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Reactogenicity of a combined hepatitis A and hepatitis B vaccine in healthy Indian children and adults

A post-marketing surveillance study was done in India to assess the reactogenicity and safety of combined hepatitis A and B vaccine, Twinrix™ (GlaxoSmithKline Biologicals®) (commercially available in India since 2002), when used in routine clinical practice as per Indian prescribing information. The study protocol was approved by the regulatory authorities and appropriate ethical review committees and conducted in accordance with ICH-GCP guidelines.

Three hundred and fifty subjects were recruited to receive three doses of the vaccine intramuscularly at 0, 1, 6 months. Seventy-four subjects aged 1-5 years and 113 aged > 5 to 15 years received the pediatric dose (Twinrix™ Junior) containing not less than 360 ELISA Units (EL.U) of inactivated hepatitis A virus (HAV) and 10 µg of recombinant hepatitis B surface antigen (HBsAg) protein. Subjects above the age of 16 years (n=163) received the adult dose (Twinrix™ Adult), containing not less than 720 EL.U of inactivated hepatitis A virus and 20 µg of recombinant HBsAg protein.

Data for solicited local and general symptoms were collected prospectively using diary cards during a 4-day period following each dose. Data on any other symptoms were collected at subsequent visits during subject interviews, and occurrence of all serious adverse events (SAEs), or pregnancies were recorded throughout the study period.

The mean (SD) ages of the subjects in the three age groups were 2.4 (1.1) years, 9.8 (2.8) years and 33.8 (10.8) years, respectively. Five subjects experienced SAEs, including one death (due to suicidal ingestion of rat poison) during the study period. None of these SAEs were related to vaccination.

Pain at the injection site was the most frequently reported solicited local symptom (Table). Under 5.5% of doses in each age group were followed by solicited general symptoms. Solicited symptoms (local and general) of severe intensity (i.e., preventing normal, everyday activities) were reported after less than 1% of doses in each group. No subjects in either group reported severe symptoms that were causally related to vaccination. Severe unsolicited symptoms were reported following 6 (1.2%) doses in the ≥16 years age group; none were considered as causally related to vaccination. Severe unsolicited symptoms were not reported by subjects in other age groups.

The study showed that the reactogenicity of the combined hepatitis A and B vaccine was low and simi-

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### Table: Incidence of symptoms reported during the 4-day follow-up period after vaccination

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Age group</th>
<th>Intensity</th>
<th>n (%)&lt;br&gt;(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1-5 y (N = 74)</td>
<td>&gt;5-15 y (N = 113)</td>
<td>≥16 y (N = 163)</td>
</tr>
<tr>
<td><strong>Solicited local symptoms</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>All</td>
<td>37 (16.7)</td>
<td>69 (20.4)</td>
</tr>
<tr>
<td></td>
<td>Related</td>
<td>(12.0-22.2)</td>
<td>(16.2-25.1)</td>
</tr>
<tr>
<td>Redness</td>
<td>All</td>
<td>6 (2.7)</td>
<td>22 (6.5)</td>
</tr>
<tr>
<td></td>
<td>Related</td>
<td>(1.0-5.8)</td>
<td>(4.1-9.7)</td>
</tr>
<tr>
<td>Swelling</td>
<td>All</td>
<td>4 (1.8)</td>
<td>14 (4.1)</td>
</tr>
<tr>
<td></td>
<td>Related</td>
<td>(0.5-4.5)</td>
<td>(2.3-6.9)</td>
</tr>
<tr>
<td><strong>Solicited general symptoms</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drowsiness</td>
<td>All</td>
<td>4 (1.8)</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td></td>
<td>Related</td>
<td>2 (0.9)</td>
<td>1 (0.1-3.2)</td>
</tr>
<tr>
<td>Irritability</td>
<td>All</td>
<td>8 (3.6)</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td></td>
<td>Related</td>
<td>1 (0.3)</td>
<td>2 (0.1-3.2)</td>
</tr>
<tr>
<td>Loss of appetite</td>
<td>All</td>
<td>8 (3.6)</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td></td>
<td>Related</td>
<td>1 (0.3)</td>
<td>2 (0.1-3.2)</td>
</tr>
<tr>
<td>Fever*</td>
<td>All</td>
<td>8 (3.6)</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td></td>
<td>Related</td>
<td>1 (0.3)</td>
<td>2 (0.1-3.2)</td>
</tr>
</tbody>
</table>

All values are as n (%; LL - UL of 95% CI)

N: number of documented doses; n (%): number (percent)-age of doses followed by at least one type of symptom CI: confidence interval; All: Incidence of symptoms irrespective of intensity or relationship; Related: symptoms considered by the investigator to have a causal relationship to vaccination. *Fever: axillary/oral temperature >37.5 °C

Similar to that observed in studies conducted previously in India and elsewhere with only a few adverse events in all the age groups, indicating good tolerance of the vaccine. The safety profile of this vaccine was comparable to that observed with that of concomitant administration of monovalent hepatitis A and hepatitis B vaccines.

Hepatitis B vaccine is recommended by the WHO as a vaccine which should be included in the Expanded Programme of Immunisations for all infants, to safeguard against the possibility of vertical transmission, while the increasing importance of hepatitis A in the developing world has found leading local experts calling for its wider use. Combined vaccination (offering a catch-up opportunity for anyone who has not previ-
ously received hepatitis A and hepatitis B vaccination) could increase protection against both viral infections for all individuals from the second year of life, without unduly increasing the workload of practitioners and number of clinic visits required. Combination vaccines offer more convenience, potentially better compliance and have often been found to be more economical when considering other associated costs and may enhance protection of the community, by facilitating the introduction of new antigens. In this case, since neither specific hepatitis A and hepatitis B vaccine component of this combination vaccine requires further boosting, 3 doses of the study vaccine could provide lifelong protection against vaccine-preventable viral hepatitis.

In conclusion, the combination hepatitis A and hepatitis B vaccine offers a more convenient and safe alternative for immunization against two important diseases.

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