Mifepristone Induction Prior to Second Trimester Abortion

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Abstract

Objective: To Study the efficacy and safety of prior use of mifepristone before misoprostol use in second trimester abortion considerably reduce the induction abortion interval with lowest possible dose and adverse reaction.

Material & Methods: A Prospective Study was conducted which include 50 patients visiting the antenatal OPD elective for abortions between 13 and 20 week of gestation as per the MTP act. They were randomly divided into two groups of 25 each - the study group received mifepristone 200 mg orally before misoprostol where as the control group was induced with misoprostol alone. The result was analyzed.

Observation: Statistical analysis of the study was done. The induction abortion interval was significantly shorter in the study group, thereby decreasing the side-effect of the drug as well as duration of hospital stay.

Conclusion: This study of offers a reliable, safe and cost effective option by using mifepristone before misoprostol to decrease the induction-abortion interval

Keyword: Mifepristone, Misoprostol, Second Trimester Abortion.

Introduction

In second Trimester abortion, the efficacy of misoprostol has been reported\(^{[1-3]}\). Misoprostol, a synthetic prostaglandin E, is an effective abortifacient and Uterotonic drug. It is used in the first trimester in conjunction with mifepristone (RU-486), orally active antiprogesterone, which has been approved by FDA. Just as in the first trimester, during second trimester pregnancy, this anti progesterone drug blocks, the progesterone receptors, causes estrogen dominance and sensitizes the myometrium to the contraction-inducing activity of prostaglandin\(^{[4]}\). Therefore, if mifepristone is given prior to induction with misoprostol, then there is disruption of pregnancy causing decidual neerosis, myometrial contractions, and cervical softening resulting in earlier and complete second trimester abortion. Though this combination is not currently FDA approved, in certain circumstances, the food and Drug administration Act recognizes that off-label uses of approved products are appropriate, rational
and accepted in medical practice if based on sound scientific evidence[4]. Trial of efficacy and safety of combining mifepristone before in our study we undertook misoprostol use in second trimester abortion to considerably reduce the induction abortion interval with lowest possible dose and adverse reaction.

**Material and Method**

A total 150 case of second trimester abortions took place during the period of 18 Month. June 2017 to December-2018. Out of these 100 cases were spontaneous abortion ie, patient admitted with leaking or bleeding per vaginum or with pain as inevitable abortions. A Prospective study which include 50 patients visiting the antenatal OPD for elective abortions between 13 and 20 weeks of gestation. They were randomly divided in to two groups of 25 each. The criteria for second trimester MTP were as per the medical Termination of pregnancy Act of 1971 revised guidelines. The opinion of two consulting Gynecologists regarding reason for MTP was taken and necessary documentation was followed

**Exclusion Criteria**

1. Intrauterine foetus death
2. Patient with leaking or bleeding per vaginum
3. Previous scar on Uterus
4. Patients with inevitable or incomplete abortion
5. Previously failed MTP with drugs (considered as incomplete abortion)

Prior to Starting the treatment regimen, proper counseling was done, and a written informed consent obtained.

Patient in the study group (Group): 200 mg of mifipristone given is the OPD on day 1 and advised admission on day 3 or as soon as pain or bleeding started. On admission (48 hr.) after mifepristone 400 mg misoprostol was inserted vaginally followed by 200 mcg 6 h till abortion accused. In the control group-2 only misoprostol was instilled vaginally in a similar dose: 400 mcg followed by 200 mcg 6 h till abortion. Patients were monitored regarding onset of contractions, bleeding side-effects like fever and shivering and completion of abortion.

Intravenous antibiotics were administered on admission to all patients after instilling vaginal misoprostol. Check curettage was done post abortion is both the groups as a standard protocol. Inj. Aut-D immunoglobulin (150 mcg) was administered to all those with negative blood group within 72 h of first dose.

