RECTOR MISOPROSTOL VS 15-METHYL PROSTAGLANDIN F2α FOR THE PREVENTION OF POST PARTUM HEMORRHAGE

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Objectives:
1. To compare the efficacy and side effects of 400µg of rectal misoprostol with intramuscular 125µg PGF2α in prevention of postpartum haemorrhage.
2. To estimate amount of blood loss during the third stage and duration of third stage of labour in both groups.
3. To know and evaluate the safety of the drugs in the management of 3rd stage of labour.

METHODOLOGY:
The present randomized study is to compare the efficacy of intramuscular PGF2α and per rectal misoprostol in the management of third stage of labour to prevent Post partum hemorrhage.
The study was conducted in the Department of Obstetrics and Gynaecology at the teaching hospitals attached namely:
1. Basaveshwar general and teaching hospital
2. Sangmeshwar general and teaching hospital,
Two hundred pregnant women at term with spontaneous onset of labour were included in the study and were randomly divided into 2 groups of 100 women each group A and group B were given per rectal misoprostol (400µg) and intramuscular PGF2α(125µg) respectively at that delivery of anterior shoulder of foetus.
200 cases admitted to the above hospitals who fulfilled the selection criteria were included for the study. The study was conducted from 2009 to 2011.

Exclusion criteria:
All patients in the age group of 19-30 years, period of gestation ranging from 37-40 weeks and gravidity ranging from 1st to 4th gravid, at term with spontaneous onset of labour were included in the study and subjected to vaginal delivery

Statistical analysis of the 2 groups was done.

RESULTS:
Table 1: Amount of Blood Loss in 3rd Stage Of Labour

<table>
<thead>
<tr>
<th>Blood loss (ml)</th>
<th>Misoprostol</th>
<th>PGF2α</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-100</td>
<td>9</td>
<td>38</td>
</tr>
<tr>
<td>101-200</td>
<td>37</td>
<td>51</td>
</tr>
<tr>
<td>201-300</td>
<td>35</td>
<td>3</td>
</tr>
<tr>
<td>301-400</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>401-500</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>501-650</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>236.8 ± 119.9</td>
<td>160 ± 127.5</td>
</tr>
<tr>
<td>Unpaired t test</td>
<td>t = 4.36</td>
<td>P &lt; 0.05, Sig</td>
</tr>
</tbody>
</table>

Graph 5: Amount of blood loss in third stage of labour

Table 2: Average fall in Hb level because of Postpartum Blood Loss

<table>
<thead>
<tr>
<th>Groups</th>
<th>Average fall in Hb (gm/dl)</th>
<th>SD</th>
<th>Significance</th>
</tr>
</thead>
</table>
| Misoprostol| 0.69                        | 0.49| t = 3.40
|            |                             |    | P < 0.05, S  |
| PGF2α      | 0.49                        | 0.31|              |

Graphs-6: Average fall in Hb level because of postpartum blood loss

Table 3: Duration of third stage of Labour in both groups
Table 4: Side Effects of Drugs in Both Groups

<table>
<thead>
<tr>
<th>Side effects</th>
<th>Misoprostol</th>
<th>PGF2α</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>13(6.5%)</td>
<td>26(13%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>4(2%)</td>
<td>7(3.5%)</td>
</tr>
<tr>
<td>Shivering</td>
<td>48(24%)</td>
<td>0</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>36(18%)</td>
<td>0</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>0</td>
<td>12(6%)</td>
</tr>
<tr>
<td>Abdominal cramps</td>
<td>26(13%)</td>
<td>35(17.5%)</td>
</tr>
</tbody>
</table>

Side effects were seen more in group Misoprostol as compared to PGF2α group. In misoprostol group nausea was seen in 6.5% of cases, vomiting in 2% of cases, shivering in 24% of cases, pyrexia in 18% of cases and abdominal cramps in 13% cases.

In PGF2α group nausea was seen in 13% of cases, vomiting in 3.5% of cases and Diarrhea in 12% of cases, Abdominal cramps in 17.5% cases.
DISCUSSION:
Comparative study between intramuscular PGF2α (125µg) and per rectal misoprostol in prophylaxis of PPH done in Department of OBG in MR Medical college showed the following.

