The laboratory assessment of a new hemostat able to clot blood containing anticoagulants

Lee Johnson, Paul Luksch, Jonathan Ranfield, & Craig Hardy, MedTrade Products Ltd, Crewe, UK (www.medtrade.co.uk)

Assessment of Clotting

Experiment 1 – Freshly drawn blood

The blood clotting time was tested in the laboratory using freshly drawn rabbit blood. 1g of the CX was added to 7ml of rabbit blood and the combination repeatedly rotated 180º back and forth approximately once per 1.5 secs. This agitation ensured good mixing. The time when the blood was fully clotted was recorded. The clots were removed from the test tube and photographed at 20 minutes. Figure 1 gives the clotting times for both the treatment group and the control. Photographs of the clots are shown in figure 2.

The new agent massively reduced the clotting time of freshly drawn rabbit blood. The resulting clots were substantially different in nature. The clot formed with the CX was easy to reshape initially and became more rigid with time.

<table>
<thead>
<tr>
<th>Clotting time (seconds)</th>
<th>CX</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>26</td>
<td>1020</td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>840</td>
<td></td>
</tr>
<tr>
<td>32</td>
<td>806</td>
<td></td>
</tr>
<tr>
<td>36</td>
<td>600</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>30.5</td>
<td>816.5</td>
</tr>
<tr>
<td>Std Dev</td>
<td>4.4</td>
<td>149.1</td>
</tr>
</tbody>
</table>

Fig. 1: Fresh rabbit blood clotting times.

Experiment 2 – Heparinised blood

Blood was drawn from a rabbit and a dose of 90.9usp per ml of heparin was added. As previously 1g of CX was added to 7ml of this blood and the combination rotated back and forth to ensure mixing. The time when the blood was fully clotted was recorded. Figure 3 shows a graph of the clotting times. As would be expected the addition of heparin inhibited the clotting of the rabbit blood. The control blood did not clot within the time of the experiment. However CX clotted blood containing heparin in an average clotting time of 48 seconds.

Fig. 3: Heparinised rabbit blood clotting times.

Experiment 3 – The effects of Coumadin (sodium warfarin)

Prior to treatment with sodium warfarin, the prethrombin time (PT) of the rabbits were tested and gave an average PT of 6.8 secs. The rabbits were received a 0.5mg/kg dose of sodium warfarin for 3 days, the dose was then increased to 1mg/kg for a further 2 days. On day five, PT was retested and had increased to an average 22.0 secs. A control animal was kept in identical conditions but received no sodium warfarin. On Day 5 the control animal had an average PT of 6.9 seconds.

Blood clot testing was completed as in Exp. 1 & 2. Figure 4 shows a graph of the clotting times. Sodium warfarin is know to increase clotting time. This was confirmed in this test with a three fold increase in prethrombin times.

The blood from the dosed rabbits clotted in an average of 1476 secs, however when 1g of CX was added clotting times were reduced dramatically to less than 30 seconds.

Fig. 4: Clotting times rabbits dosed with sodium warfarin

Conclusions

The assessment of the ability of CX to clot rabbit blood has shown that it will clot fresh blood very quickly and that it's action is largely unaffected by the presence of heparin or sodium warfarin.

With this profile, the new clotting agent is believed to work independently of the bodies normal clotting mechanisms.

CX shows great potential to assist clinicians both in speeding normally clotting blood but also in treating bleeding of patients with abnormal clotting.

This agent has a FDA 510k.

It warrants clinical assessment.

References:

Agent CX – Agent CX is Celox granular hemostat. www.celoxmedical.com

From the 21st Annual Symposium on Advanced Wound Care and the Wound Healing Society. April 24th – 27th 2008 San Diego

For further information, please contact: Medtrade Products Limited

Electra House, Crewe Business Park, Crewe, Cheshire, UK. CW1 6GL

Tel: (44) 1270 500019 Fax: (44) 1270 500045 Email: sales@medtradeproducts.co.uk