Effect of Topical Administration of Tranexamic Acid in Reducing Post-Operative Bleeding after Off-Pump Coronary Artery Bypass Surgery-A Single Center Experience

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Abstract:

Background: This study was designed to assess the role of topically applied tranexamic acid in pericardial cavity in reducing post operative bleeding.

Methods: This study is a non-randomized, double blinded, clinical trial, conducted in the Department of Cardiac Surgery, National Institute of Cardiovascular Diseases from January 2014 to December 2015 among the patients admitted for off pump coronary artery bypass (OPCAB) surgery. A total of 60 patients were recruited for the study and they were divided in two groups- 30 patients in tranexamic acid group (Group I) and 30 patients in placebo group (Group II). On completion of the grafting, before closure of the sternum tranexamic acid (2.5 g/25 ml) or placebo (25 ml of saline) diluted in 100 ml of warm saline (37 °C) was instilled into the pericardial cavity including the mediastinal tissues and left for 5 minutes. Total mediastinal bleeding and packed red cell transfusion were estimated in the postoperative period in both groups.

Results: There was no significant difference noted in baseline demographic data, basic clinical characteristics and preoperative coagulation profile between the 2 groups (P > 0.05). Total mediastinal bleeding and packed red cell transfusion in group I and group II patients was 421.67±70.32 vs 593.33±77.38ml, p<0.001 and 0.87±0.0.73 units vs1.77±0.57 units, p<0.001. No patient required reoperation for bleeding and there was no incidence of myocardial infarction (MI), thrombo-embolism, deep venous thrombosis (DVT) or stroke in none of the patients in either group.

Conclusion: Topical application of tranexamic acid can significantly and safely reduce postoperative mediastinal bleeding. It also reduces whole blood transfusion requirements during immediate postoperative period among patients undergoing OPCAB surgery.

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Keywords:
Coronary artery disease, Blood transfusion, Coronary artery bypass, Tranexamic acid, Haemorrhage.

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application of tranexamic acid in the pericardial cavity on post-operative blood loss in off-pump CABG.

Methods:
This study is a non-randomized, double blinded, clinical trial, conducted in the department of cardiac surgery, National Institute of Cardiovascular Diseases from January 2014 to December 2015 among the patients admitted for OPCAB surgery. A total 60 number of patients were enrolled for the study. They were randomly assigned in two groups-30 patients in tranexamic acid group (Group I) and 30 patients in placebo group (Group II). On completion of the grafting, before closure of the sternum tranexamic acid (2.5 g/25 ml) or placebo (25 ml of saline) diluted in 100 ml of warm saline (37 °C) was instilled into the pericardial cavity including the mediastinal tissues and left for 5 minutes. Then it was cleared out and sternum was closed. Data were collected using case record collection form from patient’s admission up to the discharge of the patient from ICU. Statistical analysis was done using SPSS version 17.0 software.

There was no significant difference noted in baseline demographic data, basic clinical characteristics and preoperative coagulation profile between the 2 groups (P>0.05). All patients were pre-medicated with tablet midazolam 7.5 mg orally the night before surgery. Injection Morphine sulphate 7.5 mg intramuscularly (I.M.) and tablet Metoprolol 25 mg per orally were given 1 hour before surgery. Standard anesthetic technique including induction, maintenance and recovery were being followed. A median sternotomy was done and at the same time Great saphenous vein and Internal mammary artery was harvested and prepared for the graft. The distal anastomosis with reverse saphenous venous graft was done with partial clamp of aorta. The drainage of the chest tubes were measured hourly and were removed when the total drainage volume of < 50 ml over the previous 12 hours and of serous color. Uniform transfusion protocol was applied to all patients. Blood and blood components were administered only when the hematocrit level < 24% or the haemoglobin level < 8.0 gm/dl in the postoperative period.

Results:
Both groups were compared according to their preoperative clinical and demographical characteristics and there were no significant statistical differences found between them. Similarly, there was no statistically significant difference among the two groups in preoperative hematological characteristics in terms of haematocrit, platelet count, INR, bleeding time and clotting time Table II (41.8±2.34 vs. 41.27±2.42%, p= 0.389; 237.5±35.05 vs. 254±37.84 x10⁹/cmm, p=0.085; 1.05±0.08 vs. 1.05±0.1 sec, p= 0.838; 4.24±0.48 vs. 4.24±0.5 min, p=0.965 and 5.89±0.42 vs. 5.88±0.41 min, p=0.958 respectively).

