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## A NOVEL APPROACH TO TREAT NEUROLOGICAL DISORDER BY USING LIPID-BASED DRUG DELIVERY SYSTEM

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**ABSTRACT:** One in every three people suffers from some kind of neurological disorder. Considering the huge burden of the disease, it is imperative to develop and treat such conditions. Because of time constraints and obstacles, treating neurological disorders remains challenging for medical professionals. The number of new pharmacologically active lipid compounds discovered using current drug development methods is steadily growing, but these compounds are water-insoluble. Having a drug for oral administration with optimal bioavailability was a huge risk. Epilepsy is a serious medical condition that requires immediate treatment. We need to make lipid-based formulations to improve their bioavailability. Surface tension-lowering agents can result in a water-insoluble formulation. Niosomes and nanoparticles will pass freely along the blood-brain barrier. The key goals in the development of nanomedicine are safety, high therapeutic effectiveness, drug targeting to specific locations to avoid off-target toxicity and increased pharmacokinetic behaviour through prolonged drug release with a significant safety margin. As a result, the highest clinical effectiveness can be reached by combining lipid and protein therapies.

**INTRODUCTION:** Neurological disorders are diseases of the nervous system. They include epilepsy, Parkinson's disease, dementia, Alzheimer's disease, multiple sclerosis, stroke, etc., and they are the leading cause of ill health and disability worldwide. Over 1 in 3 people suffer from some form of neurological condition. Disorders of the nervous system are the second leading cause of death globally, accounting for 9 million deaths per year<sup>1</sup>.

Many neurological disorders are being examined for treatment, with most relying on hyper synchronous activation of neurons in the cerebral cortex or a neurochemical imbalance in the brain. Every year, more than 500,000 patients around the world are diagnosed with epilepsy and 80% of these live in low- and middle-income countries<sup>2</sup>. Considering such huge burden associated with these conditions, it is imperative to develop and treat them.

Serotonin, dopamine, adrenaline, acetylcholine, GABA, and glutamate are neurochemicals that are affected in neurologic disorders and play critical roles<sup>3-15</sup>.

**Glutamate:** Glutamate is an excitatory neurotransmitter that promotes hyperactivity in the cortex

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when there is too much of it<sup>16</sup>. It contributes to learning, memory, and synaptic plasticity. It is implicated in neurodegenerative diseases like Alzheimer's and Parkinson's. Dysregulation can lead to disorders like epilepsy, migraines, and mood disturbances.

**GABA:** It's an inhibitory neurotransmitter that decreases neuron activity, resulting in lapses in concentration, mood swings, and drowsiness<sup>16</sup>.

**Serotonin:** 5-Hydroxytryptamine is a substitute for serotonin. It is the pleasure hormone that has a large impact on a person's mood and activities. It controls the brain's autonomic responses, such as body temperature, vasoconstriction, vasodilation, sleep, hormonal control, and the level of serotonin in depression. It's a psychoactive substance that plays a variety of roles in mental illnesses. There are various categories of drugs available to treat such conditions. A drug elicits its pharmacological action when the optimum concentration reaches the site of action rather than other tissues. Concentrations of such medications in places that are not intended lead to toxicities. There are barriers to the transport of drugs to the site of action. One such major barrier is the blood-brain barrier.

**Blood-brain Barrier and Challenges to Delivery of Drugs:** The blood barrier is a protective barrier of the brain that allows the transport of ions, chemicals, and cells between the blood and the brain. It selectively allows certain molecules to enter the brain and restricts others to maintain brain homeostasis. BBB shows selective permeability, i.e., it permits only lipophilic molecules with low molecular weight (less than 400-500 Da) to enter the brain from the bloodstream through the transcellular route. Unfortunately, approximately 98% of small molecules and nearly all large therapeutic molecules (such as monoclonal antibodies, antisense oligonucleotides, or viral vectors) cannot pass through this barrier<sup>17</sup>. Due to the BBB's prohibitive nature, conveying drugs to the brain remains a major challenge. Recent reports suggest that less than 10% of therapeutic agents for neurological diseases enter clinical trials because of poor brain penetration<sup>18</sup>. Because of the molecular mechanism, drug tolerance is high in neurological disorders<sup>19, 20, 21</sup>. Only neurological symptoms can