Mean duration of third stage of labour (in mins):
In the present study, in misoprostol group, average duration of 3rd stage of labour was found to be 8.03±3.23 mins whereas in PGF2α group it was found shorter, 5.26±1.9 mins

<table>
<thead>
<tr>
<th>Study</th>
<th>Misoprostol</th>
<th>PGF2α</th>
</tr>
</thead>
<tbody>
<tr>
<td>V. Nellore et al.</td>
<td>8.8± 2.8</td>
<td>9.2± 3.2</td>
</tr>
<tr>
<td>Present study</td>
<td>8.03± 3.23</td>
<td>5.26± 1.9</td>
</tr>
</tbody>
</table>

In study by V. Nellore et al.when misoprostol was compared to PGF2α, there was reduction in mean length of third stage from 9.2± 3.2 mins in group in PGF2α to 8.8± 2.8mins in misoprostol group.p value 0.84. In misoprostol group, average duration of III stage of labour was found to be 8.03±3.23 mins whereas in PGF2α group it was found shorter, 5.26±1.9 mins t value is 7.37 with p value of < 0.05, there by suggesting PGF2α causes statistical significant reduction in duration of III stage of labour when compared to per rectal misoprostol.

Mean hemoglobin concentration/Fall in Hb:
In our study average fall in Hb level was 0.69 g/dl in misoprostol group whereas in PGF2α group it was 0.49 g/dl
In the study by V. Nellore et al, There was no significant difference between the 2 groups in mean hemoglobin concentration, whether predelivery or postpartum. In the present study comparison of Hb changes following delivery in both the groups are statistically significant with an average fall in Hb level 0.49gm/dl in PGF2α group and 0.69 gm/dl in misoprostol group. Intergroup comparison applying unpaired t-test shows t = 3.40, p < 0.05 which is statistically significant i.e. intramuscular PGF2α results in significantly lesser reduction in Hb when compared to per rectal misoprostol.

Therefore there is reduced fall in Hb in PGF2α group is statistically significant when compared to Misoprost.

Mean blood loss (in ml):
In the present study, distribution of blood loss in the two groups showed mean blood loss of 160.6 ± 127.5ml in to PGF2α group, while in misoprostol group it was 236.8 ± 119.9ml.

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<th>PGF2α</th>
</tr>
</thead>
<tbody>
<tr>
<td>V. Nellore et al</td>
<td>245± 158</td>
<td>205± 175</td>
</tr>
<tr>
<td>Present study</td>
<td>236.8 ± 119.9</td>
<td>160.6 ± 127.5</td>
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Side effects:
In a similar study by V. Nellore et al. Five women in the misoprostol group experienced shivering, but none in the 15-methyl prostaglandin F2α group. (P = .06) Gastrointestinal adverse effects, such as nausea, vomiting, and diarrhea, were significantly higher in the 15-methyl prostaglandin F2α group than in the misoprostol group (11 vs. 3, P = .01s). 15-methyl prostaglandin F2α group than in the misoprostol group (11 vs. 3, P = .01s).

In the present study incidence of side effects like nausea (6.5%) and vomitifig (2%) & diarrhea was less in misoprostol group as compared to PGF2α group. In to PGF2α group incidence of nausea was 13% and vomiting 3.5%. Shivering was seen only in misoprostol group i.e. 24%. Incidence of pyrexia was found only in misoprostol group which was 18% Abdominal cramps were seen in 13% in misoprostol group &17.5% in PGF2α group.

CONCLUSION:
Where maternal mortality is high and resources are limited, the introduction of low cost evidence based practices to prevent and manage post partum haemorrhage can improve maternal and infant survival. Hence prophylactic aspect to reduce the incidence of complications in third stage is very important. This comparative study between intramuscular PGF2α(125µg) and per rectal misoprostol in prophylaxis of PPH done in Department of OBG in MR Medical college showed that intramuscular PGF2α(125µg) when used results in lower blood loss, more effective reduction in duration of third stage of labour, significantly lesser reduction in Hb level after delivery but is associated with unpleasant side effects like nausea, vomiting. PPH was seen in lesser number of cases as compared to misoprostol group, and risk of retained placenta was same in both the groups.

Per rectal misoprostol, inexpensive and does not need refrigeration is safe but side effects were comparatively more in misoprostol and is relatively less effective in preventing blood loss, results in higher fall of Hb level with greater number of cases requiring blood transfusion (8 cases as compared to 7 in PGF2α(125µg) group) and required additional oxytocics with a higher frequency, evidence of retained placenta was same 0.5% in both groups. Hence a cafeteria approach is required in usage of these drugs in general in reducing post partum haemorrhage and thereby maternal morbidity and mortality.

REFERENCES
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29. Fraser DM, Cooper MA. Physiology and management of the third stage of labour in Myles textbook for midwives. 14th edn. China, Churchill Livingstone; p. 507-530.