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NOVEL NANOTECHNOLOGY METHOD FOR HIV/AIDS TREATMENT AND PREVENTION

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ABSTRACT:

Despite decades of research, the development of an effective HIV vaccine remains a significant challenge. Recent findings from three large vaccine efficacy trials have identified antibodies against the V1V2 domain of the HIV envelope glycoprotein as a potential correlate of reduced infection risk, offering a promising avenue for improving vaccine efficacy. Vaccine-elicited anti-V1V2 antibodies do not mediate potent virus-neutralizing activities, but they mediate Fc-dependent effector functions.

The use of Antiretroviral drugs in treating HIV/ AIDS patients has enormously increased their life spans with serious disadvantages. The virus infection still remains a public health problem worldwide with no cure and vaccine for the viral agent until now. The use of

nanoparticles (NPs) for the treatment and prevention of HIV/AIDS is an emerging technology of the 21st century. NPs are solid and colloid particles with 10 nm to <1000 nm size range; although, less than 200 nm is the recommended size for nanomedical usage. There are NPs with therapeutic capabilities such as liposomes, micelles, dendrimers and nanocapsules. The particle enters the body mainly via oral intake, direct injection and inhalation. It has been proven to have potentials of advancing the prevention and treatment of the viral agent. Certain NPs have been shown to have selftherapeutic activity for the virus in vitro. Strategies that are novel are emerging which can be used to improve nanotechnology, such as genetic treatment and immunotherapy. In this review, nanoparticles, the types and its characteristics in drug delivery were discussed. The light was furthermore shed on its implications in the prevention and treatment of HIV/AIDS.

KEYWORDS: Asymmetrical flow field-flow fractionation; Dynamic light scattering; Nanovaccine; Polymeric nanoparticles. AIDS; ARTs; HIV; Nanoparticles; implications; nanotechnology; therapy.

INTRODUCTION:

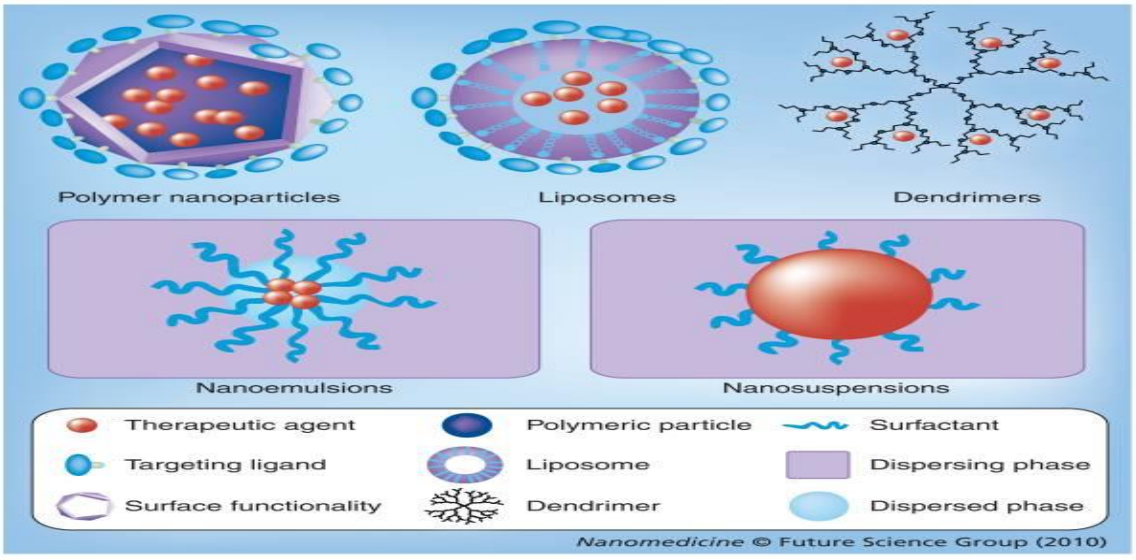
In December 2019, a novel coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), caused a series of acute atypical respiratory diseases in Wuhan, Hubei Province, China . The disease was termed coronavirus disease 2019 (COVID-19) by the World Health Organization (WHO). The clinical symptoms of COVID-19 include fever, fatigue, and dry cough, and some patients also experience nasal congestion, runny nose, inappetence, diarrhoea and pneumonia on computed tomography (CT) . Some severe cases can rapidly develop into acute respiratory distress syndrome (ARDS), refractory metabolic acidosis, septic shock, and coagulation dysfunction (clinical features of patients infected with 2019 novel coronavirus in Wuhan). COVID-19 has spread more rapidly than severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) . Specifically, COVID-19 has spread to more than 200 countries across the world and has claimed more than 1014,152 human lives as of October 1, 2020. Unfortunately, there is currently no vaccine or antiviral treatment for patients with suspected or confirmed COVID-19 . The drugs that are clinically used include remdesivir, abidol, and RNA synthesis hormones , but the efficacy and safety of these drugs still need further clinical confirmation. With respect to vaccines, 30 vaccine candidates have been reported to the WHO and are in the clinical phase, but only six vaccines have entered the III clinical phase as of August 20, 2020 . However, the