be cured with a drug that can cross the BBB. The lipophilic molecule with a low molecular weight will easily penetrate or cross the BBB. Transporters play a key role in preventing molecules from reaching the brain. Few transporters, in particular, require therapeutic drug molecules to enter the brain<sup>22-25</sup>. One of the ABC family's most studied BBB transporters is the ATP binding cassette transporter (ABC Transporter) & P-glycoprotein. NRx opioid molecules such as phenytoin, phenobarbital, and levetiracetam can be eliminated by P-glycoprotein<sup>26-28</sup>. Another transporter, known as the solute carrier (SLC) transporter, is found in neurons and contains organic anion transporter. The presence of the BBB and different efflux transporters contribute significantly to the poor penetration of drugs to the brain and contribute to drug tolerance.

Even though many drugs are available to treat such conditions, the protective structural and physiological barriers hinder the delivery of drugs to the target tissue. The development of novel therapeutic strategies also faces obstacles to the delivery of drugs to the central nervous system due to the lack of understanding of the disease biology, low predictive value of animal models, variability in study population, lack of pharmacodynamic markers, and scarce trial-ready patients. Therefore, there is a need for alternative delivery systems that overcome these barriers and obstacles and provide predictable drug delivery<sup>29</sup>. **Fig. 1** represents factors responsible for the low bioavailability of poorly water-soluble drugs.

