CLINICAL Q&A

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Handling and Disposal of Monoclonal Antibodies

QUESTION: Have guidelines been established for the handling and disposal of monoclonal antibodies?

ANSWER: Monoclonal antibodies (MoAbs) are forms of biotherapy that are being used increasingly for diagnosis and targeted treatment of many diverse diseases. MoAbs are used in the diagnostic imaging of colon, ovarian, and prostate cancer. MoAbs also are being used as both standard treatment and in clinical trials for a number of hematologic and solid tumors, including the treatment of CD20-positive non-Hodgkin's lymphoma, CD33-positive relapsed acute myelogenous leukemia (AML), CD52-positive relapsed chronic lymphocytic leukemia, and metastatic breast cancer. These agents also are being used in a variety of other treatment settings, including refractory asthma, inflammatory bowel disease, rheumatoid arthritis, organ transplant, cardiology, and in the prophylaxis of respiratory synctial virus in pediatric patients. See Table 1 for a list of MoAbs and their uses.

TABLE 1. MONOCLONAL ANTIBODIES AND THEIR USES

USE OF MONOCLONAL ANTIBODIES	TYPE OF MONOCLONAL ANTIBODY
Diagnostic imaging	
Colon and ovarian cancer	Satumomab pendetide (OncoScint®, Cytogen Corp., Princeton, NJ)
Prostate cancer	Capromab pendetide (ProctaScint®, Cytogen)
Cancer treatment	
CD20-positive non-Hodgkin's lymphoma	Rituximab (Rituxan®, Genentech, Inc., South San Francisco, CA) Iodine-131 tositumomab (Bexxar®, Corixia Corp., Seattle, WA) Yttrium-90 ibritumomab (Zevalin®, Genentech, Inc.)
CD33-positive relapsed acute myelogenous leukemia	Gemtuzumab ozogamicin (Mylotarg®, Wyeth-Ayerst, Philadelphia, PA)
CD52-positive relapsed chronic lymphocytic leukemia	Alemtuzumab (Campath®, Berlex Laboratories, Richmond, CA)
Metastatic breast cancer	Trastuzumab (Herceptin®, Genentech, Inc.)
Other treatment indications	
Inflammatory bowel disease and rheumatoid arthritis	Infliximab (Remicade®, Centocor, Malvern, PA)
Organ transplant	Basiliximab (Simulect®, Novartis, East Hanover, NJ) Muromomab-CD3 (Orthoclone®, OKT3, Ortho-Biotech, Raritan, NJ) Dacliveizumab (Zenopax®, Roche Laboratories, Nutley, NJ)
Cardiology	Abciximab (ReoPro®, Centocor)
Prophylaxis of respiratory synctial virus in children	Pavlivizumab (Synagis®, Medimmune, Inc., Gaithersburg, MD)

Note. Based on manufacturers' product information.

Antibodies are proteins produced by the body's humoral immune system in response to harmful substances (i.e., antigens). After binding to a unique site on an antigen, antibodies induce cellular destruction by recruiting the body's immune system to destroy harmful or nonself substances. MoAbs are proteins produced in large quantities from a single clone. MoAbs have a specific affinity for one antigen (e.g., the CD33 antigen on the AML cell) and belong to a family of proteins known as immunoglobulins. Early MoAbs were of mouse origin or murine based. When injected into patients, the murine product may elicit a human antiglobulin response, producing a human antimouse antibody (HAMA) response. Recognition of the murine portion of the MoAb as foreign results in the development of immune complex, which may negate the antitumor effect of the MoAb and prevent future treatment with the product. With new molecular and genetic engineering techniques, the hybridoma process has been refined to produce chimeric (i.e., human and mouse origin) and humanized (i.e., human origin) MoAbs to prevent the HAMA response (Rieger, 2001).

The mechanism of action of the MoAbs is different from traditional chemotherapy, which acts on all actively dividing cells (i.e., both normal and tumor cells). MoAbs affect only the cells that carry the MoAbs' targeted antigen on their cell surface. After binding to the target antigen, MoAbs trigger the host immune system to destroy the tumor cell by cell lysis. Monoclonal antibodies also can be conjugated (joined) to radioisotopes (radioimmunoconjugates or RIT), chemotherapy drugs (chemoimmunoconjugates), or toxins (immunotoxin) to enhance their effect. The specificity of the MoAb to target specific antigens allows the conjugated MoAb to provide targeted therapy.

To date, no formal research has been completed to evaluate the safest way to handle biologic agents. The last Occupational Safety and Health Agency update regarding the handling and disposal of hazardous agents was in 1995 and did not address MoAbs. The majority of MoAbss do not directly affect DNA and, therefore, are not considered mutagenic. Clinicians should use common sense when handling MoAbs and take extra precautions to avoid unnecessary exposure, including avoiding contact with skin and generating aerosoles (Conrad & Horrell, 1995). MoAbs conjugated to chemotherapeutic drugs are handled and disposed of in the same manner as the chemotherapy used. This includes the use of personal protective equipment, such as gloves, gowns, and goggles, as outlined in the Oncology Nursing Society publication, *Chemotherapy and Biotherapy Guidelines and Recommendations for Practice* (Brown et al., 2001), whenever a risk exists of cytotoxic agents being released into the environment.

When working with patients who are receiving MoAbs conjugated to RIT, radiation precautions are to be maintained. Knowing the properties of the radioisotope being used is important when determining the type and length of time radiation precautions are to

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