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ISSN: 2161-1459
Journal of Clinical & Experimental Pharmacology

Commentary

Pharmacology of Antibodies as Clinically Useful Drugs

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DESCRIPTION

Monoclonal Antibodies (mAbs) have been used to treat a variety of diseases for over 20 years and combine high specificity with generally low toxicity. Their pharmacokinetic properties are significantly different from those of non-antibody drugs, and these properties may have important clinical implications. mAbs are given intravenously, intramuscularly, or subcutaneously. Oral administration is not possible due to molecular size, hydrophobicity, and intra gastric degradation of mAbs. Due to the molecular size of mAb, the tissue distribution is slow and the volume of distribution is generally small. mAbs are metabolized to peptides and amino acids in multiple tissues by circulating phagocytes or cells containing their target antigens. Antibodies and endogenous immunoglobulins are protected from degradation by binding to protective receptors (newborn Fccreceptors [FcRn]). This explains their long elimination half-life (up to 4 weeks) [1,2]. Population pharmacokinetic analysis was used to assess covariates in the properties of mAbs. Both linear and non-linear eliminations have been reported for mAbs, probably caused by target-mediated properties. Factors that may affect mAb clearance include the amount of target antigen, immune response to the antibody, and patient demographics. Body weight and/or body surface area are generally associated with mAb clearance, but clinically less often. Metabolic drug-drug interactions are rare in mAbs. For some mAbs, the relationship between exposure and reaction is explained [3]. In summary, the most characteristic clinical pharmacokinetic properties of mAbs are parenteral administration, slow tissue distribution, and long elimination half-life.

Immunoglobulin molecules (antibodies) are multifunctional components of the immune system. Antibodies promote a number of cellular and humoral responses to a variety of antigens, including host (self) and foreign body antigens.

Most antibodies produced as part of a normal immune response are polyclonal. That is, because they are produced by many different B lymphocytes, each has a slightly different specificity for the target antigen (for example, by binding to a different epitope or binding to the same epitope). However, it is possible to produce large amounts of antibody from a single B cell clone. Since 1985, approximately 100 monoclonal antibodies (mAbs) have been designated as pharmaceuticals. New approvals are constantly being added. Available mAbs are directed against a large number of antigens and used for the treatment of immunologic diseases, reversal of drug effects, and cancer therapy. The World Health Organization (WHO), which is responsible for therapeutic mAb nomenclature, reported in 2017 that over 500 mAb names have been provided [4]. This topic will provide an overview of therapeutic mAbs, including their mechanisms of action, production, modifications, nomenclature, administration, and adverse effects. Separate topic reviews discuss clinical uses of polyclonal antibodies, including subcutaneous, intramuscular, and intravenous immune globulin products.

For nearly 20 years, biology in general, especially monoclonal antibodies and antibody-derived products (collectively referred to as mAbs) has become the mainstay of modern pharmacotherapy weapons for many indications. Like most small molecule drugs, most Abs were initially approved for adult indications and then followed for juvenile, pediatric, and in some cases neonatal indications. However, in rare cases, pediatric indications may be the first target of the mAb development program. B. Palivizumab for the prevention of respiratory syncytial virus infection in newborns and infants. Similar to small molecule drugs [5], the Pharmacokinetic (PK) and Pharmacokinetic/Pharmacodynamic (PK/PD) relationships of biologics are influenced by infant maturation changes in the pharmacokinetic processes associated with this particular group of compounds. In addition, size-specific adjustments to dosing are expected based on the established relationship between body size measurements and clearance as a determinant of systemic drug exposure, especially as a predictor of steady-state concentration.

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Received: 01-Mar -2022, Manuscript No. CPECR-22-16201; **Editor assigned:** 04-Mar-2022, Pre QC No. CPECR-22-16201 (PQ); **Reviewed:** 15-Mar-2022, QC No CPECR-22-16201; **Revised:** 25-Mar-2022, Manuscript No. CPECR-22-16201 (R); **Published:** 04-Apr-2022, DOI: 10.35248/2329-6925.22.12.299.

Citation: Assefa S (2022) Pharmacology of Antibodies as Clinically Useful Drugs. J Clin Exp Pharmacol. 12:299.

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