

## Comparison of Feasibility, Efficacy and Patient Acceptability of Manual Vacuum Aspiration Vs Sublingual Misoprostol in Early Pregnancy Loss

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### ABSTRACT

**Objective:** To compare feasibility, efficacy and patient acceptability of manual vacuum aspiration with sublingual Misoprostol in early pregnancy loss.

**Study Design:** Comparative prospective study.

**Place and Duration of Study:** Gynecology and Obstetrics Department, Combined Military Hospital Okara Pakistan, from Aug 2019 to Apr 2020.

**Methodology:** 200 Patients with early pregnancy loss (missed, incomplete abortion) at gestational age 6 to 12 weeks were randomly allocated to Manual vacuum aspiration (group A) and oral Misoprostol (group B) by lottery methods. Manual vacuum aspiration was done in the outpatient department. While in Group B, oral Misoprostol was given with a protocol 600 micro gram sublingual stat observe for 1 hour for any complication. Afterwards, they were given Misoprostol 600 micrograms sublingual, 3 hourly total of 2 doses. Patients from both groups were called for follow-up after one week.

**Results:** Efficacy, feasibility and patient acceptability was 88%;  $p$ -value  $<0.001$ , 95%;  $p$ -value  $<0.001$  and 97% respectively in manual vacuum aspiration group as compared to 64%, 68% and 70% in sublingual Misoprostol group. There were fewer systemic side effects and fewer visits in manual vacuum aspiration group 1 vs 3 in the sublingual Misoprostol group.

**Conclusion:** Manual vacuum aspiration is more effective than Misoprostol as it has no systemic effects. Both options are cheap and can be achieved in outpatient settings. However, manual vacuum aspiration provides complete evacuation and is a good option for low resource settings and a developing country like Pakistan with frequent electricity disruptions. It offers a substantial saving on resources, cost and time.

**Keywords:** Acceptability, Efficacy, Feasibility, Misoprostol, Manual vacuum aspiration.

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### INTRODUCTION

The most typical complication associated with pregnancy is Early Pregnancy loss or miscarriage. Early pregnancy loss is defined as the natural death of an embryo before 24 weeks of gestation. Most of the miscarriages, almost 80%, occur at or around 12 weeks of gestation.<sup>1</sup> Multiple risk factors like history of previous miscarriage, advanced maternal age, obesity, substance abuse, maternal medical illness, radiation exposure and drugs contribute to early pregnancy loss.<sup>2,3</sup> At the same time, established causes of miscarriage include genetic predisposition, uterine anomalies, luteal phase deficiency, tissue rejection and genital tract infections. Many times miscarriages occur spontaneously without requiring medical or surgical intervention.<sup>4</sup> At the same time, others may require medical or procedural intervention.

The overall early pregnancy loss rate is 15-20%,<sup>5</sup> while the recurrent pregnancy loss rate is 1%. 2.9% of

women experience early pregnancy loss in Pakistan per year during the second to the fourth decade of their life. This accounts for 10-12% of the maternal mortality.<sup>6,7</sup>

The treatment options can be individualized according to the patient's desires and gestational age, determined by asking LMP or measuring the size of products of conception. Treatment may be medical (prostaglandins) and surgical intervention, i.e. ERPOC by vacuum aspiration, suction curettage and conventional dilatation and curettage. Surgery may be required in 88% of patients with early pregnancy loss. Misoprostol is a synthetic prostaglandin E1 analogue. It is used in the medical management of miscarriage, induction of labour, cervical ripening before surgical procedures, and the treatment and prophylaxis of PPH. It is on the world health organization's model list of essential medicines. It can be administered through oral, sublingual, buccal, vaginal or rectal routes.<sup>8</sup>

Both Manual vacuum aspiration and Misoprostol are effective methods used for termination of pregnancy as per data from south Asia (Pakistan, India,

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Nepal and Bangladesh) and Africa.<sup>9</sup>

Manual vacuum aspiration was first introduced in 1958 by Wu Yuantai and Xianzhen in China. Later on, improvements were made by Harvey Karman of the USA, Dorothea Kerslake of the UK and Henry Morgentaler of Canada. It can be performed under local anaesthesia. It is an alternative to standard electrical vacuum aspiration. It has been declared a safe and effective procedure for managing early pregnancy loss.<sup>9</sup>

In Pakistan, the public health sector is overburdened by a high fertility rate (3.8%), low contraceptive prevalence, inadequate access to safe abortion care, lack of trained staff, and poor understanding of legislation by health care providers. Therefore, in Pakistan, there is a need to shift from traditional dilatation and curettage to outdoor procedures, which are inexpensive, easy, convenient and do not require electricity, so that the burden of the health sector can be relieved a bit.<sup>10</sup>

The objective of study was to assess the feasibility, efficacy and women's acceptability of manual vacuum aspiration vs Misoprostol in early pregnancy loss.

## METHODOLOGY

This prospective comparative study was carried out at the Gynaecology and Obstetrics Department of CMH Okara, from August 2019 to April 2020. Taking a 25% prevalence of early pregnancy loss with an 80% power and a 4% margin of error, the sample size calculated was approximately 2103.<sup>11</sup> This was done using a WHO sample size calculator.

