



Clinician Perspective on Postmarketing Surveillance of Modern Geriatric Dosage Forms

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Abstract This review article will discuss the importance of modern lipid and polymer-based drug delivery systems that are emerging in the market for treating ailments dominant in older adults. This is a new field of science and the application use is still in clinical trials and the procedural advancements may take another five years to reach out to the consumer at large. Though, there has been an innovative approach for treating geriatric diseases by using medications in form of lipid and polymer hybrid drug delivery systems there needs extensive surveillance on its regimen. Post-marketing surveillance is still a growing science which has a great potential in enhancing the treatment options of older adults in improving their wellbeing. A well organize and sustainable system need still exists in third world developing country like India that has big pharma companies' as well large consumers.

Keywords Geriatric, Dosageform, Lipids, Polymers, Drug Delivery, Post-marketing surveillance

1. Introduction

Older adults are vulnerable and susceptible to having multiple comorbid conditions such as diabetes, hypertension, chronic heart disease, arthritis, and some form of cognitive impairment. Older adults also show a high level of hypersensitivity for any new biologic or medication due to impaired elementary functions [1-2]. It is pivotal to understand the role any medication plays on older adults as some of the novel medication advancements are proven to be effective in treating specialty conditions such as cancer in geriatric patients [3-4]. However, these drug delivery systems can increase the drug payload when enhanced with specific nanoparticles which have a high possibility to targeted therapies for hepatic cancers. It is also important to defer the use of these any new hybrid lipid/polymer nanoparticle medication in persons with moderate or severe acute illness [5-7]. Using the nanoparticles, itself comes with caution and appropriate care in administering any of these lipid polymer hybrids should be considered as a priority and special precaution should be taken for patients with severely compromised cardiovascular and/or pulmonary function in whom a system reaction would pose a significant risk. Also hypocholesterolemic properties of chitosan decrease the risk of atherosclerosis and other cardiovascular dysfunctions common in elderly population [8-10]. As geriatric patients with chronic conditions may be considered for immune-compromised patients, it is important to analyze the health conditions of the individuals before administering these medications. Also *alginate* is used for rejuvenation of *geriatric* larynx [11-12]. As there are



consequences and personal risk. The lipid-polymer geriatric patients with Diabetes Mellitus type 2 who have impaired glycemic control should be monitored regularly while using lipid-polymer hybrids. Intra-articular *hyaluronic acid* is used as treatment in *elderly* and middle-aged patients with knee osteoarthritis [13-15]. *Nanocrystals* are pure drug crystals with sizes in the nanometer range stabilized to overcome difficulties in swallowing tablets by pediatric or *geriatric* patients [16]. The lipid polymer-based drug delivery systems have improved the bioavailability of the medication and reduced the potent side effects of the medications [17-18]. The majority of the older adults with chronic disease conditions are at risk of polypharmacy and the drug-induced complications are on the rise for these vulnerable populations [19-20]. The targeted release of these nanoparticles reduces the impact of damage on the cellular levels of these geriatric patients. PVP formulations have been employed to fabricate preferred solution viscosity for use in elderly patients also [21-23].

2. Marketed Polymer / Lipid-Based Drug Delivery Systems for Geriatric Use

A recommendation from a Health care practitioner is very important while administering any of these drugs, biologics, or molecules [24-25]. There is a change of developing pulmonary lesions and these lesions may reduce the oxygen diffusing capacity. Functional polymer *coatings are used* to address immediate release requirements and potential swallowability issues for *geriatric* patients [26-27]. Many of the individuals may experience asthenia, fatigue, and myalgia. Clinicians who are prescribing these novel drug delivery systems through lipid/polymers should consider the potency of the drug and the health condition of the geriatric patient receiving the medication [28-29]. Zein, a natural protein of plant origin is used in controlled drug and biomedical delivery systems [30]. It should be considered as a supplemental means for treating ailments along with quality lifestyle modifications and diet changes [31-32]. It is pivotal to describe the mode of action and the release time of these special nanoparticles to the patient. *Electrospun* nanofibers prepared from polymers are used to *deliver* antibiotic and anticancer agents, DNA, RNA, proteins and growth factors [33]. Patient counseling on managing their disease condition elevates the effectiveness and efficiency of the medication [34-36].

