A comparative study of single intramuscular injection 15-methyl-PGF$_{2\alpha}$ and intravaginal misoprostol prior to manual vacuum aspiration in first trimester MTP

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To evaluate and compare the effects and complications of single intramuscular injection of 15-methyl-PGF$_{2\alpha}$ / intravaginal misoprostol given 3 hours prior to vacuum aspiration in first trimester MTP with each other and with the control group.
A comparative study of single intramuscular injection 15-methyl-PGF$_{2a}$ and intravaginal misoprostol prior to manual vacuum aspiration in first trimester MTP

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ABSTRACT

AIMS AND OBJECTIVES:
To evaluate and compare the effects and complications of single intramuscular injection of 15-methyl-PGF$_{2a}$/ intravaginal misoprostol given 3 hours prior to vacuum aspiration in first trimester MTP with each other and with the control group.

MATERIAL & METHODS:
150 pregnant women for medical termination of pregnancy with gestation upto 10 weeks were included in the study and were randomly divided into 3 groups: Group I-50 cases were given 125 microgram of injection 15-methyl-PGF$_{2a}$ intramuscularly & Group II-50 cases were inserted 200 microgram of Tab Misoprostol intravaginally, 3 hours prior to vacuum aspiration. Group III-50 cases were taken as control.

RESULTS: The mean cervical dilatation was 6.42 ± 0.64 mm, 6.68 ±0.77 mm and 5.22 ± 0.82 mm in group I, II & III respectively and results were statistically significant

CONCLUSION: Cervical priming followed by suction evacuation should be a method of choice for first trimester abortion.

KEY WORDS: Cervical ripening, misoprostol, 15-methyl-PGF$_{2a}$, MTP

Introduction:
Induced abortion is one of the most common surgical procedures. First trimester surgical abortion is a safe procedure. When performed under 12 weeks gestation the mortality rate is 0.7 per 100,000 procedures and major complication rate is less than 1%. Various surgical methods of termination of pregnancy in first trimester are:  
- Menstrual Regulation.
- Dilatation and Curettage.
- Dilatation and suction evacuation/manual vacuum aspiration (MVA).

Manual vacuum aspiration (MVA) is one of the most commonly used methods for pregnancy termination in first trimester. It is a single most promising procedure that can generate a vast access to safe abortion for women in need throughout the developing world. Cervical dilatation before suction aspiration can be the most difficult part of the abortion procedure for both the patient and the provider. A gentle, adequate and atraumatic cervical dilatation is a crucial step for a successful medical termination of pregnancy during first trimester.
The pharmacological dilatation which closely simulates physiological dilatation is to be preferred over rapid mechanical dilatation. Prostaglandins offer an essential possibility of being used as pharmacological agents to achieve adequate cervical dilatation and softness prior to vacuum aspiration and reduce intraoperative complications. The major action of prostaglandins on cervix is that it softens and dilates the cervix commonly referred to as cervical ripening.

We undertook this study to compare two agents-15methyl PGF2 alpha and intravaginal misoprostol used for cervical ripening in the first trimester abortion.

AIMS AND OBJECTIVES
1) To evaluate the effects and complications of single intramuscular injection of 15methyl PGF2 alpha (Prostodin), given 3 hours prior to vacuum aspiration in the first trimester MTP.
2) To evaluate the effects and complications of intravaginal misoprostol inserted 3 hours prior to vacuum aspiration in the first trimester MTP.
3) To compare the above two groups with each other and with the control group. (Where no pre-treatment was given prior to vacuum aspiration in the first trimester MTP).

MATERIAL AND METHODS
The present study was conducted in the Department of Obstetrics and Gynecology Dayanand Medical College and Hospital, Ludhiana. 150 pregnant women were studied. Informed consent was taken after counseling and patients were randomly divided into 3 groups:
Group I- 50 cases were given 125 microgram of injection Prostodin intramuscularly, 3 hours prior to vacuum aspiration.
Group II- 50 cases were inserted 200 microgram of Tab Misoprostol intravaginal, 3 hours prior to vacuum aspiration.
Group III- 50 were taken as control.

