Editorial

The Logic of Biologics

Susan Resnick, OD, FAAO, Dipl.[1]

[1] CRO (Clinical & Refractive Optometry) Journal, Editor in Chief

Keywords: biologics, Giant Cell Arteritis, cenegermin, Tocilizumab

https://doi.org/10.57204/001c.68199

CRO (Clinical & Refractive Optometry) Journal

I have a confession to make. For the past twenty plus years I have been using a performance enhancing drug. No, I am not a competitive athlete, nor would I ever consider cheating. I take oral prednisone daily for severe asthma. Certainly, I am aware of the risks: osteoporosis, glaucoma, and cataracts, to name just a few. But, to preserve any sort of normal aerobic functioning, I remain a dependent user.

The good news (and hence the idea for this editorial) is that I just returned home from my second monthly injected biologic for severe asthmatics. While this is not the first drug in this class for this disease, it is the newest and first to be indicated for patients like me who do not test positive for eosinophilia or any other specific biomarkers. Although it is too early to assess whether this medication will prove to be "steroid sparing" for me, I am committed to the simple, quick, and relatively painless therapeutic regimen.

According to the FDA, biologics are complex mixtures that are not easily identified or characterized. They are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies. They may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available.[1]

Not a day goes by where I am not edutained by a TV commercial touting the efficacy (as well as the requisite list of possible adverse effects) of a biologic for some chronic and often life-threatening condition. These include, but are not limited to rheumatoid arthritis, psoriasis, Crohn' disease, diabetes, breast cancer and colon cancer.

Unlike non-biologic medications, biologics have a more target specific mechanism of action. For example, in autoimmune therapy, they may block a specific receptor for a molecule in the immune system. In cancer therapy these proteins "mark" cancer cells so that they will be more susceptible to recognition and destruction by the patient's own immune system. One common class of drugs in this category is mono clonal antibodies.

The conventional, older method of mono clonal antibody production involved a series of steps beginning with the injection of an antigen into mice which triggered antibody-producing splenocytes. These were then fused *in vitro* with myeloma cells, the hybrid of which was capable of unlimited growth. Today's monoclonal antibodies are produced using recombinant DNA technology. Recombinant "humanized" monoclonal antibodies are produced solely using *in vitro* cloning. Genes for an antibody's light and heavy chains are inserted into expression vectors, which are then transfected into host cells for expression. This "humanization" limits or eliminates the mouse cell protein which can cause unwanted immune reactions. Additionally, the production of recombinant antibodies does not require the use of animals and is, therefore, readily scalable.[2]

Of particular interest and importance to us, of course, is the role of biologics in eyecare. Among the ocular diseases that can be targeted with biologics are giant cell arteritis, exudative age-related macular degeneration, neurotrophic keratopathy, and uveitis. Here, too, biologics are being introduced to replace older therapies such as steroids that are associated with more and serious side effects. Risks of biologics include rash at the injection site, infection, headache, allergic reaction, and tuberculosis.[3]

Tocilizumab is approved for the treatment of Giant Cell Arteritis. It is administered by injection every four weeks with a tapering course of glucocorticoids or alone, following discontinuation. Anti-vascular endothelial growth factor drugs, which are all biologics, are currently used for the treatment of exudative age-related macular degeneration. These medications are injected monthly until resolution of the choroidal neovascularization and used again as needed. For neurotrophic keratopathy, we now have cenegermin, a topical medication applied six times a day for eight weeks.

While these advanced drugs all come with high promise, they also come with high cost. Fortunately, there are supplemental manufacturer sponsored programs available to enable access to these treatments for those in need.

As a practitioner, I am grateful for these pharmaceutical advances that propel treatment to greater efficacy with fewer downsides. As a patient, it's only logical that I, too, look towards a positive result with my new biologic.

Submitted: December 22, 2022 EST, Accepted: January 02, 2023 EST

REFERENCES

1. Accessed October 21, 2022. https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers

2. Accessed October 21, 2022. https://www.bio-techne.com

3. Accessed October 21, 2022. https://www.optometrytimes.com/view/biologics-a-new-road-into-the-future-of-medicine