Original Article

To Compare the Safety and Efficacy of Manual Vacuum Aspiration with Misoprostol (ST mom) 600mg in Incomplete Miscarriage

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ABSTRACT

OBJECTIVE: To compare the efficacy and safety of manual vacuum aspiration, and oral misoprostol in incomplete miscarriage.
STUDY DESIGN: Comparative randomized controlled trial study.
STUDY SETTING: Department of Obstetrics & Gynaecology (Unit-II) Liaquat University Hospital Hyderabad, Sindh from May 2011 to April 2012.
MATERIAL AND METHOD: All eligible women who full filled the inclusion criteria were included in study after taking written informed consent. A total 222 women were included in study. In each group 111 were randomized either with 600 microgram ST mom or suction evacuation by MVA. Sample was randomized using computer generated random sequence. Opaque sealed study envelop were used for allocation. Primary outcome measure was to assess the efficacy of method in form of complete evacuation. Secondary outcome measure was occurrence of complication.
RESULTS: 111 patients were randomized in each group. Mean age (years), parity and gestational age of study population were 28.4± 5.2, 3± 2 and 8.9± 12. Three patients in misoprostol (ST mom) group complain of pain while in MVA group none of patient complain of pain. So for safety is concern MVA is safer than misoprostol (p-value less than 0.031).
CONCLUSION: Both MVA and misoprostol can be used, as an effective method of uterine evacuation in incomplete abortion of < 12 weeks. MVA is significantly safer than misoprostol in terms of side effects.

KEYWORDS: Manual vacuum aspiration, Misoprostol (ST mom), Pregnancy loss.

INTRODUCTION

Early pregnancy failure is among world's most widely experienced medical conditions. Nearly 20% of clinically recognised pregnancy ends up in miscarriage.[1] Approximately 500,000 mothers die annually in the world, in other words there is one maternal death per minute. It is estimated that out of these 500,000 maternal deaths 100,000-200,000 deaths are related to poorly performed miscarriage. WHO estimate that 10-20 million women risk their lives annually by subjecting themselves to termination of pregnancy[2-3] South Asia (Pakistan, Bangladesh, Nepal, India and Srilanka) comprises 28% of world's population and thirty percent of worlds maternal mortality occur in these four countries. According to WHO thirteen percent of maternal deaths in south Asia are related to induced miscarriage. It is not only mortality but between two to seven million women survive unsafe miscarriage each year, but sustain long term damage or disease like chronic pelvic pain ,pelvic inflammatory disease and infertility.[4] 890,000 of women present with induced miscarriage in Pakistan [5] The reason of such a high-induced abortion rate is multifactorial. Apart from illiteracy, unwanted pregnancies, lack of availability accessibility to contraception and public does not know the change in legal status of abortion. Since 1997, it is recommended by Supreme Court of Pakistan that it is women right to obtain an abortion by her own choice within the first 120 days of pregnancy. It is the legal right of every woman to have safe pregnancy, safe delivery and safe miscarriage. Safe miscarriage can be life saving for women and if performed in unsafe environment leads to maternal injuries and deaths. All these deaths and injuries show social injustice because these all are preventable compare to other main causes of maternal deaths. It become a safe procedure when performed under aseptic measures by qualified health care provider.[6] The standard management of incomplete miscarriage up to the 1990's was the evacuation of retained products of conceptions under general anaesthesia and this management was in practice for the preceding 60-70 years. However currently, there are many options for management of first trimester abortion. These include both

medical and surgical methods. Among options available, in poor countries women can benefit from misoprostol alone or in combination of MVA or from MVA alone. Moreover, both technologies can be used to manage incomplete abortions.

Viewed in this context present study was under taken to compare MVA with misoprostol in first trimester pregnancy loss to know which is more safe and efficient.

MATERIALS AND METHODS

This was a hospital based study and data was collected from May 2011 to April 2012. Subject for study were enrolled from obstetrics and gynecology unit II after taking informed consent. All patients with gestational age less than 12 weeks and incomplete miscarriage were included in the study while patients with induced miscarriage, missed miscarriage and pregnancy more than 12 weeks were excluded from the study. A total of 222 patients with an incomplete miscarriage were included in study. From which 111 were randomized to each group that is MVA or ST mom 600 mg. Diagnosis of incomplete abortion was made on history of gestational amenorrhea of less than 12 weeks with vaginal bleeding and open cervical os on clinical examination Clinical finding were supported by ultrasound. Sample was randomized using computer generated random sequence, treatment was printed on a card and that card was closed in a envelop. Envelops were then sealed and were mixed randomly, then serial numbers were given to envelops from 1 to 222. Eligible women were randomly assigned to one of two treatments. After treatment both groups of patients were observed in hospital for 4-6 hours and patients were advised follow-up visit after seven days. Primary outcome measure was to assess the complete uterine evacuation that is efficacy and secondary outcome included side effects that were fever, pain and hemorrhage. Information was collected on specially designed proforma. Data was entered in SPSS version 14 for analysis. Continuous and categorical variable were compared. Age, parity and gestational age was presented as mean ± standard deviation. Data of categorical variables like presenting complains and efficacy & safety (i.e. pain, bleeding & fever) was presented as proportion or percentages. Chi – square test was applied to compare efficacy between two groups and P-value of < 0.05 was considered statistically significant.

RESULTS

222 patients were included in this study. Mean age of the patients in both groups were 28.4 ± 5.2 years with average 3.0 ± 2.0 parity. The mean gestational age was 8.9 ± 1.7 weeks. Efficacy of MVA was 98.2 % (109) while it was 97.3% (108) in misoprostol group and p-value were 0.65. Safety in MVA group was 95.5% (106) while in misoprostol group was 87.4% (97) and p-value were 0.031 So for pain and bleeding there were no significant difference in both groups (p-values>0.05). But fever were more observed in misoprostol group than in MVA group and it was statistical significant (p-value=0.024). When safety was compared between two groups.

TABLE I: PATIENTS CHARACTERISTICS (n=222)

Characters	Results
Mean ±S.D age	28.4 ± 5.2
Mean ±S.D Parity	3.0 ± 2.0
Gestational age (weeks)	8.9 ± 1.2

TABLE II: COMPARISON OF VARIOUS SAFETY PARAMETERS BY GROUPS (n1=111, n2=111)

Variables	MVA (Group I)	Oral Misoprostol (Group II)	p-value
Pain	0	3 (2.7%)	0.08
Bleeding	5 (4.5%)	6 (5.4%)	0.76
Fever	0	5 (4.5%)	0.024*
Safety	106(95.5%)	97 (87.4%)	0.031*
Efficacy	109(98.2%)	108 (97.3%)	0.65

*Significant

DISCUSSION

Option for women with incomplete miscarriage is expectant medical and surgical. Standard dilatation and evacuation is losing its popularity because of longer hospital stay, procedure under general anaesthesia and over burden on operation list. Two methods that is surgical evacuation with manual vacuum aspiration (MVA) and medical method with misoprostol are in practice for uterine evacuation for incomplete miscarriage for last few decades. Blum proposal for inclusion of misoprostol in WHO list of essential medication has revolutionized care of 15% of women who experience

miscarriage worldwide[8]. Success rate of misoprostol in miscarriage have been reported from 87-97%.[9] However, guideline set forth by royal college of obstetricians and gynaecologist (RCOG) for rating quality of evidence, 600-microgram oral dose of misoprostol has strong evidence base[10]. So for surgical option is concerned WHO has listed MVA as a safe, effective and cheap method for management of miscarriage. Its efficacy in literature has been proved to be up to 98% [11-12] Evacuation of uterus with MVA for incomplete miscarriage under local anaesthesia appears to be feasible and acceptable to women due to short hospital stay and lower cost. Current study proved that there is no significant difference in efficacy of both procedures (p value 0.65), similar were reported by Shwekerela[13] in a study from Tanzania but in contrast to study by Weeks[14] from Uganda in which misoprostol (96%) was more effective than MVA (92%). While in studies by Bano[5] and Bique[15] MVA was 100% effective while misoprostol was 92% and 91%.

Regarding safety of both treatment modalities, present study demonstrates that, women in misoprostol arm experienced more side effects than women in MVA group.(p-value 0.031).In misoprostol, group fever was common and statically significant side effect as compare to MVA counterpart (p-value 0.024). similar were observed by in studies by Bique, week and Shwekerela but it is in contrast to montensionus[16].In present study although bleeding and pain was more common in misoprostol group but both were not statically significant (For bleeding p-value 0.76 and for pain p-value 0.08), it was in contrast to Shwekerala, he reported pain and bleeding as statically significant side effect in MVA group than in misoprostol group but similar to Montensinous, in his study there were no significant difference between two methods, in term of pain and bleeding. (p-value < 0.001).

In present study, both MVA and single dose of 600-microgram oral misoprostol were equally effective for treatment of incomplete miscarriage of less than 12 weeks. Regarding safety of both methods, MVA appeared to be safer than misoprostol.

CONCLUSION

This study concludes that manual vacuum aspiration is as effective as single dose of 600-microgram oral misoprostol but MVA is safer than misoprostol. Patients can be optioned for any of the two procedures after counselling and discussing risk and benefit of both methods.

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