in vivo effectiveness and side effects of these vaccines and chemical candidates need further evaluation.

Nanotechnology for antiretroviral drug delivery:

The use of nanotechnology platforms for delivery of drugs is revolutionizing medicine in many areas of disease treatment . Cancer patients have been the biggest beneficiaries of this revolution so far, with significant advances in the last few decades. Many nanoscale systems for systemic cancer therapy are either FDA approved or in clinical trials . This tremendous success has been due to the unique features that nanotechnology imparts on drug delivery systems. Using nanotechnology, it has become possible to achieve improved delivery of poorly water-soluble drugs, targeted delivery of drugs to specific cells or tissues and intracellular delivery of macromolecules.

Moreover, by controlling the release profiles of the delivery systems, drugs could be released over a longer time and at higher effective doses to the specific targets. Various nanoscale drug delivery systems shown in Figure 1 could be explored for these purposes. The use of nanotechnology systems for delivery of antiretroviral drugs has been extensively reviewed by Nowacek *et al.* and Amiji *et al.* . In this section, we only highlight a few of the most recent and significant examples of nanotechnology-based drug delivery.



NANO TECHNOLOGY FOR HIV TREATMENT:

HIV treatment is based on the action of drugs that target the life cycle and the multiplication process of the viral antigen. Currently, the antiretroviral therapy (ART) includes nucleotide

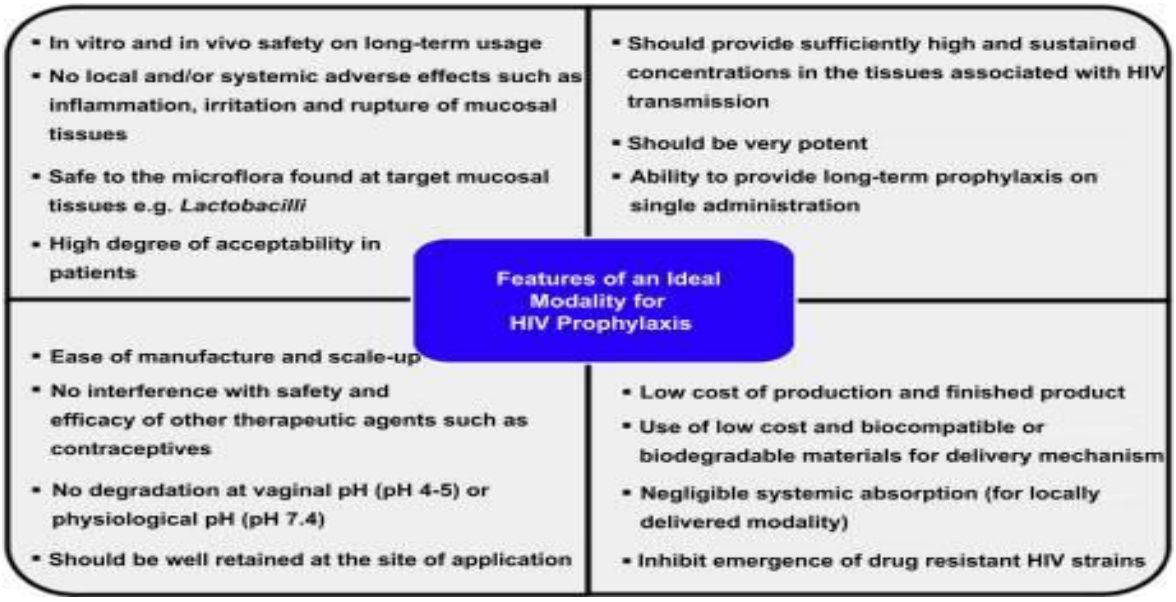
reverse transcriptase inhibitors , non-nucleoside inhibitors , protease inhibitors , entry/fusion inhibitors , CCR5 antagonists , and integrase inhibitors . To increase the efficacy of treatment and subsequently improve the quality of life, a combination of three or more drugs, called highly active ART (HAART) among HIV infected individuals will be employed . Despite its effectiveness, the treatment is not devoid of unwanted occurrences due to suboptimal adherence, heavy pill burdens, toxicity, treatment side effects, and drug resistance development. Hence, it needs to have novel methods to enhance the inhibition of HIV infection, one of which is nanotechnology.

