82 (91.1%) women. Estimated gestation age was ≤6 weeks in 41 (45.6%) and 7-13 weeks in 49 (54.4%). Parity was zero in 42 (46.7%) while ≤ 1 in 48 (53.3%). Treatment failure was significantly lower in manual vacuum aspiration group as compared to

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misoprostol group (45.6% vs 36.7%, p=0.05). Misoprostol group showed low adverse events rash, pyrexia, uterine perforation and diarrhea as compared to MVA group (0% vs 5.6%, 2.2% vs 4.4%, 0% vs 3.3%, 3.3% vs 3.3%, pain 0% vs 1.1% respectively, p=0.03) as shown in table 1.

**Table 1:** Comparison of Treatment Failure and Adverse Events in Misoprostol and Manual Vacuum Aspiration Group

| Variables | Interventional Groups | | Total | p-Value |
|---|---|---|---|---|
| | Misoprostol Group N (%) | Manual Vacuum Group N (%) | | |
| **Treatment Failure/Incomplete Uterine Evacuation** | | | | |
| No | 33 (36.7%) | 33 (36.7%) | 74 (82.2%) | 0.05 |
| Yes | 12 (13.3%) | 12 (13.3%) | 16 (17.8%) | |
| **Adverse Events** | | | | |
| No | 40 (44.4%) | 29 (32.2%) | 70 (77.8%) | 0.03 |
| Rash | 0 (0%) | 5 (5.6%) | 5 (5.6%) | |
| Pyrexia | 2 (2.2%) | 4 (4.4%) | 6 (6.7%) | |
| Uterine Perforation | 0 (0%) | 3 (3.3%) | 3 (3.3%) | |
| Diarrhea | 3 (3.3%) | 3 (3.3%) | 6 (6.7%) | |
| Pain | 0 (0%) | 1 (1.1) | 1 (1.1%) | |
| Total | 45 (50%) | 45 (50%) | 90 (100%) | |

Misoprostol group patients shows more satisfaction scores as compared to manual vacuum aspirator (extremely satisfied 6.7% vs 0%, satisfied 11.1% vs 13.3%, slightly satisfied 8.9% vs 4.4%, neutral 6.7% vs 4.4%, slightly dissatisfied 11.1% vs 6.7%, dissatisfied 2.2% vs 11.1% and extremely unsatisfied 3.3% vs 10% respectively, p=0.00) as shown in table 2. Treatment failure showed significant association with elder age group (0.02) and low level of education (p=0.03) while in significant association with education (p=0.564) and parity (p=0.231). Safety/adverse events and satisfaction showed in significant association with age, education, occupation and parity (p>0.05) explained in table 2.

**Table 2:** Comparisons of Satisfaction in Misoprostol and Manual Vacuum Aspirator Using Satisfaction with Life Scale

| Satisfaction | Interventional Groups | | Total N (%) | p-Value |
|---|---|---|---|---|
| | Misoprostol Group N (%) | Manual Vacuum Group N (%) | | |
| 31-35 Scores= Extremely Satisfied | 6 (6.7%) | 0 (0%) | 6 (6.7%) | 0.008 |
| 26-30 Scores= Satisfied | 10 (11.1%) | 12 (13.3%) | 22 (24.4%) | |
| 21-25 Scores= Slightly satisfied | 8 (8.9%) | 4 (4.4%) | 12 (13.3%) | |
| 20 Scores= Neutral | 6 (6.7%) | 4 (4.4%) | 10 (11.1%) | |
| 15-19 Scores= Slightly Dissatisfied | 10 (11.1%) | 6 (6.7%) | 16 (17.8%) | |
| 10-14 Scores= Dissatisfied | 2 (2.2%) | 10 (11.1%) | 12 (13.3%) | |
| 5-9=Extremely Unsatisfied | 3 (3.3%) | 9 (10%) | 12 (13.3%) | |
| Total | 45 (50%) | 45 (50%) | 90 (100%) | |

## DISCUSSION

Spontaneous and unsafe miscarriages are leading cause of maternal emergency worldwide. [12]. Misoprostol is cheap, safe, heat-stable, easy to store, and requires no surgical skills to administer, making it attractive for use [13]. In preset study, manual vacuum aspiration group patients showed better efficacy in terms of less treatment failure as compared to misoprostol group women (p=0.05). Shwekerela *et al.*, reported that success rate was high in both MVA and misoprostol group, however, misoprostol was found to be more effective in treating incomplete miscarriages with <12 weeks of uterine size [14]. Niinimaki *et al.*, reported that medical (misoprostol) and surgical (MVA) treatment both are effective for evacuation of debris. However, surgical treatment showed more evacuation as compared to medical option [15]. Another similar study reported that complete uterine evacuation rate was high in MVA group as compared to misoprostol (p<0.001). [9]. Weeks *et al.*, reported a slight difference in success rate of both treatments for 8-10 weeks of gestation. Moreover, they concluded that efficacy of each treatment is dependent upon provider skills of performing MVA and misoprostol quality [16]. In our study, misoprostol showed less adverse events diarrhea and pyrexia while manual vacuum aspirator showed slightly high adverse events (diarrhea, pyrexia, rash, pain and uterine perforation) (p=0.03). Kim *et al.*, reported that misoprostol is associated with pyrexia, chills and nausea as compared to MVA [17]. Elati *et al.*, reported that most common side effect of misoprostol is pyrexia on central thermoregulatory center [18]. Bique *et al.*, reported that manual vacuum aspirator is reported as more painful procedure as compared to misoprostol [19]. In our study, patients were found more satisfied with misoprostol as compared to MVA (p=0.00) using Satisfaction with Life Scale (SWLS). Dao *et al.*, reported high satisfaction with both misoprostol and MVA due to high tolerability. Several participants in their study were willing to grecommend both treatments to their family and friend to consider it as a better approach [20]. However, Dabash *et al.*, found majority of patients satisfied with misoprostol due to less pain and discomfort as compared to MVA [21].

## CONCLUSIONS

Manual vacuum aspirator is more effective in complete uterine evacuation as compared to misoprostol. However, misoprostol is found as more safe with limited side effects and highly acceptable drug as compared to manual vacuum aspirator. It is recommended to use misoprostol as a better choice for management of early pregnancy loss in resource limited areas.

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## Authors Contribution

Conceptualization: HP
Methodology: SS, AA
Formal analysis: NS, UK
Writing, review and editing: HS, HP, SS, AA, NS, UK

All authors have read and agreed to the published version of the manuscript.

## Conflicts of Interest

The authors declare no conflict of interest.

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