CONCISE REPORT

Pennsylvania State-Wide Hemophilia Program: Summary of Immediate Reactions With the Use of Factor VIII and Factor IX Concentrate

By David Prager, Isaac Djerassi, M. Elaine Eyster, Frances M. Gill, Nehdi K. Kajani, Jessica H. Lewis, Charles Lusch, Samuel Rice, and Sandor S. Shapiro

SINCE September, 1977, the Pennsylvania statewide hemophilia centers have recorded data concerning immediate reactions occurring after administration of commercial factor VIII and factor IX concentrates. This communication reports the frequencies and types of the immediate reactions caused by these concentrates. Generally, there were two broad types of immediate reactions (Table 1): allergic and nonspecific. The allergic reaction usually consisted of one or more of the following signs or symptoms: excessive lacrimation, periorbital edema, generalized warm sensation, rhinitis, and urticaria. The nonspecific reactions consisted of variable subjective complaints such as dizziness, "coldness in the back of the throat," headache, and shortness of breath. All reactions occurred either during

<table>
<thead>
<tr>
<th>Treatment Center</th>
<th>Factor VIII Concentrate (Reactions/Total Units)</th>
<th>Factor IX Concentrate (Reactions/Total Units)</th>
<th>Type of Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4/1,326,039</td>
<td>0/15,720</td>
<td>Lacrimation, headache, dizziness, rhinitis postinfusion (factor VIII)</td>
</tr>
<tr>
<td>2</td>
<td>0/493,003</td>
<td>0/199,000</td>
<td>Headache, rash, conjunctivitis postinfusion (factor VIII)</td>
</tr>
<tr>
<td>3</td>
<td>2/1,182,320</td>
<td>0/71,000</td>
<td>Hot flashes, headache, dizziness, ear pressure postinfusion (factor VIII)</td>
</tr>
<tr>
<td>4</td>
<td>2/1,929,564</td>
<td>0/352,200</td>
<td>Shortness of breath postinfusion (factor VIII)</td>
</tr>
<tr>
<td>5</td>
<td>1/1,878,078</td>
<td>0/829,123</td>
<td>None used</td>
</tr>
<tr>
<td>6</td>
<td>0/1,015,389</td>
<td>0/498,700</td>
<td>Urticaria and periorbital edema postinfusion (factor IX)</td>
</tr>
<tr>
<td>7</td>
<td>0/4,401,191</td>
<td>2/1,150,790</td>
<td>None used</td>
</tr>
<tr>
<td>8</td>
<td>0/3,040,836</td>
<td>0/47,500</td>
<td>None used</td>
</tr>
<tr>
<td>9</td>
<td>0/682,510</td>
<td>2/3,161,033</td>
<td>None used</td>
</tr>
<tr>
<td>Totals</td>
<td>9/15,948,930</td>
<td>2/3,161,033</td>
<td>None used</td>
</tr>
</tbody>
</table>

From the Allentown Hospital, Allentown, Pa., the Mercy Catholic Medical Center, Philadelphia, Pa., the Department of Medicine, Milton S. Hershey Medical Center, Pennsylvania State University, Hershey, Pa., the Children's Hospital of Philadelphia, University of Pennsylvania School of Medicine, Philadelphia, Pa., the Einstein Medical Center, Philadelphia, Pa., the Central Blood Bank of Pittsburgh, Pittsburgh, Pa., the Reading Hospital, Reading, Pa., St. Joseph's Hospital, Lancaster, Pa., and the Cardeza Foundation, Jefferson Medical College, Philadelphia, Pa.

Submitted December 20, 1978; accepted January 10, 1979.

Supported by Pennsylvania Department of Health Contract 491907.

Address reprint requests to David Prager, M.D., 1730 Chew Street, Allentown, Pa. 18104.

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Blood, Vol. 53, No. 5 (May), 1979
REACTIONS WITH COAGULATION CONCENTRATES

infusion of the concentrate or within 5 min after infusion. Only the allergic-type
reactions were noted with factor IX concentrate.

Factor VIII concentrate was supplied by six different pharmaceutical compa-
nies. There was no relationship between the product source and the frequency of
any immediate reaction. Factor IX concentrate was supplied by two commercial
sources; again, no difference was noted between these two commercial sources. No
anaphylactic reactions or deaths occurred as a result of such concentrate usage.

In summary, the immediate reaction rates to factor VIII and factor IX
concentrates have been 9 reactions per 15,948,930 units and 2 reactions per
3,161,033 units, respectively. It appears that the risk of an immediate reaction with
currently available factor VIII or factor IX concentrate is remote. These data
should not be confused with the risk associated with the delayed effects of
concentrate, namely hepatitis.
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