Physicians should consider the overall biological psychological and sociological aspects of an individual before prescribing these medications. An isocratic RP-HPLC Method for analysis of Rivastigmine in pharmaceutical dosage forms infrequent types of dementia in *old age* patients [37]. As potential complications may arise in any of the aspects mentioned above, and any changes in biological, psychological, and sociological variants reduce the wellbeing of the individual [38-39].

Proliposomes of lisinopril dihydrate are used for transdermal delivery [40]. Therefore, it is important to create a holistic approach when prescribing these drug delivery options to geriatric patients [41-42]. The family members, caregivers, and any individual part of the decision making for the older adult should be involved in the care management process [43]. It is also, important to disclose any risk associated with the use of nanoparticles to the patient and family members directly [44-45]. The recent advancements in medicine and formulations have created an adjuvant role in improving the conventional dosage options to novel drug delivery systems that enhances the effectiveness of the medication, bioavailability, safety, and stability [46]. *Self-nanoemulsifying drug delivery system* (SNEDDS) are required to be administered to special populations such as *geriatric* [47]. The drug target therapy is the need of the hour for treated life-threatening conditions which can be managed with lipid/polymer drug delivery systems [48-50].

3. Clinician Perspective in Prescribing Marketed Lipid/Polymer-Based Delivery Systems to Patients and Post-Marketing Surveillance

As a clinical gerontologist, we are fascinated with the approach the novel medication delivery system has improved in the last five years. We believe that these options of medication deliveries will create many manageable conditions that would be otherwise life-threatening [51-52]. The futuristic medicine form is already on the clinical trial and the professional needs to understand the core competence of this novel drug delivery system [53-54]. I do understand that there are potential side effects and risk of adverse events. However, analyzing the risk-benefit ratio we feel these options can help more individuals to improve overall health [55-56]. Most of the medications are in phase 3



clinical trials and some of them are approved especially the delivery of Doxorubicin and Diclofenac Sodium for treating cancerous cells in individuals, colloidal gold has been used as a model to create the nanoparticle-based delivery systems in combined cancer therapy [57-59]. Core-shell nanoparticles were used in treated Human Immuno Virus (HIV) while combining antiretroviral drugs with carboxymethylcellulose and compritol PEG [60-62].

4. Pharmacovigilance Study in Geriatric Population

Main goal of pharmacovigilance in geriatric patients is to improve the safe and rational use of medicines and thereby improving patient care, health of the society [63-65]. Pharmacovigilance is particularly concerned with the adverse drug reactions (ADR's). Hence closer pharmacovigilance studies are needed in the older age group due to polypharmacy, which can cause ADR's leading to hospital readmission and the treatment cost to treat these ADR's [66-67].

Pharmacovigilance must be carried out throughout the lifecycle of the nanopharmaceutical. A detailed pharmacovigilance plan alongwith marketing authorization application must be submitted by the product developer [68-70]. Pharmacovigilance plan must mention: » Safety data from clinical development » All the potential risks of the nanopharmaceutical » Summary of anticipated risks » Situations not adequately studied » All the potential drug-drug and drug-food interactions of the nanopharmaceutical either as a separate document with pharmacovigilance plan or pharmacovigilance strategies or in the section referring to safety specifications of the document [71-73].

5. Conclusion

The advancements in modern medicine and formulations have created multiple options for humankind and the efficiency has been raised considering the changes in the last five years. It is innovative and progressive to see these effective treatment options helping individuals to manage their geriatric ailments. Adhering to the new delivery systems will create fewer polypharmacy impacts on older adults, improved health outcomes, and fewer side effects. A more robust sustainable system needs to be constructed that can identify, rationalise, record and manage single side to adverse effects arising by consuming these modern dosage forms. The need still exists for an organized Pharmacovigilance especially in India.

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