Modern drug design, which can incorporate ART drug delivery with nano-systems, can decrease the dosage requirements and toxic side effects associated with current heavy pill burdens to improve the treatment's safety and efficacy .

Previous studies supported the evidence of effective treatment by nanotechnology. Chiodo et al. conducted a study on the NRTI drugs abacavir (ABC) and lamivudine (3 TC) attaching to glucose nanoparticles (GNPs) *in vitro*. There was efficient function through the drug's primary hydroxyl groups via an ester bond that can be cleaved off in acidic conditions. After the experiment, the researcher illustrated a new level of multi-functionalization of GNPs as multivalent drug delivery systems for the treatment of HIV. It was previously known that the regulatory T (Treg) cells were a specialized subpopulation of T-cells . These T cells are components of the immune system and susceptible to HIV infection . HIV infection leads to immune hyperactivation, which can subsequently result in erosion, depletion, or exhaustion of T-cells by preventing HIV disease progression.

MODALITIES FOR PROPHYLAXIS OF HIV:

The process of development of prophylactic modality is always focused on making it widely available for disease prevention. Over the years, various modalities have been and are being developed for prophylaxis of HIV. The desired properties of an ideal modality for HIV prophylaxis are shown in . Broadly, prophylactic modalities can be divided into four categories viz. vaccines, macromolecular HIV entry inhibitors, antiretroviral drugs, and nucleic acid-based therapeutics . There are numerous reviews that discuss each of these modalities in detail . In this review, we intend to give an overview of various modalities available for HIV prophylaxis.



Importance of Understanding HIV Pathogenesis to Enable Effective Anti-HIV Drug Delivery:

Unlike traditional pathogens that coevolved with mankind for millions of years, HIV is an exotic pathogen that crossed species from African primates to humans in at least five independent events (hence HIV-1 groups M, N, O and P and HIV-2) starting approximately a century ago. Consequently, humans have not had sufficient time to develop an adequate immune response. While broadly neutralizing antibodies eventually develop in 10 to 30% of patients, the overwhelming majority of these antibodies (~ 99%) are not potent enough to stop the progression of disease. In addition, the induction of these antibodies through vaccination has been unsuccessful.

HIV is a member of the lentivirus genus in the retroviridae family. The high mutation rate allows HIV to evade destruction by host immune responses. The provirus form of HIV can hide in the genome of latently-infected CD4+ memory T cells for years without revealing any sign of infection to host immune surveillance. It also does not provide an obvious target for eradicative treatment. Natural eradication of any pathogen relies on host immunity. However, HIV is unique among retroviral pathogens because its main target is CD4+ helper T cells, which serve as key coordinators within the immune system. As the CD4+ T cell pool is progressively depleted, host immune function becomes weaker, making eradication increasingly difficult. Compounding the reduction in CD4+ T-cells is the establishment of cellular HIV reservoirs, defined in the context of eradication as a cell type or anatomical site that allows persistence of replication-competent HIV-1 on a timescale of years in patients on optimal ART.