**Inclusion Criteria:** Patients with missed miscarriage, incomplete miscarriage, haemodynamically stable patient, parous women or well-motivated nulliparous patient who can tolerate speculum examination, and no clinical signs of infection were included in the study.

**Exclusion Criteria:** Patients with more than 12 weeks of gestation, molar pregnancies, active pelvic infection, coagulation problems, medically unstable patients, septic induced abortion, and highly anxious patients were excluded from the study.

For the study, missed miscarriage was defined as a gestational sac with a mean diameter of >25 mm with no fetal pole or fetal pole >7mm with no cardiac flicker.<sup>12</sup> At the same time, an incomplete miscarriage was defined as the passage of products of conception with residual tissue measuring 5-12 mm and uterine size less than 13 weeks.<sup>13</sup>

After approval of the study protocol by the Hospital's Ethical Committee, IERC/OBS/2020/01. A total of 210 patients fulfilling these criteria were included in the study. Unfortunately, ten patients did not show up in OPD for follow-up. Therefore, the study was carried out on 200 patients. Informed, written consent was obtained from every patient. The Women were allocated to the manual vacuum aspiration (MVA) group (Group A) and Misoprostol (Group B) by lottery method.

History, physical examination and ultrasound were done for all patients. In the MVA group, the procedure was done within the examination room. Cervical priming with 400 microgram Misoprostol sublingually was done 1 hour prior to surgery only for those patients with a closed cervical os. A paracervical block combined with intramuscular Diclofenac Sodium or oral Ibuprofen for analgesia with Ipas MVA system. While in Group B, oral Misoprostol was given with a protocol 600 micro gram sublingual stat observe for 1 hour for any complication. Afterwards, they were given Misoprostol 600 micrograms sublingual, 3 hourly total of 2 doses. Oral antibiotic Cap Doxycycline 200 mg BD for five days in both groups. Anti D prophylaxis was given to all the Rhesus negative patients in group A.

The feasibility of successfully completing the procedure without using general anaesthesia and other operation theatre facilities was assessed. Efficacy meant complete uterine evacuation without further medical or surgical intervention. Patient acceptability was assessed from patient satisfaction, measured using the visual analogue scale (VAS). So primary outcome measures were feasibility, efficacy, and patient acceptability (patient satisfaction). While secondary outcome measures like the number of patient visits, systemic effects of Misoprostol like nausea, vomiting and fever, complications including infection, perforation, retained RPOC, vasovagal syncope and need for repeat evacuation were also noted on pre-designed proforma. All the patients were offered to follow up visit after one week. Ultrasound of all the patients was done. The outcome was measured on follow up visit. If the patient presented with RPOCs, they were called for a second follow-up visit one week after treatment.

The data were analyzed using the SPSS version 20. Forage, gestational age, parity and number of visits mean was calculated. In addition, other parameters like feasibility, efficacy, patient acceptability, indication for TOP, complete evacuation, need for repeat

MVA, nausea, vomiting fever, and patient satisfaction frequency were calculated. Chi square test was used for measuring efficacy and feasibility. The *p*-value ≤0.05 was considered significant.

**RESULTS**

Two hundred patients with early pregnancy failure were randomly allocated to MVA (Group A) n=100 and oral Misoprostol (Group B) n=100. The mean age of the women in group A was 22 ± 2.0 years, and in group B, it was 23 ± 2.3 years. The parity ranged from 0 to 7 in either group. The gestational age ranged from 6 to 12 weeks. The means gestational age in the MVA group was 9 ± 1.787 weeks and 9.2 ± 1.620 weeks in the Misoprostol group.

Indication for termination of pregnancy in both groups was comparable, with 65 cases of missed miscarriage and 35 incomplete mis-cariage in the MVA group, while 59 missed mis-cariages and 41 incomplete miscarriages in the Misoprostol group. The complete evacuation was achieved in 94% of patients in group A. Rest of the patients, 6%, had scanty RPOC <2 mm, which were expelled spontaneously, confirmed on the second follow up visit done two weeks post-procedure. While in group B, the complete evacuation was achieved in 80%, the rest of the patients (n=20) under-went MVA on the follow-up visit. None (n=0) of the patients in Group A required repeat MVA. Procedure feasibility was 95%, *p*-value <0.001 in group A as compared to 68% in group B. The efficacy of group A was 88% *p*-value <0.001, and in group B, it was 64% as shown in the Figure.

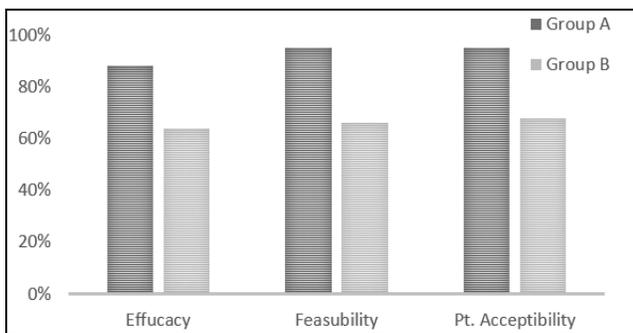


Figure: Comparison of efficacy, feasibility and patient acceptability in both groups.