INCLUSION CRITERIA
Patients for medical termination of pregnancy with gestational age upto 10 weeks as calculated from the last menstrual period, irrespective of maternal age or socio-economic status.

EXCLUSION CRITERIA
• Gestational age greater than 10 weeks.
• Known medical disorders like:-
  – Bronchial asthma
  – Cardiac disease
  – Renal disease
  – Pulmonary disease
  – Hepatic disease
  – Epilepsy
• History of hypersensitive reaction to prostaglandins.
• Anaemia (Hb <8gm%)
• Known coagulopathy or on anticoagulants
• History of previous uterine surgery

Method: The detailed general and obstetric history along with general physical, systemic and Bimanual Pelvic examination was done. Investigations included haemoglobin, bleeding and clotting time, ABO&Rh blood grouping (if not known) & urine routine examination. Ultrasonography, if done, was noted. During the study, the patients in group I were given injection prostodin 125 microgram deep intramuscularly in gluteal region and in the patients in group II, tab misoprostol 200 microgram was inserted intravaginally, 3 hours prior to vacuum aspiration. The endeavor was to compare the requirement of mechanical dilatation, complications and blood loss in three groups. Any side effects of the injection Prostodin and vaginal misoprostol prior to evacuation were noted. Vitals of the patients were monitored. After 3 hours, evacuation was done under general anesthesia. Dilatation of cervix was noted with Hegar’s dilator in retrograde fashion. First of all no. 8 Hegar’s dilator was used and was noted whether it could pass the internal os without any resistance. If it did not then progressively lower number dilator was used till it passed without any resistance and number of the dilator was noted. Suction evacuation was done with the help of Karman’s cannula & MR syringe. Bleeding per vaginum was noted. A sterile bowl was taken with gauze spread over it. Products of conception from MR syringe were placed over the gauze, which helped to separate the products of conception from blood. The amount of blood loss was then estimated by the help of syringe. Any other complication was noted.

OBSERVATIONS
Mean age in group I was 30.24 ± 3.51 years, group II was 28.84 ± 3.47 years and in group III was 30.08 ± 4.03 years.
Mean gestational age in group I was 6.89 ± 1.021 weeks, group II was 7.49 ± 1.09 weeks and in group III was 7.03 ± 1.19 weeks. Maximum number of the subjects in all the three groups had gestational age between 6-8 weeks.
Mean parity in group I was 3 ± 0.97, in group II was 2.88 ± 0.77 and 2.96 ± 0.83.
Mean of previous abortions in group I was 0.12 ± 0.44, group II was 0.06 ± 0.24 and group III was 0.22 ± 0.51.
Mean Hb level in group I was 11.32 ± 0.44 gm%, in group II was 11.29 ± 0.58 gm% and 11.30 ± 0.64 gm% in group III.
Uterus size was between 6-10 weeks in 60% subjects in group I, 50% in group II and 48% in group III.
The mean cervical dilatation was 6.42 ± 0.64 mm, 6.68 ±0.77 mm and 5.22 ± 0.82 mm in group I, II & III respectively and results were statistically significant.
The mean blood loss in group I was 5.82 ± 2.69 cc, in group II was 4.50 ± 3.32cc and in group III was 8.82 ± 2.92cc, which were statistically significant.
Side-effects:
  a) 18(36%) in group I, 5(10%) in group II had nausea and vomiting and difference was statistically significant.
  b) 4(8%) in each group I and II had spotting per vaginum.
  c) 11(22%) in group I and 4(8%) in group II had pain abdomen.
DISCUSSION