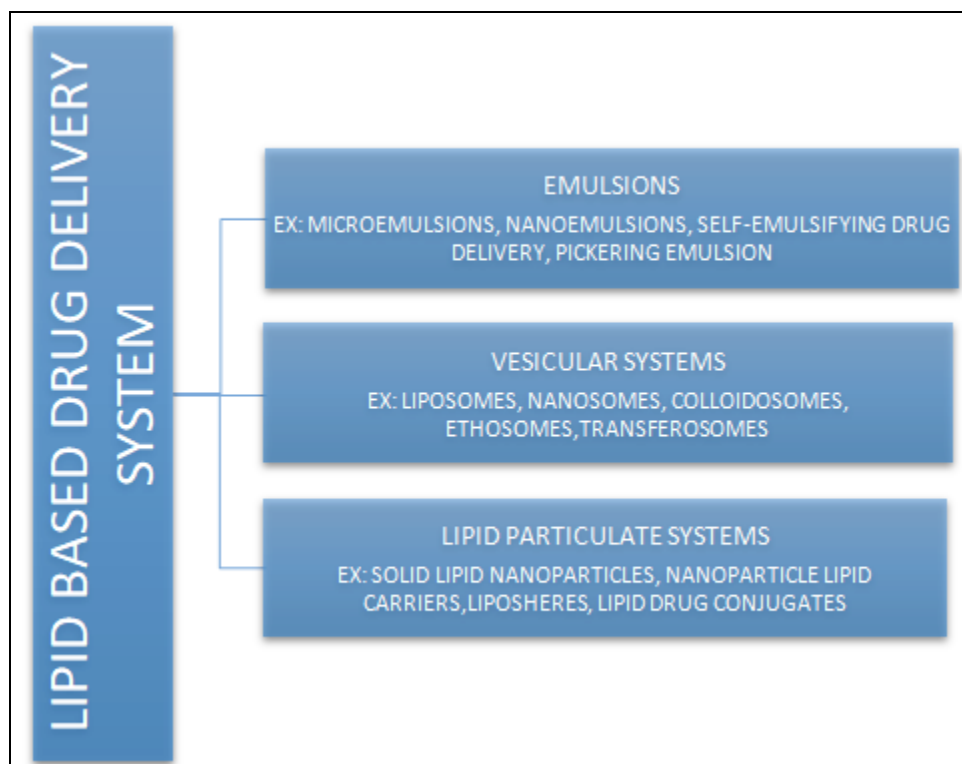


**FIG. 1: REASONS FOR POOR BIOAVAILABILITY OF WATER-INSOLUBLE DRUGS**

**Lipid-based Drug Delivery Systems:** Drug delivery systems are one of the many approaches for accomplishing targeted delivery and controlled release of pharmacological agents in the body. One such targeted delivery system is the Lipid-Based Drug Delivery System (LBDDS). Lipid-based drug delivery systems consist of a various group of formulations, each having different properties that are open to changes achieved by varying the configuration of lipid excipients and other additives, thus increasing the bioavailability of lipophilic drugs. In addition, lipid nanoparticles release the drug slowly from the lipid matrix into circulation, protecting it from enzymatic and chemical degradation thereby improving therapeutic profiles compared to free drugs. Therefore, due to their physiological and biodegradable properties, LBDDS decreases adverse effects and toxicities when compared to others of a polymeric nature<sup>30</sup>. Lipid nanoparticles, liposomes, solid lipid nanoparticles, and non-structured lipid carriers are a few examples of LBDDS. **Fig. 2** represents the different classes of LBDDS. They are promising tools for the treatment

of neurological diseases because of their ability to overcome biological barriers, increase solubility, and provision of targeted drug delivery. They improve drug transport across BBB through passive diffusion, receptor-mediated transcytosis, and adsorptive-mediated transcytosis. They improve drug solubility and stability thereby enhancing bioavailability and drug efficacy. Lipid matrices may provide sustained release of drug, prolonging the duration of action. Some Lipid excipients used in these systems are triglycerides, mixed glycerides, polar oils, cosolvents like ethanol, Polyethylene glycol, and surfactants. Lipid systems inhibit efflux transporters and promote intestinal lymphatic transport. Solid lipid nanoparticles provide improved solubility and stability. Nanostructured lipid carriers are advanced solid nanoparticles which combine both solid and liquid lipids, enhancing drug loading and release<sup>31</sup>.

Polymer nanoparticles are effective in drug delivery, imaging, and therapy. They provide controlled release, targeted therapy, and stability enhancement.



**FIG. 2: TYPES OF LIPID-BASED DRUG DELIVERY SYSTEMS**

**Formulation of Lipid and Polymer Delivery Systems:** SLNs are formulated with solid lipids, emulsifiers, and water/solvents. The lipids used

may be triglycerides (tri-stearin), partial glycerides, fatty acids (stearic acid, palmitic acid), steroids (cholesterol), and waxes (cetyl palmitate). Various

emulsifiers and their combination have been used to stabilize lipid dispersion. Solid lipid nanoparticles (SLN) are colloidal carriers, where the liquid lipid (oil) has been substituted by a solid lipid. SLN offers unique properties such as small size, large surface area, high drug loading, and the interaction of phases at the interfaces. They are more slowly released and elicit superior pharmacological action than the conventional formulations<sup>32</sup>. Their disadvantage is limited drug loading capacity. To increase drug loading capacity and prevent drug expulsion, nanostructured lipid carriers (NLC) were developed.

Drugs showing higher solubility in oils can be dissolved in oil and coated with solid lipid outside which prevents its degradation by formulating it as NLC. Lipid drug conjugates (LDC) are one more form of LBBDS where an insoluble drug-lipid conjugate bulk is first prepared either by salt formation or by covalent bonding. The product is then treated with an aqueous surfactant and homogenized using a high-pressure homogenizer to a nanoparticle formulation. This will increase the drug loading capacity. The accompanying points will help you develop compelling frameworks for the conveyance of lipids and polymers. The main components of the frameworks are formulating frameworks for the separation of lipids and polymers, for example, dissolving point and unsaturated lipids frameworks<sup>33-35</sup>. This ought to be reasonable with API and prepared to additionally foster a definition trustworthiness plan of appropriate animal models to test in vivo execution of the picked enumerating and work on the definition with the suitable prescription stacking and deterioration profile<sup>36, 37</sup>. Careful selection of lipid components, optimization of formulation parameters, and thorough evaluation of toxicity profiles are essential to ensure patient safety. Preclinical studies have demonstrated the feasibility and efficacy of LBBDS in animal models, paving the way for clinical trials in humans.

