Biologics for Passive Immunity

Human Immune Sera and Globulins (Homologous Sera)

Human immune sera, or homologous sera, include immunoglobulin and hyperimmune sera for specific diseases. These contain the specific antibodies obtained from the blood of humans and produced as a result of having had the specific disease or having been immunized against it with a specific biologic product. The source of homologous sera is the pooled plasma of adult donors, either from the general population (for immunoglobulin) or from hyperimmunized donors (for immunoglobulins for specific diseases). Thus, these products confer passive immunity.

The pooled plasma from adult donors must be free of hepatitis B antigen and antibodies to HIV. Processing steps include fractional precipitation (e.g., with cold ethanol), maintaining rigorous control of pH and ionic strength. Further purification takes place with a finished biologic product that contains not <15% and not more than 18% protein. There are of course exceptions (e.g., varicella-zoster immunoglobulins [VZIGs] contain not <10% protein).

These preparations are for intramuscular (IM) injection and should not be administered intravenously. However, immunoglobulin intravenous (3% to 12% protein) and cytomegalovirus immunoglobulin are administered intravenously.

Sera have the greatest value for the treatment of acute disease, although they are also useful in some instances to prevent illness when immediate protection is needed. Immunity resulting from the injection of an immune serum is brief (a few weeks) because the foreign serum and the antibodies it produces are eliminated from the body within a few weeks.

Animal Immune Sera (Heterologous Sera)

Most commonly employed immune sera are prepared by immunization of horses against the specific immunogen (e.g., toxin, venom). After the plasma is harvested, it is separated by fractional precipitation into two components: immunologically active (immunoglobulins) and immunologically inactive (albumins, clotting factors) ones. The immunologically active component is treated with pepsin to remove the complement-activating component of the molecules and render it less immunogenic. Subsequently, the active component is recovered through dialysis and fractional precipitation or centrifugation.

This category of pharmaceuticals includes antitoxins and antivenins. Antitoxins are produced by inoculating horses with increasing doses of the toxoids and exotoxins. After several injections over weeks or months, the animal is bled with adequate safeguards to avoid contamination and the plasma harvested. Antivenins are produced similarly, by inoculating horses with the venom of selected species and harvesting the plasma.

Before using these products, precautions must be taken to ensure the safety of the patient, who may be sensitive to horse protein. Appropriate measures, including a sensitivity test with suitable controls, should be taken to detect any dangerous hypersensitivity.

Table 16.1 lists representative biologics by category. Although the scope of this book does not permit a thorough description of each according to its intended use, adverse effects, and so on, the list demonstrates the wide applicability of these products to produce active or passive immunity, provide prophylaxis, or serve as a diagnostic tool.

ADMINISTRATION AND TOXICITY ASSOCIATED WITH BIOLOGIC PRODUCTS

Table 16.1 lists examples of official biologics, and Table 16.2 lists the composition of some example biologic products.

Biologics must be dispensed in the original container to avoid contamination and deterioration. They are sterile when packaged and are injected by aseptic techniques. A few are administered by mouth.

Traditional vaccines, often constituted by inactivated whole cells, can cause unwanted side effects. Those developed from selected antigens have demonstrated fewer systemic