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Review Article

Next Generation Approaches to Combat Cardiovascular Disease

Rajvi Adhavaryu¹, Zalak Dave^{*2}

¹B. Pharmacy Student of Krishna School of Pharmacy & Research (Formerly, Babaria Institute of Pharmacy), Drs. Kiran and Pallavi Patel Global University, Krishna Edu Campus, Varṇama, Vadodara, Gujarat, India

²Assistant Professor Department of Quality Assurance, Krishna School of Pharmacy (Formerly, Babaria Institute of Pharmacy), Drs. Kiran and Pallavi Patel Global University, Krishna Edu Campus, Varṇama, Vadodara, Gujarat, India.

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ABSTRACT

Background: Cardiovascular diseases have remained the major cause of morbidity and mortality across the globe, thereby calling for more novel therapeutics. Such conventional ways of drug delivery have their own pitfalls like poor bioavailability, systemic toxicity, and limited target specified delivery. Objective: The motivation of the review is to highlight the most recent advancements made in novel drug delivery systems for cardiovascular diseases, covering prescription and intent that may drive their applications in personalized medicine. Methods: Emerging NDDS comprising microneedles, transdermal patches, nanotechnology-based carriers, hydrogels, and smart drug-delivery platforms were examined. Their ability to impart controlled, sustained, and site-specific drug release was emphasized. Nanoparticles, liposomes, and polymeric carriers that enhance drug stability and bioavailability were described. In addition, targeted cardiovascular therapies such as drug-eluting stents, gene therapy vectors, RNA-based therapeutics, and biodegradable scaffolds for myocardial regeneration among others were evaluated. Results: NDDS demonstrated the great potential to improve the outcome of therapeutics by providing enhanced efficacy, reduced adverse effect, and compliance from the patient's end. Preclinical and clinical studies have been very hopeful in terms of their effects on site-specific drug delivery and regenerative cardiovascular medicine however still have restrictions in biocompatibility, large-scale manufacturing, and regulatory compliance to be met to eradicate the hindrances in clinical applications. Conclusion: Novel drug delivery systems provide a paradigm shift in the management of CVD toward imbedding precision in treatment and consequently improving the outcome. Addressing the concerns discussed will go a long way in ensuring the clinical translation of this

***Corresponding Author:** Zalak Dave

Address: Assistant Professor Department of Quality Assurance, Krishna School of Pharmacy (Formerly, Babaria Institute of Pharmacy), Drs. Kiran and Pallavi Patel Global University, Krishna Edu Campus, Varṇama, Vadodara, Gujarat, India.

Email ✉: zalakdave.ksp@kpgu.ac.in

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innovative technology eventually contributing toward a healthy populace across the global search.

INTRODUCTION

Cardiovascular Diseases remain the top source of morbidity and mortality globally, resulting in extensive consequences for health care systems and economies. Cardiovascular diseases impact millions, including coronary artery disease, hypertension, heart failure and stroke, and calls for treatment. Although cardiovascular medicine has advanced, treatment continues to be difficult due to limitations of the drug's effectiveness, side effects, and patient compliance. Established drug delivery systems for cardiovascular diseases treatment suffer from poor bioavailability, rapid metabolism, and side effects, which ultimately prevent treatment from being effective. Oral and intravenous is the most common drug delivery method, but a major limitation of the oral and/or intravenous administration routes is that they do not allow for a sustained release of drug and/or targeted action which, in turn, can produce suboptimal therapeutic effects. Low patient compliance resulting from frequent dosing is another significant barrier to successful disease management. Novel drug delivery systems (NDDS) have gained attention as instruments for addressing some of the limitations stated above. NDDS, which include nanocarriers, liposomes, polymeric systems and targeted drug delivery systems, serve as promising platforms to improve drug effectiveness, reduce side effects, and improve patient compliance. NDDS enables controlled and site-specific release which would optimize the therapeutic success of cardiovascular management. Overall, NDDS is a relatively new approach to treatment delivery which aims to promote cardiovascular treatment, quality of life which will ultimately result in improved patient comfort.