CURRENT SITUATION AND RESTRICTIONS OF CONVENTIONAL DRUG THERAPY AND TREATMENT FOR HIV:

Precise and speedy diagnosis of HIV significantly affects the clinical treatment of the disease.Currently used traditional diagnostic approaches are mostly influenced by HIV antibody detection in the plasma or the serum by the most sophisticated techniques, such as the ELISA or Western blot assays.Besides such an advancement in HIV diagnosis, there are many lacunae in the techniques, including false positive and false negative results caused by the reactions among the antigens and the samples.

The HIV and AIDS treatment methods can be summarized into five different types. The first one is the use of blockers to halt the HIV binding to the target cells.The second approach uses inhibitors that can inhibit the reverse transcriptase enzyme and the HIV precursor protease enzyme.The third approach utilizes the inhibitors to hinder the expression of the HIV gene. The fourth approach involves blockers to stop the assembly and release of HIV.The fifth approach uses highly active antiretroviral therapy, most commonly called the HAART treatment, to kill the HIV completely.

The ligand receptor and antibody-based HIV treatment are used that interfere with the entry of the virus into the patient's body or for providing therapeutic drugs to the infected cells, with antibodies aiming at the viral proteins and host cell receptors, and ligands aiming at definite cellular receptors on the infected cells.The strategies for antibody treatment include neutralization of the antibodies that block the attachment of the virus and bispecific antibodies that involve the immune cells to kill the infected cells. While the ligand-based antibodies use ligands to bind to the receptors on the infected cells, thereby enhancing the drug delivery effects and decreasing the toxicity effects. Several pre-clinical and clinical studies have been carried out recently on the development of therapeutic long-term effects on the immune control of HIV-1 when antiretroviral therapy is not available. Advancements in the chimeric antigen receptor technology and enhanced design established that potent HIV-1-specific T cells can be produced. Continuing and strategic clinical trials of anti-HIV-1 chimeric antigen receptor cell therapy could provide further understanding into the amount of antigen required to activate the cells, the role of C-C chemokine receptor type 5, the in vivo effectiveness, and determination of these reengineered chimeric antigen receptor cells, and their effect on escape mutants.

FUTURE PROSPECTIVE:

During the last three decades, great improvements in the diagnosis, treatment, and prevention of HIV have been made. Cabotegravir and rilpivirine are two long-acting retroviral nanoformulations whose preclinical and clinical trials, respectively, have been successful. Their discovery demonstrates the benefits of this type of formulation on the nanoscale: greater potency, half-life, and sustained circulation time in plasma, giving a greater amount of the drug deposited in specific tissues. Since then, many efforts have been made in research focused on the goal of viral eradication and improvement of new drugs, NSs and their possible combinations. This includes a better understanding of the effects of charge, size, structure, and potential toxic side effects of NSs. In addition, as understanding of the many mechanisms of viral persistence increases, new approaches to interrupt and to target latency are moving towards clinical testing.

There is great hope in nanogel-drug conjugated systems that improve the efficacy of antiviral therapy. This is due not only to the aforementioned advantages, but because of their size, they can cross the BBB and act on the central nervous system, eradicating HIV infection in the brain.

Without a doubt, prevention is better than cure, therefore, the ultimate goal would be to provide an easy-to-use option against sexually-transmitted diseases for sexually active people. The use of effective microbicides, condoms, and eventually AIDS vaccines will give society a wider variety of protective technologies.