Procedure acceptability assessed through patient satisfaction was 97% and 70 % in groups A and B, respectively. 6% patients in the MVA group required second follow-up visits. While in the Misoprostol group mean number of visits was 3 ± 1.63. Incidence of complications in both groups is shown in the Table.

Table: Comparison of complications.

| Complications         | (Group-A) n (%) | (Group-B) n (%) |
|-----------------------|-----------------|-----------------|
| Incomplete Evacuation | 6 (6%)          | 18 (18%)        |
| Perforation           | None            | None            |
| infection             | None            | None            |
| Vasovagal Syncope     | 2 (2%)          | None            |
| Nausea/Vomiting       | None            | 11 (11%)        |

**DISCUSSION**

In our hospitals, conventional dilatation and curettage and suction curettage under general anaesthesia is the most commonly offered option to patients with early pregnancy loss. However, there is the risk of anaesthesia and surgery, and exposure to infection by staying in the hospital contributes to maternal morbidity and hospital cost.<sup>5</sup>

MVA involves using a hand held syringe as a source of suction. It can be used for first-trimester miscarriage, missed and incomplete miscarriage, endometrial sampling and following failed medical termination of pregnancy.

The largest study was conducted by Zaidi *et al*, in Pakistan and Bangladesh about the prevailing deteriorating situation regarding abortion. They assessed a significant unmet need for improvement in safe abortion care to achieve sustained development goals.<sup>11</sup> In Pakistan, most healthcare workers and public sector hospital administrators are unaware of changes in legislation (implemented in 1997) permitting pregnancy termination to save women's lives in certain life-threatening medical conditions.<sup>11</sup>

Procedure feasibility in the MVA group was 95% in our study. This is comparable to a study carried out by Kumar *et al*, in Birmingham.<sup>12</sup> The procedure was acceptable to the patients, as 82% reported it as short as expected, while 68% wanted to recommend this procedure to a friend, and the rest would like to opt for the same method again if required in future pregnancy.<sup>12</sup> The procedure was more acceptable to the patients 97% because of single follow-up visits, complete evacuation, and 0% (n=0) need for repeat MVA. MVA is safe and cost-effective with increased convenience and reduced recovery time than other methods for TOP3. Cervical priming where required resulted in safer evacuation, minimizing cervical trauma and reducing the discomfort of cervical dilatation.

No case of uterine perforation was observed in the MVA group. This may be attributed to the soft, flexible and easy to handle cannula used for MVA. MVA is especially valuable in a setting with a shortage of electricity. Office-based management reduces

waiting time, the need for admission to hospital and a sooner return to home due to early mobilization. Complete evacuation in our study in the MVA group was 94%. In comparison, a study by Khalil and Shaheen in 2019,<sup>13</sup> at Cantonment General Hospital Rawalpindi revealed 100% evacuation in the MVA group compared to 82% in the Misoprostol group. The mean number of visits in the MVA group was 1, which was the same as in Khalil *et al*, whereas, in the Misoprostol group, it was 3 in our study compared to 2.8 + 0.837.<sup>13</sup> A study conducted by Tahir and Aamir in Jinnah Medical and Dental College at Karachi in 2018 revealed the efficacy of MVA at 97.1%, and the Misoprostol group was 93.9% in first-trimester in-complete miscarriage, whereas 88% in the MVA group and 64% in Misoprostol group in our study.<sup>14</sup>

A study conducted in 2016 by Chung *et al*, in Prince Wales Hospital Hong Kong revealed ultrasound-guided MVA. With the efficacy of 97.1 %, it was achievable in office settings and was associated with a high degree of patient satisfaction with many advantages over medical management with Misoprostol.<sup>15</sup> After completion of the procedure, the products of conception are collected in a kidney tray. The additional benefit of MVA was obtaining products of the conception of 94.3% for cytogenetic analysis.<sup>16</sup> The conception products are challenging to retrieve in the medical termination group. They have also mentioned that suction curettage damages chorionic villi n reduces culture success rate, so MVA is the best option with the least disruption of villi.<sup>17</sup> Besides cost effectiveness and convenience, outpatient provision of termination of pregnancy facilities is extremely useful in rural areas, where access to established medical facilities is not available.<sup>18</sup>

Careful patient selection and effective counselling can give better results and fewer follow-up visits. Institutions should have Proper training for staff new to the procedure. There should be availability and timely replacement of MVA kits. We must conduct regular audits and get patients' feedback to improve this out-door procedure to reduce the hospital inpatient burden.

## CONCLUSION

Manual vacuum aspiration is more effective than Misoprostol as it has no systemic effects. Both options are cheap and can be achieved in outpatient settings. However, MVA provides complete evacuation and is a good option for low resource settings and a developing country like Pakistan with frequent electricity disruptions. It offers substantial savings in resources, cost and time.

**Conflict of Interest:** None.

## Authors' Contribution

NL: Main author, BZ: Data collection, RQA: SPSS, FS: Article review.

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