Traditional Methods of Drug Delivery for CVD

The management of cardiovascular diseases typically involves traditional methods of medication delivery, including oral or intravenous (IV) administration. This is a common practice due to the ease of use and immediate availability of the medication in the bloodstream. However, there are limitations that may lead to poor efficacy of treatment in patients.

Oral Drug Administration

Oral administration is the most prominent and feasible mode of delivery for cardiovascular medication, including antihypertensives, anticoagulants, and statins. Nonetheless, oral administration presents its own difficulties:

Poor Bioavailability: Many cardiovascular drugs undergo significant first-pass metabolism by the liver, thus limiting the amount of the active drug that enters systemic circulation, necessitating increased dosing which in turn heightens the chances for side effects.

Variable Absorption: Drug absorption is subject to interference by food, gastric pH, and intestinal activity of enzymes, resulting in variability of the therapeutic effect.

Patient Compliance Issues: There are many drugs for cardiovascular disease that are prescribed for prolonged or lifelong use. Long-term dosing schedules, as well as the possibility of gastrointestinal upset and missed doses, often leads to poor patient discontinuation of important therapy, potentially jeopardizing the treatment.

Intravenous Drug Administration

The use of intravenous (IV) administration is frequently employed for acute cardiovascular events, such as myocardial infarction, heart



failure, or stroke, when a rapid therapeutic drug effect is needed. Administering agents via IV route certainly produces an immediate drug effect, but it has multiple associated drawbacks:

Systemic Side Effects: The rapid administration of drugs into the circulation can produce rapid swings in the concentration of a drug, leading to increased risk of adverse effects for example hypotension when using an antihypertensive agent or bleeding complications in anticoagulant therapy, toxicity requiring medical supervision, which limits the feasibility for outpatient cardiovascular disease management

Need for Improved Drug Delivery Approaches

At this point, there is an increased need for advanced drug delivery systems that can increase the bioavailability of drugs, minimize systemic side effects and improve patient compliance. Novel drug delivery strategies such as the use of nanotechnology-based carriers, controlled release formulations, and targeted delivery strategies would support an advancement in the methods of drug delivery in cardiovascular diseases treatment.

METHODOLOGY

Novel Drug Delivery Systems for Cardiovascular Disease Management

Some recent advancements in delivery technologies and have opened up possibilities for innovations in cardiovascular disease management. Novel Drug Delivery Systems (NDDS) are designed to reduce the limitations of traditional delivery approaches that maximize the bioavailability of pharmacotherapy, targeted delivery, and controlled therapeutic delivery. With many new systems developed with the aim of improving treatment outcomes for CVD.

Nanotechnology has transformed the treatment of CVD by enabling drug targeting to improve therapeutic delivery, reduce systemic toxicity, and increase bioavailability. Several nanocarriers have been reviewed and developed for CVD drug delivery including:

Nanoparticles: Nanoparticles are carriers that are very small (1-1000 nm), which can encapsulate drugs, protect drugs from degradation, enhance solubility, and enable controllable release of therapeutics. These nanoparticles can take several forms including:

Liposomes: Phospholipid vesicles that encapsulate drugs that can reduce drug toxicity, increase circulation time or delivery and have been involved in the controlled delivery of statins, antihypertensive therapies, and thrombolytics.

Polymeric Nanoparticles: Composed of biodegradable polymers (for example, PLGA), these nanoparticles can release drugs in a targeted and sustained manner. For example, polymeric nanoparticles encoding nitric oxide donors have been studied for the treatment of hypertension and atherosclerosis.

Solid Lipid Nanoparticles (SLNs): These lipid nanoparticles improve drug stability and provide a sustained-release mechanism. SLNs can be used to deliver anticoagulants and anti-inflammatory medication in the treatment of CVD.