**Observation**

1. The age of patients is both groups ranged between 20 and 38 years, the average being 29.5 year.
2. 94% of females from the trial group aborted within 16 h as against 25% in the control group. (Table -1)
3. The mean induction – abortion interval was 8 h 30 min is the study group where as the control group, it was more than. 24 hrs. About 17 patients. (>50%), aborted between 24 h. and 36 h after the first dose. (Table-2)
4. The average dose of misoprostol required in group was 600 mcg, where as in group 2 it was 1600 microgram misoprostol (Table-3)

b. Both the world health organization and RCOG recomaend regimens in which mifipristone in combination with misoprostol offers safest and most-expeditious method to induce abortion in the second trimester
5. The mean duration of hospital stay (in hours) was 32 h in the study group, where as it ranged between 36 and 72 h in control (fig.4)
6. The Mean parity in
   a. Study group 64% were G3 or more, 36% were primis, or with one previous child.
b. Control group 68% were G3 or more, 32% were primis, or with one living issue (fig.5)

7. The mean period of gestation is both the group was between 16 and 17 weeks.
8. The amount of blood lost was directly proportional to the period of gestation. Yet, none of the patients required a blood transfusion. Those patients with pre-op or Post-op Hb<8 g% (total 12 patients) were given intravenous iron sucrose post procedure and discharged on double oral iron therapy for 3 weeks.

The complication noted were
a. Fever (> 2 Spikes till abortion): 10 in study group and 27 in control group.

b. Shivering : 5 in study group and 25 in control and

c. Failure of MTP (failure to abort >24 h. after first dose of misoprostol): None in study group and 18 in control group. However, only 2 patients failed to abort after 48 h of misoprostol alone in which case, prostaglandin PGF2α, was used to complete the procedure.

- The induction– abortion interval was significantly shorter in the study group. There by decreasing the side – effects of the drug as well as duration of hospital stay.

### Table 1 Completion of procedure with drugs versus time

<table>
<thead>
<tr>
<th>Drugs used in Group and Control Group</th>
<th>Time</th>
<th>Percentage %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Group (Mifi and Miso)</td>
<td>Within 16 hr.</td>
<td>94%</td>
</tr>
<tr>
<td>Control Group (Miso alon)</td>
<td>A &gt; 24 hr.</td>
<td>25%</td>
</tr>
<tr>
<td></td>
<td>B between 24 hr –36hr.</td>
<td>50%</td>
</tr>
</tbody>
</table>

### Table 2 Comparing induction – abortion interval in hours

<table>
<thead>
<tr>
<th>Drugs used in Group and Control Group</th>
<th>induction – abortion interval in hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Group (Mifi + Miso)</td>
<td>8 hours 30 min.</td>
</tr>
<tr>
<td>Control Group (only Miso)</td>
<td>24 hrs.</td>
</tr>
</tbody>
</table>

### Table 3 Dose of Misoprostol required

<table>
<thead>
<tr>
<th>Group</th>
<th>Dose of Misoprostol required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study group</td>
<td>600 mcg</td>
</tr>
<tr>
<td>Control Group</td>
<td>1,600 mcg</td>
</tr>
</tbody>
</table>

### Table 4 Duration of Hospital stay in hours in both groups

<table>
<thead>
<tr>
<th>Groups</th>
<th>Duration of hospital stay in hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study</td>
<td>32 h.</td>
</tr>
<tr>
<td>Control</td>
<td>Between 36 – 72 h</td>
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</tbody>
</table>

### Table 5 Gravidity statistics (Study groups)

<table>
<thead>
<tr>
<th>Gravidity</th>
<th>Percentage %</th>
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</thead>
<tbody>
<tr>
<td>Primi or P1</td>
<td>36 %</td>
</tr>
<tr>
<td>P2 or More</td>
<td>64%</td>
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</tbody>
</table>

### Conclusion

The incidence of second trimester abortion has significantly reduced off – late, thanks to the PNDT act. Yet, when the condition does not have a favorable outcome, i.e.) Hazardous to the life of either the foetus or mother the benefit of pregnancy termination outweigh the risk of continuation. This process, rightly known as mini – labour, is not only painful physically, but also impacts psychologically. It is our concern to reduce this stressful period to the shortest, this study, like many others offers a reliable, safe and cost-effective opinion by combining mifipristone before misoprostol to decease the induction abortion interval.

### References


6. Medical Termination of Pregnancy act MTP act (1971) and MTP rule (1972) : Govt. of India.