ABSTRACT... Objectives: The aim of this study was to compare the medical treatment with surgical evacuation of uterus in the management of first trimester missed miscarriage. Study Design: Randomized controlled trial. Place and Duration of Study: The study was conducted in the Obstetrics and Gynecology department civil hospital Bahawalpur from 1st January 2014 to 31 December 2014. Material and Methods: Total 120 patients were included in the study diagnosed as a case of first trimester missed abortion. Patients were randomly assigned either medical or surgical group. In the surgical group (controlled group) dilatation and the evacuation was performed. In the medical group misoprostol was used for medical termination. The criteria for success was complete expulsion of products of conception. Results: There was no statistically significant difference regarding demographic and clinical characteristics between the two groups. Complete expulsion of the conceptus was less in medical group (83.3%) than the surgical group (88.3%) but the difference was not significant. Almost 16.7% patients in the medical group had failure of expulsion and underwent surgical evacuation. Duration of bleeding after the procedure was 9±2.6 days in surgical group and 12±3.4 in medical group. Conclusion: Medical termination of first trimester missed miscarriage using Misoprostol (800mcg initial dose followed by 400mcg 4 hourly 3 doses if need) is an efficacious and safe alternative to the surgery.

Key words: Missed abortion, medical treatment, Misoprostol, surgical evacuation.

INTRODUCTION

Early pregnancy failure also known as an-embryonic pregnancy or embryonic/fetal demise complicates 15-20% of all pregnancies. It is characterized by the arrest of the embryonic development, or the death of the embryo/fetus. The cervix is closed and there is no or slight vaginal bleeding. Ultrasound examination shows an empty gestational sac or an embryo/fetus without cardiac activity. Surgical evacuation has been traditionally used for its treatment. It is associated with a 4% -10% rate of hemorrhage, infection, uterine perforation, cervical trauma, impaired fertility, uterine adhesions and complications due to anaesthesia. The successful medical treatment of legal abortion up to 9 weeks of gestation, suggested that the medical treatment can be an alternative for the management of missed abortion. It can improve the patient satisfaction and reduce the complications and cost generated by surgical evacuation. The reported success rate of medical treatment of missed miscarriage has been conflicting. In series of studies success rate of vaginal Misoprostol has been reported up to 90%. However some studies reported lower success rate. These variations may be due to difference in patient selection, dosages and the methods of applications. On the other hand there are some reports about the complications of misoprostol.

Because of the controversial reports about the efficacy and complications of misoprostol and to determine whether the medical treatment of early pregnancy failure represents a reasonable alternative to surgical evacuation, we have designed this study to compare the medical treatment with surgical evacuation of uterus in the management of first trimester missed miscarriage.
MATERIALS AND METHODS
It was a randomized controlled trial. The study was conducted in the Obstetrics and Gynecology department civil hospital Bahawalpur from 1st January 2014 to 31 December 2014. Total 120 patients were included in the study who were diagnosed as a case of missed miscarriage with period of gestation equivalent to 13 weeks or less after counseling. Diagnosis was made on history, examination and ultrasonography. All Patients having the cardiac diseases, asthma, hypersensitivity to prostaglandins, excessive bleeding and dilated cervix were excluded. Patients were randomly assigned either medical or surgical group. In the surgical group (controlled group) dilatation and the evacuation was performed. In the medical group initially 800 mcg misoprostol was placed within the posterior vaginal fornix and as required it was repeated 400ug sublingually every four hours up to 3 doses. During the treatment patients vital signs (pulse, blood pressure, and temperature) were being recorded every 1 hour. Abdominal pain was relived with Nalbuphene or Dicloran intramuscularly and fever with acetaminophen 500mg. In the cases of heavy bleeding during the treatment surgical evacuation was done. The criteria for success was complete expulsion of products of conception which was confirmed on ultrasonography.

If the pregnancy was not completely aborted after 48 hours of initial dose, it was considered as the failure of therapy and surgical evacuation was done but the patient was not included in the surgical group. The complications of the surgical and medical treatment were recorded on data sheet. Patients in each group were discharged the next day and called for follow up after 2 weeks. Patients were asked regarding the severity and duration of bleeding. Statistical analysis was performed.