Dendrimers: Dendrimers are highly branched, nanosized polymers that can provide a controlled and sustained release of drugs, ultimately improving patient compliance.

Dendrimers also provide multifunctionality, whereby multiple anti-atherosclerosis drugs or multiple imaging agents could be attached and/or

delivered for combination therapy and/or diagnostics of the CVD.

Carbon Nanotubes (CNTs): CNTs have the potential for unique new drug carriers due to their high drug-loading capacity to provide targeted delivery of thrombolytic agents to break apart blood clots and ability to be used in gene therapy as a way to deliver RNA-based therapies for heart failure and ischemia.

Microneedle and Transdermal Patches

- Microneedles and transdermal patches can provide a non-invasive, painless, and patient-friendly way of delivering medication instead of oral medication or intravenous injection.
- Enhanced Bioavailability and Sustained Release.
- Microneedles generate micro-channels in the skin that enable the drug to bypass metabolism in the first pass and improve bioavailability.
- Transdermal patches allow for gradual and continuous drug release, avoiding sudden peaks in drug concentration in the blood.

Recent Developments in Cardiovascular Drug Patches:

Hypertension Treatment: Transdermal patches deliver β -blocker medications (e.g., propranolol) providing effective treatment of hypertension and ensuring steady-state concentrations of the medicine, reducing the potential for cardiovascular side effects.

Anticoagulant Drug Patches: A patch that uses an anticoagulant drug, e.g., warfarin or heparin, demonstrates complete control over the anticoagulant drug release over a much longer period than s/c, but the use of the patch reduces frequency of dosing or risk of bleeding.

Nitroglycerine Patches: Nitroglycerine patches can be used clinically in the treatment of angina and provide a steady state release of a vasodilator drug to prevent hypotension that occurs when the drug is ingested too quickly.

Hydrogel-Based Drug Delivery

Hydrogel-based drug delivery is of interest because hydrogels are biocompatible and have a highwater content and controlled-release mechanism. Hydrogel-based systems are ideal for cardiac regeneration and vascular disease.

Biocompatibility and Controlled Drug Release:

- Hydrogels have an improved biocompatibility as a biomaterial because they mimic natural tissue and can function as cardiac tissue engineering, as well as drug delivery systems.
- Hydrogels exhibit stimuli-responsive properties to release the drug (e.g., thermal, pH-responsive) which enable site- specific drug activation.
- Application of Hydrogel-based Drug Delivery in Myocardial Infarction and Atherosclerosis:
- In Myocardial Infarction: Injectable hydrogels can inject growth factors or stem cells where there is ischemia with the therapy to tissue healing.
- In Atherosclerosis: The injectable hydrogel can be designed to contain anti-inflammation drugs (e.g., statins, siRNA) that can be delivered slowly, over time, to mitigate plaque accumulation, resulting in lower potential risk of atherosclerosis and cardiovascular disease.

Implantable and Injectable Systems

There are injectable and implantable drug delivery systems to deliver localized doses of drugs over long periods, to be able to treat cardiac patients.



Drug-Eluting Stents for Coronary Artery Disease (CAD)

Drug-eluting stents (DES) are utilized in coronary artery disease (CAD) and coated with antiproliferative medications (e.g., sirolimus and paclitaxel) for the prevention of restenosis following balloon angioplasty and stent implantation.

Biodegradable stents, which dissolve as the artery is healed via an anti-restenosis process, are in development to lessen the burden of long-term complications from a permanent foreign body.

Biodegradable Implants for Localized Drug Release

Biodegradable implants loaded with antithrombotic or anti-inflammatory medications release medication slowly via the sustained release of an antithrombotic drug to prevent clot formation, or to provide sustained-release injectable gel statins for chronic medical management by delivering statins to the arterial wall of an affected artery.

Smart Drug Delivery Systems

Smart drug delivery systems act as a real-time monitoring system and link to a responsive drug release mechanism, which has potential in improving personalized therapy in patients with cardiovascular disease (CVD).