DRUG DELIVERY STRATEGIES FOR TREATMENT OF AIDS:

When a person is infected by the HIV virus, usually, the virus is confined to the blood or the transmission site. It proceeds quickly to the lymphoid nodes and lymphoid tissues including those in the gastrointestinal tract. HIV is a disease that can be controlled but not cured because it is difficult for anti-AIDS drugs to reach the lymphoid organs or be kept there long enough to make an impact. Therefore, a reservoir of virus remains in the lymph nodes of HIV patients on HAART even with when virus is undetectable in plasma. Rodney J. Y. Ho, Professor of Pharmaceutics, University of Washington and Fred Hutchinson Cancer Research Center, Seattle, WA, USA, pointed out that the existing anti-AIDS drugs are relatively safe and very selective for viral targets; however, drugs given either orally or by IV injection often produce lower levels in lymph nodes and lymphoid tissues than in blood.

As a result, lymphocytes (target of HIV infection in the lymphoid tissues) is exposed to lower drug concentration by about 67–70% than the corresponding cells found in the circulating

blood. This sheltering from drug exposure in lymphoid tissue allows the virus to continue to replicate, although at a much lower rate. This hypothesis is consistent with the reports that virus in lymphoid tissues replicates at a low level and is still sensitive to highly active antiretroviral therapy. The present challenge is to devise ways to deliver anti-HIV drugs to lymphoid tissues more efficiently and achieve concentrations high enough to eradicate the viral sanctuaries.

The main goal of Professor Ho's research is to use various nanoparticles as platforms to improve the therapeutic index of drugs, which includes enhancing drug localization in HIV-infected target cells and reducing drug localization in off-target "normal cells". Anti-HIV drug delivery system targeting to lymphoid tissues with pH-responsive nanoparticles was developed. Dr. Ho's study showed that the intracellular levels of anti-HIV protease inhibitor in lymph node mononuclear cells are about 25–35% of mononuclear cells in blood. To improve drug concentration in lymphoid tissues, pH-dependent indinavir-incorporated lipid–indinavir nanoparticles (50–80 nm in diameter) in suspension was given by subcutaneous injection (10-mg/kg lipid-associated indinavir) to macaques. The results indicated that ratio of indinavir concentration in lymph node/plasma ranged from 2.5- to 22.7-fold between 6 and 28 h after the administration of lipid-associated indinavir, much higher than the ratio of the soluble form of free indinavir (25 mg/kg) given orally. Also, only HIV-2-infected macaques treated with lipid-free drug showed evidence of HIV-2 RNA in lymph nodes as compared to animals treated with lipid-associated indinavir.

CONCLUSION:

Nanotechnology has revolutionized the world by offering innovative solutions to multiple problems associated with various areas of healthcare today. The recent advances in the design and engineering of nanomedicines have offered a number of advantages over conventional methods of prevention, diagnosis, and treatment of viral infections. The superiority of nanomedicine approaches lies in presenting unique characteristics like small particle size, high area to volume ratio, flexibility to get surface modified in order to achieve desired selectivity, and biocompatibility. Additionally, these novel approaches present enormous potential in antiviral therapeutics by helping to overcome the problems of resistance to therapy, low solubility and bioavailability of drugs, burst release, and short duration of action.

Future research can be directed to achieve 'multifunctionalization' of nanomaterials in order to achieve site-specific, concurrent delivery of multiple drugs and 'multiplexing' in order to

achieve treatment of broad spectrum of diseases and associated comorbidities in a heterogeneous population. Development of theranostics which can bring about accurate diagnosis along with effective treatment and real-time monitoring is becoming increasingly essential in the field of viral infections. Various technologies like nanotraps, nanodiamonds, and nanofibers have found their way in ongoing research against influenza and HIV-1 viruses and can be further extended to other viral infections. Studies to enhance immune response and usage of nanomaterials as adjuvant to antiviral vaccines have been promising in the prevention and control of viral infections.

Among the few barriers in the development of these advanced forms of nanomaterials are the complexities involved in their fabrication and characterization and their large-scale production. The concern of long-term toxicity should be given paramount importance while designing the nanomaterials. However, with rapid advancements in the field of material chemistry, biology, and technology, one can be hopeful that the rate at which the emergence of new viral infections takes place can be controlled and the overall management of viral infections can be more effective.

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