MTP in first trimester is being taken up as day care, employing of rapid dilatation with dilators followed by evacuation of products of conception by suction. Cervical dilatation can be achieved mechanically or primed by preinsertion of laminaria tents, which have its known infective morbidity.\(^1\) There is evidence to show that rapid mechanical dilatation is associated with both immediate and late complications affecting the outcome of subsequent pregnancies.\(^7\) Pharmacological agents such as prostaglandin analogues can be used for cervical priming in first trimester. In a study conducted by N. Vimala et al (2005)\(^8\) after cervical priming with sublingual misoprostol vs. 15 methyl prostaglandin F2 alpha prior to surgical abortion, the mean cervical dilatation was 8.8 mm ± 1.6 in sublingual misoprostol group as compared to 7 mm ± 1.4 in intramuscular Carboprost group. Side-effects were also more in carboprost group like nausea/vomiting in 20%, abdominal pain in 93.3% and preoperative vaginal bleeding in 80% as compared to 3.3%, 70% and 5.3% respectively in misoprostol group. In a study by Agrawal V. et al (2001)\(^5\) cervical dilatation was easier in the study group after intramuscular injection of Prostodin and cervix was already dilated up to 7-8 mm in 86% cases while in the control group, the cervical dilatation was less than 4 mm in 92% cases. In another study conducted by Kanwal G. et al (2004)\(^7\), cervical dilatation of ≥ 8 mm in case of viable pregnancies was achieved in 69.2% cases after pre-treatment with 400 µg of vaginal misoprostol.

In our study also mean cervical dilatation was more in misoprostol group (6.68±0.77 mm) as compared to Prostodin group (6.42±0.64 mm). 50% cases had cervical dilatation of ≥ 7 mm as compared to 66% in group II and only 2% had cervical dilatation of 7-8 mm in control group. Also side effects were more in group II. Nausea was observed in 36% in group I compared to 10% in group II and pain abdomen was in 22% in group I and in 8% in group II.

SUMMARY AND CONCLUSION

Hence, we conclude that cervical priming with 200 µg vaginal misoprostol or 125 µg of intramuscular injection Prostodin, followed by suction evacuation should be a method of choice, for first trimester abortion. Its high efficacy, simplicity of technique, minimizing the use of mechanical dilator, safety with minimum side-effects and minimum hospitalization, makes it preferred method for termination of pregnancy in the first trimester. The cervical dilatation was easier because the cervix is already dilated and uterus is contracted and hence the blood loss is less. The only distressing factors were pre-operative nausea and vomiting which could be controlled by Metoclopramide.

So, we can conclude that vaginal misoprostol appears to be better option than injection prostodin for cervical priming and meets the basic need for doing MTP as:-

i) It leads to minimal blood loss.

ii) Less adverse effects.

iii) Inexpensive.

iv) Can be stored at room temperature.
### TABLE 1: DISTRIBUTION ACCORDING TO SIDE-EFFECTS

<table>
<thead>
<tr>
<th>Side Effects</th>
<th>Group-I</th>
<th></th>
<th>Group-II</th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Nausea</td>
<td>18</td>
<td>36.00</td>
<td>5</td>
<td>10.00</td>
</tr>
<tr>
<td>Spotting P/V</td>
<td>4</td>
<td>8.00</td>
<td>4</td>
<td>8.00</td>
</tr>
<tr>
<td>Pain Abd</td>
<td>11</td>
<td>22.00</td>
<td>4</td>
<td>8.00</td>
</tr>
</tbody>
</table>

### TABLE 2: DISTRIBUTION OF SUBJECTS ACCORDING TO CERVICAL DILATATION

<table>
<thead>
<tr>
<th>Dilatation (in mm)</th>
<th>Group-I</th>
<th></th>
<th>Group-II</th>
<th></th>
<th>Group-III</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>0.00</td>
<td>0</td>
<td>0.00</td>
<td>11</td>
<td>22.00</td>
</tr>
<tr>
<td>5</td>
<td>4</td>
<td>8.00</td>
<td>4</td>
<td>8.00</td>
<td>18</td>
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</tr>
<tr>
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<td>21</td>
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<td>13</td>
<td>26.00</td>
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<tr>
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<td>25</td>
<td>50.00</td>
<td>28</td>
<td>56.00</td>
<td>1</td>
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</tr>
<tr>
<td>8</td>
<td>0</td>
<td>0.00</td>
<td>5</td>
<td>10.00</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100%</td>
<td>50</td>
<td>100%</td>
<td>50</td>
<td>100%</td>
</tr>
</tbody>
</table>

### TABLE 3: MEAN BLOOD LOSS

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean Blood Loss (in cc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>5.82</td>
</tr>
<tr>
<td>II</td>
<td>4.50</td>
</tr>
<tr>
<td>III</td>
<td>8.82</td>
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### REFERENCES