Responsive Drug Release Mechanisms

pH-Sensitive Drug Release Systems: These systems can release drug in response to acidic conditions which would be present in ischemic heart tissue.

Enzyme-Triggered Drug Release: These systems are designed to release drug based on

increased localized cardiac enzymes in the patient, such as troponin levels in patients presenting to the emergency room for treatment of myocardial infarction

Integration of Wearable Technology for Real-Time Monitoring

Wearable smart patches and implantable sensors can act as a monitoring device and deliver medications to the patient in conjunction with physiologic monitoring (e.g. heart rate, blood pressure, and oxygen levels).

AI algorithms can also provide optimal dosing regimens based on the physiological data obtained from the patient.

Clinical Applications and Future Directions

The development of new drug delivery systems for the management of cardiovascular disease (CVD) have demonstrated significant effectiveness in preclinical and clinical care settings. These innovative delivery technologies are designed to improve therapeutic effectiveness, decrease rate of adverse effects, and facilitate patient adherence (compliance). However, there remain significant challenges related to regulation pathways, manufacturing, and commercialization of novel delivery technologies. The potential exists for future clinical opportunity when NDDS are implemented with personalized medicine in addition too potential use with artificial intelligence that will alter the landscape of CVD therapy.

Recent Clinical Trials and FDA Approved NDDS for CVD

There are multiple NDDS based therapies that have completed clinical trials and have received FDA approval. These technologies include micelle and/or nanoparticle based carriers, implantable



drug delivery systems, and transdermal patches that enhance cardiovascular therapy.

FDA Approved NDDS for the Treatment of CVD

Drug-Eluting Stents (DES)

Sirolimus-Eluting and Paclitaxel-Eluting Stents (Cypher®, Taxus®) were approved to reduce the incidence of stent restenosis in patients with coronary artery disease.

Biodegradable Stents (Absorb GT1 Bioresorbable Vascular Scaffold) provides temporary scaffolding for arteries that incorporates and biodissolves over a period of approximately 12 months.

Nitroglycerin Transdermal Patches

The FDA approved transdermal patches including the Nitro-Dur® which allows for the controlled release of nitroglycerin for the treatment of angina pectoris.

Microneedle-Based Delivery Systems:

Several microneedle patches delivering antihypertensive drugs are in ongoing phase 2 and 3 trials, and aim to supplant oral antihypertensive agents to manage blood pressure effectively.

Lipid-Based Nanoparticle Therapies:

PCSK9 Inhibitors (Inclisiran) - Leqvio® is an approved siRNA delivery lipid nanoparticle therapy for treatment of LDL cholesterol in patients at risk of cardiovascular events.

Ongoing Clinical Trials of NDDS in CVD

- **Hydrogel-Based Cardiac Regeneration** (ClinicalTrials.gov Identifier: NCT03441027): The trial is evaluating injectable hydrogels which contains growth factors and stem cells

for cardiac regeneration in patients with myocardial infarctions.

- **Nanoparticle-Based Anti-Inflammatory Therapy:** Several ongoing trials are evaluating polymeric nanoparticles containing anti-inflammatory drugs for the treatment of atherosclerotic plaque burden and progression.
- **Smart Drug Delivery Devices:** Wearable patches combined with biosensors, or methods of controlled drug release, are in clinical trials to manage hypertension and arrhythmia on a real-time basis.
- While there are promising and developing methods available in NDDS approaches and technologies, there are barriers to overcome in the regulatory approval and the commercialisation process.

Limitations and Challenges in the Regulatory Approval and Commercialization

Stringent Regulatory Requirements

The FDA and EMA have some strict regulations require considerable preclinical and clinical data prior to commercialization to demonstrate safety and efficacy of the drug.

NDDS products should must provide long-term safety evidence especially in the case of cardiovascular applications where these products are typically required to provide long-term drug delivery.