**Silica-Based Materials for Solid Carriers:** Silica-based items have customarily influenced the conveyance of lipids and polymers. Silica is an exceptionally critical excipient that expands surface region and lifts drug absorbance. Mesoporous materials incorporate MCM-41 and SBA-15.

Silica-based materials have provoked specialists' curiosity as conveyance instruments for a wide scope of hydrophilic and hydrophobic medication substances<sup>36</sup>. The organic attributes of silica-based materials make it successful in streamlining the disintegration paces of medication and oral assimilation of medication by different instruments, including (i) safeguarding medication particles in the microscopically scattered (for example indistinct) structure, (ii) keeping the medication in touch with the strong surface and equilibrium intermolecular collaborations in watery media since silica-based materials are hydrophilic (iii) It works with drug assimilation by permitting supersaturated medication solubilization<sup>37, 38</sup>.

**Challenges in Lipid and Polymer Delivery Systems:** The ability to control the movement of the drug in the brain could help improve its penetration. This system could be used for the treatment of various neurological conditions. Due to the higher benefits of lipid and polymer delivery systems, they are leading from the front<sup>39-43</sup>. Various biocompatibility and bio-economic factors help deliver better formulations for a variety of products. Delivery systems such as polymers and lipids have been studied to improve drug solubility and bioavailability. They have low cost, fewer side effects, and are more convenient for patients. The development of LBBDS has led to the discovery of new drug molecules with promising potential. However, the key issue is that these new drugs have high molecular weights and are classified as biotherapeutics under the BCS-II classification system<sup>44-47</sup>. The lack of dissolved oxygen and low solubility of drugs are known to have a negative effect on the absorption and dissolution properties of tablets. This impairs the drug's ability to provide a high level of oral bioavailability<sup>48-54</sup>. A small number of drugs can improve the bioavailability of many drugs. However, to develop effective and safe drugs, the developers must first find ways to minimize toxicity and body disposition issues.

The bioavailability of orally regulated medications is tested by these two qualities. The items, then again, have low solvency, which brings about helpless disintegration and ingestion properties<sup>55-59</sup>. The atoms' feeble solvency brings about low oral bioavailability, yet in addition in high between and intracellular inconstancy, and an absence of

portion reactions. At the point when given food, few medications can further develop bioavailability<sup>60-64</sup>. To foster such medications that are both viable and safe, we should find some kind of harmony between bioavailability, body demeanor, and poisonousness. Micronization, complexation with cyclodextrins, strong scatterings, surfactants, and pervasion enhancers are a portion of the strategies that have been recognized to handle penetrability and dissolvability issues<sup>65-74</sup>.

**Assessment of Safety and Toxicity Concerns of Delivery Systems in Neurological Disorders:** The utilization of novel materials for lipid and polymer conveyance frameworks would hold an assortment of administrative difficulties, including guaranteeing biocompatibility and human well-being. Although oral organization is viewed as more secure than different types of organization (for example parenteral), Because of ongoing progressions in the field of nanomedicine, administrative organizations have set a more noteworthy accentuation on the assurance of nanostructured materials<sup>75, 76</sup>.

For instance, repurposing existing and bio-compatible excipients like montmorillonite starch and carbonate salts for cementing lipid and polymer conveyance frameworks faces insignificant administrative obstacles when seeking advertising endorsement. Lipid and polymer conveyance frameworks are a minimal-expense, biocompatible way to deal with growing new neurologic treatments<sup>77-79</sup>.

**CONCLUSION:** Lipid and polymer conveyance frameworks intend to develop the bioavailability of ineffectively water-dissolvable medications further while reducing costs. Both hydrophobic and hydrophilic medications can be conveyed utilizing lipid and polymer conveyance frameworks. Lipid and polymer conveyance frameworks, for example, silica-based, work on the district of assimilation of medications, bringing about more advantageous ingestion. On the off chance that the medication is caught up in the ideal way, the penetrability and smooth transportation of the medication through the obstructions would be satisfactory. There are some administrative obstructions to survival, however, when they are survived, the ideal restorative activity can be accomplished with less

mischief and prescription waste. The medication's biopharmaceutical effectiveness is improved by lipid and polymer conveyance frameworks.

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