Postoperative bleeding – two different ways to calculate Heparin and Protamine dosages.

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Background

• Postoperative bleeding is one of the most common complications after open heart surgery.

• Heparin is used for patients undergoing open heart surgery during cardio- pulmonary bypass (CBP) and Protamine is given to reverse the Heparin effect.

• Studies have shown that a more accurate dosage of Heparin and Protamine, will reduce the postoperative drainage of blood.

Aim of the study

1. Can postoperative bleeding and blood transfusions be reduced by using Heparin/Protamin titration system HEMOCHRON® RxDx® Response.

2. Are the dosage of Heparin and Protamine given less using the HEMOCHRON® RxDx® method, compared with the local guideline of Odense University Hospital (OUH).

Preliminary procedure

• Application and protocol to the Ethical Committee

• Application for using patient data to the Danish Data Protection Agency

• Instructing the anaesthesiologists

• Instructing the surgeons

Inclusion Criteria

• Patient’s undergoing open heart surgery using CBP
Exclusion Criteria

- Emergency surgery
- Informed consent not obtained
- Jehovah's Witness

Assurance for continuity

- CPB: Jostra HL 20, with Quadrox (Maquet) upset
- Activat Clotting Time (ACT) was measured using HEMOCHRON® RxDx® Respons machine no. 3
- One person taking all samples and shaking the tubes

Methods

51 patients were included.

Group 1 (Test group).
Hemocron® RxDx® Respons.

Group 2 (Control group).
Local guideline of the OUH standard method.

24 patients in group 1
27 patients in group 2
Randomization was performed using: www.randomize.dk.

Randomization

Group 1 = Testgroup = RxDx

- Patients got Heparin- og Protamin dose, calculated on HEMOCHRON® RxDx® Respons.
Gruppe 2 = Control Group

The local guideline of OUH standard method:
Heparin dose is calculated based on the patients weight (3,0 mg/kg). (+ 50% if the patient was treated with Fragmin).
Heparin was reversed with Protamine 150-200 mg (depending on the Heparin dose and final ACT)

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Patient data

<table>
<thead>
<tr>
<th></th>
<th>Test group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female / male</td>
<td>13 / 11</td>
<td>9 / 18</td>
</tr>
<tr>
<td>Age</td>
<td>66 (39-82) years</td>
<td>66 (39-80) years</td>
</tr>
<tr>
<td>Weight</td>
<td>74 (52-116) kg.</td>
<td>80 (52-101) kg.</td>
</tr>
</tbody>
</table>

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CPB data

<table>
<thead>
<tr>
<th></th>
<th>Test group</th>
<th>Control group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of Operation</td>
<td>1:46 (0:53-3:17) t:mm</td>
<td>2:07 (0:55-4:51) t:mm</td>
<td>0.2129</td>
</tr>
<tr>
<td>Cross clamp time</td>
<td>1:18 (0:32-2:46) hours</td>
<td>1:29 (0:27-2:51) hours</td>
<td>0.2068</td>
</tr>
<tr>
<td>Initial Heparin</td>
<td>5.2 (2.7-8.0) ml.</td>
<td>5.6 (3.2-9.0) ml.</td>
<td>0.2454</td>
</tr>
<tr>
<td>Additional Heparin</td>
<td>1.3 (0.0-6.0) ml.</td>
<td>2.0 (0.0-5.0) ml.</td>
<td>0.0406</td>
</tr>
<tr>
<td>Heparin total</td>
<td>6.5 (3.2-14.0) ml.</td>
<td>7.6 (4.6-10.8) ml.</td>
<td>0.0272</td>
</tr>
<tr>
<td>Protamine total</td>
<td>18.2 (8.2-32.4) ml.</td>
<td>25.4 (20.0-45.0) ml.</td>
<td>0.0005</td>
</tr>
</tbody>
</table>

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Heparin total

Hep_total
Standard RxDx
group
Protamine total

Postoperative VITA data

<table>
<thead>
<tr>
<th></th>
<th>Test group</th>
<th>Control group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding</td>
<td>770.0 (125-2250) mL</td>
<td>779.0 (220-1930) mL</td>
<td>0.5522</td>
</tr>
<tr>
<td>Blood products total</td>
<td>571.0 (0-3279) mL</td>
<td>690.0 (0-4948) mL</td>
<td>0.6228</td>
</tr>
<tr>
<td>Drain removal</td>
<td>13:24 (6:00-28:13) t:mm</td>
<td>13:53 (6:05-24:27) t:mm</td>
<td>0.7199</td>
</tr>
</tbody>
</table>

Blood Products by sex

<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Products</td>
<td>775.6 (0-4948) mL</td>
<td>368.6 (0-2418) mL</td>
</tr>
</tbody>
</table>

Conclusion

- Less total Heparin is given using the HEMOCHRON® RxDx ® method; \( p = 0.0272 \)
- Less Protamine is given using the HEMOCHRON® RxDx ® method; \( p = 0.0005 \).
- There is no significant difference in bleeding postoperatively, the total amount of blood products given and time to drain removal.
- There is a trend towards giving more blood to women than to men.