Average amount of bleeding at 4 hours post operatively was 116.67±44.2 ml in tranexamic acid group and 190±44.33 ml in placebo group (p<0.01). Post operative mediastinal bleeding at 12 hours and at the end of chest tube removal were also significantly higher in placebo group than the study group (345±74.68 vs. 511.67±66.54 ml, p<0.01) and (421.67±70.32 vs. 593.33±77.38 ml, p<0.01) respectively. The average number of units of whole blood transfusion post operatively in study group and control group was 0.87±0.73 units and 1.77±0.57 units respectively (p<0.001). (1 unit= about 450 ml). Although regarding transfusion of fresh frozen plasma (FFP), both the groups did not have significant difference (Group 1: 0.93±0.9 vs. group 2: 1.2±0.76; p=0.22). No patient required reoperation

### Table-I

<table>
<thead>
<tr>
<th>Investigation profile</th>
<th>Group of the patient</th>
<th>Total</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group I (n=30)</td>
<td>Group II (n=30)</td>
<td></td>
</tr>
<tr>
<td>Haematocrit (%)</td>
<td>41.8±2.34</td>
<td>41.27±2.42</td>
<td>41.53±2.38</td>
</tr>
<tr>
<td>Platelet count (x10⁹/cmm)</td>
<td>237.5±35.05</td>
<td>254.0±37.84</td>
<td>245.75±37.11</td>
</tr>
<tr>
<td>INR</td>
<td>1.05±0.08</td>
<td>1.05±0.1</td>
<td>1.05±0.09</td>
</tr>
<tr>
<td>Bleeding time (min)</td>
<td>4.24±0.48</td>
<td>4.24±0.5</td>
<td>4.24±0.49</td>
</tr>
<tr>
<td>Clotting time (min)</td>
<td>5.89±0.42</td>
<td>5.88±0.41</td>
<td>5.89±0.41</td>
</tr>
</tbody>
</table>

Data were analyzed using Student’s t-Test and presented as mean ± SD.
Table-II

Distribution of the patients according to Postoperative bleeding

<table>
<thead>
<tr>
<th>Postoperative mediastinal bleeding</th>
<th>Group I (n=30)</th>
<th>Group II (n=30)</th>
<th>Total p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 4 hours (ml)</td>
<td>116.67±44.2</td>
<td>190±44.33</td>
<td>153.33±57.39</td>
</tr>
<tr>
<td>At 12 hours (ml)</td>
<td>345.00±74.68</td>
<td>511.67±66.54</td>
<td>428.33±109.45</td>
</tr>
<tr>
<td>Total bleeding (ml)</td>
<td>421.67±70.32</td>
<td>593.33±77.38</td>
<td>507.5±113.43</td>
</tr>
</tbody>
</table>

Data were analyzed using Student’s t-Test and presented as mean ± SD

Table-III

Distribution of the patients according to postoperative transfusion

<table>
<thead>
<tr>
<th>Blood &amp; blood products</th>
<th>Group I (n=30)</th>
<th>Group II (n=30)</th>
<th>Total p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood transfusion (units)</td>
<td>0.87±0.73</td>
<td>1.77±0.57</td>
<td>1.32±0.79</td>
</tr>
<tr>
<td>FFP (units)</td>
<td>0.93±0.9</td>
<td>1.2±0.76</td>
<td>1.07±0.84</td>
</tr>
</tbody>
</table>

Data were analyzed using Student’s t-Test and presented as mean ± SD

for bleeding. There was no incidence of MI, thromboembolism, DVT or stroke.

Discussion:

In our study postoperative mediastinal bleeding at 4 hours, 12 hours in group I and group II patients were 116.67±44.2 ml vs. 190±44.33 ml (p = 0.000), 345±74.68 ml vs. 511.67±66.54 ml (p = 0.000) respectively. Total postoperative mediastinal bleeding was also significantly lower in tranexamic acid group than in placebo group (421.67±70.32 vs. 593.33±77.38 ml; p = 0.000).

Baric and his colleagues reported cumulative blood loss within 24 h 633±343 ml in tranexamic acid group and 903±733 ml in placebo group. This study included patients undergoing coronary surgery, valve surgery and other cardiac surgeries. The tranexamic acid group received 2.5 gm tranexamic acid in 250 ml normal saline and the other group received 250 ml of normal saline in the pericardial cavity and over the mediastinal tissue before median sternotomy closure.  

Hossein and his colleagues reported to enroll 71 patients in prospective study and grouped patients into two groups. In tranexamic acid group median of postoperative bleeding at the end of 24 hours was 366 ml in comparison to 788 ml in placebo group bearing significant difference. Though he used lower amount of tranexamic acid (1 gm) in his study.  

Nouraei and his colleagues reported total blood loss in Tranexamic acid group to be 313±173 ml and 454±268 ml in control group (p<0.01). In the study tranexamic acid (2 g/20 mL) or placebo (20 mL of saline) was diluted in 500 mL of warm saline (37 °C), poured into the pericardial cavity, and left for 5 min on completion of CABG (on pump) before sternotomy wound closure. The volume of blood loss were similar to our study.  

Aoki and his colleagues reported that the volume of blood loss in 24 h after intensive care unit admission was 492±180 ml in control group and 303±112 ml in tranexamic acid group (p<0.0001). They investigated 100 consecutive patients undergoing off-pump coronary artery bypass. In the study group 10 mL of a solution containing 1 g of tranexamic acid was sprayed into the pericardial cavity and mediastinum before the sternum was closed. Our study showed similar volume of blood loss.

Conclusion:

The result of this study allows us to conclude that the topical application of tranexamic acid leads to reduction of blood loss after off-pump CABG procedure. In addition it decreases whole blood transfusion requirement after CABG surgery.

Conflict of Interest - None.

References:


