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Eye-based Marketing of Therapeutic Proteins

Suzan Hater*

Department of Pediatrics, University of Dammam, Dammam, Saudi Arabia

Description

One-third of all drugs on the global market have been therapeutic proteins, such as monoclonal antibodies, single chain variable fragment (ScFv), crystallisable fragment (Fc) and fragment antigen binding (Fab). Specifically, these drugs have been widely used in ocular therapies to treat a variety of conditions, including diabetic retinopathy, age-related macular degeneration, corneal neovascularization and retinal vein occlusion. However, the immunogenicity, high molecular weight, complex structure, instability, short half-life, enzymatic degradation and difficult formulation of these bio macromolecules result in therapy failure. By altering the structure of the protein or incorporating it into new delivery systems, various efforts have been made to overcome the ocular barriers and enable the efficient delivery of therapeutic proteins. Not only are these strategies cost-effective and beneficial to patients, but it has also been demonstrated that they permit fewer drug side effects. The use of injectable micro Nano carriers, hydrogels, implants, iontophoresis, cell-based therapy and combination techniques are some of the factors that influence the design of formulations and the delivery of therapeutic proteins to ocular tissues. Other strategies for increasing these proteins' bioavailability in the posterior segments of the eye without compromising their stability are also briefly discussed in this section. The development of formulations for the ocular delivery of therapeutic proteins that are more cost-effective, stable, non-invasive and effective should be the focus of future research. Preclinical-to-clinical translation also requires more understanding. Diabetic retinopathy (DR), a neurodegenerative retinal disorder that affects millions of people worldwide, is one of the most common causes of blindness with complications like corneal neovascularization and retinal vein occlusion [1,2]

No proliferative DR, in which there is no new blood vessel growth and patients have dilation of pre-existing capillaries, oedema, capillary occlusion, micro aneurysms and intraregional neo-angiogenesis, which results in the formation of tortuous blood vessels, is a form of DR that does not present any initial symptoms. Proliferative DR is a type of severe damage to blood vessels that results in the growth of fragile leaky blood vessels (neo-angiogenesis) in the retina. These proliferative DR leak a jelly-like substance into the centre of the vitreous, resulting in the retina's detachment from the eye's back. Glaucoma, haemorrhage in the vitreous and black spots or floating strings in the vision are some of the conditions that can result in gradual vision loss in patients. Age-related macular degeneration (AMD), in which patients exhibit degeneration of the retinal pigment epithelial cells and choroid neovascularization, is a common cause of vision loss in older people. In some patients with dry AMD, the macula thins out (atrophies) as they get older. Neo-vascular wet AMD is characterized by the rapid onset of central RVO accompanied by new vessel growth, which results in capillary occlusion, tissue hypoxia, elevated vascular endothelial growth factor (VEGF) expression and retinal proliferation of new vessels. As a result, new treatments that use monoclonal antibodies, vascular growth factors, oligonucleotides, genes and anti-VEGF agents (such as ranibizumab, bevacizumab and aflibercept) to stop neo-angiogenesis, stabilize vascular leakage and reduce oedema are being investigated [3].

For the treatment of ocular diseases, several therapeutic proteins have recently been approved for sale on the market. The physiological and anatomical barriers of the ocular tissues limit the efficacy of these proteins when administered to the posterior segments of the eye, despite the fact that many of them have a low molecular weight and a short half-life. Additionally, the ocular environment renders them unstable and inactive, resulting in treatment failure. The vitreous's presence of proteolysis enzymes like trypsin, which can increase with age and lead to the degradation of injectable proteins, is one factor that contributes to this. Additionally, therapeutic proteins have short half-lives due to various static, dynamic and metabolic barriers. The intravitreal delivery of anti-VEGF to the posterior segment of the eye, which requires a needle to penetrate the globe and release the drug into the vitreous, is extremely painful. In addition, the treatment necessitates numerous injections, which increases the risk of additional complications like endophthalmitis, retinal detachment, cataracts and retinal tears [4].

As a result, the focus of the research should be on developing novel non-invasive methods or devices for drug administration and reducing the frequency of dosing (such as novel formulations with prolonged release). To minimize the limitations or gaps in the current therapies involving therapeutic proteins, lessen patient administration pain and increase compliance, a number of treatments for retinal diseases have been studied by researchers around the world. Implants, cell-based systems, depot formulations of injectable carriers containing drug-loaded micro- or nanoparticles, injectable in situ hydrogels and cell-based systems are some of the most effective methods for delivering therapeutic proteins to the eyes in a safe and sustained manner. These formulations have the potential to increase drug residence time within the intraocular tissues, enhance treatment efficacy and encourage patient compliance by reducing drug administration frequency and increasing ocular drug bioavailability. In addition, phase III clinical trials on an anti-inflammatory peptide conjugated CPP delivery indicate that cell-based systems and cell-penetrating peptides (CPPs) offer good ocular bioavailability [5].

Conclusion

The ideal therapeutic protein ocular delivery systems should have low systemic exposure, minimal invasiveness, sustained release and stable delivery of encapsulated proteins to the target tissues. Combining technologies, such as liposomes or nanoparticles coated with bio adhesive polymers, injectable hydrogels containing nano- or micro particles and so on, is a common practice. The benefits of sustained delivery of therapeutic protein formulations include reduced dosage and dosing frequency, reduced side effects, improved patient compliance and local delivery with fewer side effects. In the treatment of ocular disorders affecting the anterior and posterior segments of the eye, significant focus is currently being placed on the creation of a sustained, non-invasive drug delivery method that is more effective. In order to increase patient compliance by increasing bioavailability for a longer period of time while minimizing side effects, we discuss the most recent methods for protein delivery to ocular tissues in this review. In order to improve the ocular bioavailability and provide sustained release of therapeutic proteins to the ocular tissues in the posterior segments of the eye, various methods, such as injectable micro/nanocarriers, injectable hydrogels, ocular implants, iontophoresis and periocular injections, are discussed.

***Address for Correspondence:** Suzan Hater, Department of Pediatrics, University of Dammam, Dammam, Saudi Arabia, E-mail: hater@9uod.edu.sa*

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Conflict of interest

No potential conflict of interest was reported by the authors.

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