Biocompatibility and Long-Term Implications

Materials, including nanoparticles, hydrogels, and biodegradable implants, need to be biocompatible and free of long-term toxicity.

The concerns include the potential for nanoparticles to accumulate within a tissue and their ability to induce inflammation or cause toxicity to the underlying organ.



Manufacturing and Upscaling Problems

Many NDDS technologies involve complex fabrication processes, which complicate the ability to scale-up manufacturing and create products for the market cost effectively.

Batch-to-batch variation in a nanoparticle and hydrogel formulations may compromise reproducibility and stability.

High Development Costs and Commercial Viability

NDDS-based therapies require considerable research and development (R&D) investment, making them expensive to develop, and cumbersome to commercialize.

Pharmaceutical companies require incentives (i.e., funding support, fast track approval program) to invest in NDDS.

These challenges will need to be addressed through cooperation between regulatory agencies, researchers, and industry partners, in order to successfully transition NDDS into clinical practice.

Future Perspectives: Personalized Medicine and AI-Driven Drug Delivery

The future of drug delivery for cardiovascular medicine is moving toward personalized medicine and the use of AI to drive drug delivery, to precision therapy with every individual patient.

RESULT:

Cardiovascular diseases (CVD) continue to be a major source of morbidity and mortality across the globe prompting the development of drug delivery systems to improve therapeutic effect and patient outcomes. Conventional drug delivery systems,

via oral, intravenous routes, intramuscular routes are limited by poor bioavailability, potential side effects, and adherence. To overcome all these limitations, novel drug delivery systems (NDDS) have been developed which allowed for targeted, controlled, and sustained drug release in cardiovascular diseases (CVD) patients.

Key advancements in NDDS for CVD include:

Nanotechnology-Based Drug Delivery: Liposomes, polymeric nanoparticles, and solid lipid nanoparticles improve drug stability, bioavailability, and targeted delivery.

Dendrimers and carbon nanotubes suggest that they can achieve controlled drug release in addition to cardiovascular gene therapy.

Microneedles and transdermal patches:

Non-invasive technology used to sustain drug release over time to encourage patient compliance was developed.

Transdermal patches for hypertension, anticoagulants, and nitro-glycerine all have strong clinical promise

Hydrogel-based delivery systems:

Biocompatible hydrogels were made to provide localized time-controlled drug release with applications for myocardial infarction repair and atherosclerosis.

Implantable and injectable systems:

Drug-eluting stents produced to prevent coronary artery disease restenosis and biodegradable implanted systems for sustained local drug delivery were produced.

Smart drug delivery systems:



Mechanisms that utilize artificial intelligence are now developed to adapt to a patient's physiological state of the patient by, for example, having controlled release mechanisms, such as pH-sensitive, or enzymatic triggered.

In addition, it could integrate with wearable biosensors to improve personalized cardiovascular therapeutic options. These systems have been clinically translated with promising success, including FDA-approved variants like drug-eluting stents, lipid nanoparticle therapies, and transdermal patches. Regulatory burden, biocompatibility challenges, and expense of development are true barriers to widespread adoption.

CONCLUSION: The drug delivery landscape for cardiovascular diseases (CVD) is evolving at a rapid pace with NDDS. NDDS is crucial to increase the drug efficacy, side effects, and compliance. The increasing number of FDA-approved NDDS, as well as ongoing clinical trials, indicate that progress is being made; however, these still need to overcome challenges related to regulatory approval, commercialization, and scalability. Looking forward, the future of CVD therapies will include the role of AI-enabled drug delivery, as well as personalized medicine and smart nanotechnologies. The emerging use of wearable biosensors and real-time monitoring technologies will ultimately lead to adaptive patient-specific therapy in monitoring patient clinical outcomes and quality of life in CVD patients. Addressing all these challenges and utilizing innovative technologies will position the new drug delivery systems to define the future of cardiovascular medicine in the years to come.

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