RESULTS
There was no statistically significant difference regarding demographic and clinical characteristics between the two groups. Most of the patients in both groups were between age group 20 to 30 years with the mean 25 ± 5.8 in Medical group and 25 ± 5.6 in surgical group. (Table-I). The mean period of gestation according to LMP in medical group was 80 ± 17days and 78 ± 15days in surgical group, On the other hand the mean period of gestation according to Ultrasonography (USG) was 52.7 ± 12.4 in medical group and 53.5 ± 14.4 days in surgical group. (Table-I)

Complete expulsion of the conceptus was less in medical group (83.3%) than the surgical group (88.3%) but the difference was not significant. (Table-II) 16.7% patients in the medical group had failure of expulsion and underwent surgical evacuation. 11.7% patients in the surgical group had retained products of conception <1.5cm in anterioposterior diameter and were advised misoprostol in post-operative period. (Table-II) Duration of bleeding was 9±2.6 in surgical group and 12±3.4 in medical group. (Table-III)

The most common complication seen in the studied group was abdominal pain which was seen in 50% patients in misoprostol group and 42% in surgical group. The other side effects seen in medical group were fever, shivering and bleeding but the difference was not significant. Most important complications seen in surgical group were infection (8.3%) and uterine perforation (1 patient, 1.6%). None of patient in both groups needed blood transfusion. (Table-IV)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Surgical therapy</th>
<th>Medical therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Age</td>
<td>25 ± 5.6 (years)</td>
<td>25 ± 5.8 (years)</td>
</tr>
<tr>
<td>2 Gestational age based on LMP</td>
<td>78.5 ± 15 (days)</td>
<td>80.3 ± 17 (days)</td>
</tr>
<tr>
<td>3 Gestational age based on USG</td>
<td>53.5 ± 14.4</td>
<td>52.7 ± 12.4</td>
</tr>
<tr>
<td>4 Abortion history</td>
<td>20</td>
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<td>5 Nulliparity</td>
<td>24</td>
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</tr>
</tbody>
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Table-I. Clinical characteristics of the studied population
DISCUSSION

Miscarriage is the most common complication of pregnancy. Missed miscarriage has been defined as, when the embryo fails to grow or there is death of embryo/fetus. The diagnosis is made on ultrasonography because the patient is usually asymptomatic, however sometime has mild vaginal bleeding. Previously surgical evacuation was being used for its treatment. Recently developments in non-surgical treatment, offer an opportunity to improve management and to remove the need for surgery and anesthesia. Medical management has also been used as an alternative to surgical management. Treatment regimens include the use of the antiprogesterone, mifepristone, and a prostaglandin analogue, the most commonly used of which is misoprostol.10,11 Various randomized controlled trials have compared medical and surgical management.2,12 The success rate reported in the most of them (60-90%) depend on the dosage and frequency of drug administration. The complete abortion rate in our study (83%) is compare able to the study by Beharashi in 2006. (87%) and Creinin et al. (88%) and Zalanyi et al(88%).8,13 Lower success rate reported by Szymanskaet al. (2003).9 As Compared to our study they used 400mcg rather than 800mcg and this difference may be due to this reason. Differences in the initial dose, time interval during drug administration, methods of administration and the criteria for the diagnosis may be the suggested reason for the variation in success rate. Despite the fact that surgical evacuation has more success rate but this difference is not significant statistically as shown in our study as well as the other mentioned studies.8,11,12,13,14 The medical termination has many advantages. It is less invasive even when it fails and the patient need surgical evacuation, the cervix is already dilated and there are less chances of bleeding, pain and uterine perforation. The patients preference is also more for the misoprostol group as the treatment started early (no need for waiting for operation theatre), patient remain awake, less chances of infection and the complications associated with anesthesia are removed.
Although the patients experience more pain and duration of bleeding is also more as compared to surgical evacuation but this pain can be relieved by medication and the bleeding is also mild and the difference in duration is also not significant. (Table-III)

The success rate of medical management of miscarriage quoted in much of the literature is in the region of 80-91%.15-17 Side effects of medical treatment include nausea, vomiting, cramping and diarrhoea. In other studies which compared acceptability of medical versus surgical management of early pregnancy failure, although women in the medical treatment group reported greater pain acceptability was similar between the groups.18-20

Medical treatment is cost effective which is important in the treatment for a developing country like Pakistan.

CONCLUSION
Medical termination of first trimester missed miscarriage using Misoprostol (800mcg initial dose followed by 400mcg 4 hourly 3 doses if need) is an efficacious and safe alternative to the surgery.

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REFERENCES
