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Review Paper

Transdermal Patches: Novel Carriers and Drug Delivery

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ABSTRACT

Transdermal drug delivery systems (TDDS), particularly transdermal patches, have gained significant attention as a non-invasive, patient-friendly approach to systemic drug administration. These systems offer numerous advantages over traditional oral and parenteral routes, including improved patient compliance, sustained drug release, avoidance of first-pass metabolism, and reduced dosing frequency. This review provides an in-depth overview of transdermal patch , focusing on formulation, benefits methods The use of Chemical Enhancer, Iontophoresis, Electroporation, Microneedles, in overcoming the stratum corneum barrier is critically discussed. Additionally, the review highlights types of transdermal patches along with it's basic components and factors affecting Transdermal Drug Delivery. Criteria of drug selection. Overall, this paper aims to offer a comprehensive understanding of the evolving landscape of transdermal drug delivery and its potential to transform future pharmaceutical care.

INTRODUCTION

Controlled release medication may be defined as the permeation-moderated transfer of an active material from a reservoir to a target surface to maintain a predetermined concentration or emission level for a specified period of time. Transdermal drug delivery system can be defined as the controlled release of drugs through intact skin. Controlled release technology has received increasing attention in the face of a growing awareness that substances are frequently toxic and sometimes ineffective when administered or applied by conventional means. The transdermal route now ranks with oral treatment as the most successful innovative research area in drug delivery, with around 40 % of the drug delivery candidate products under clinical evaluation related to transdermal or dermal system

A transdermal patch is a medicated adhesive patch placed on skin to deliver a time released dose of medication through the skin for treating topical or systematic illness. Since early 1990, this dosage form of transdermal therapeutic system has been available in the pharmaceutical market.1 A recent approach to drug delivery is to deliver the drug into

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systemic circulation at predetermined rate using skin as a site of application. A transdermal drug delivery is a formulation or device that maintains the blood concentration of the drug within therapeutic window ensuring that drug levels neither fall below the minimum effective concentration nor exceed minimum toxic dose.2 Such a system offers variety of significant clinical benefits over other systems, such as tablet and injections. For example, it provides controlled release of the drug and produces a steady blood-level profile leading to reduced systemic side effects and, sometimes, improved efficacy over other dosage form. In addition transdermal dosage form is user-friendly, convenient, painless, and offers multi-day dosing, it generally leads to improved patient compliance.3 It offers many important advantages over oral drug delivery, e.g., gastrointestinal and hepatic first pass metabolism, reduces variation in delivery rates, avoids interference due to presence of food, controls absorption rate, suitable for unconscious patients, and enables fast termination of drug delivery, if needed.

Criteria of Drug to be candidate for Transdermal Drug Delivery

Basically, not every drug or chemical is a candidate for transdermal drug delivery. The choice of drug is the most important decision in the successful development of a transdermal product. The most
important drug properties that affect its diffusion through the devices as well as the skin include molecular weight, chemical functionality and melting point. It is generally accepted that the best drug candidates for passive adhesive transdermal patches must be nonionic, low molecular weight (less than 500 Daltons), have adequate solubility in oil and water (log P in the range of 1 to 3), a low melting point (less than 200 °C), short plasma half-life, and are potent (dose is less than 50 mg per day, and ideally less than 10 mg per day). Given these operating parameters, the number of drug candidates for passive transdermal patches is low, owing to the challenge of diffusing across the bilayers in the tortuous stratum corneum. But, many new opportunities still exist for novel passive transdermal patch products. The new transdermal technologies that were introduced in the previous section challenge the paradigm that there are only a few drug candidates for transdermal drug delivery. With the active and micropore-creating transdermal technologies, molecular size is not a limiting factor. The same applies for other physiochemical drug properties, such as ionization state, melting point, and solubility. Finally, the active and micropore-creating technologies also enable therapeutic delivery of drugs at doses higher than 10 mg. Clearly, the opportunities for transdermal drug delivery have been greatly expanded through the application of new formulation technologies and active delivery systems. Now, a much wider set of drug compounds, including macromolecules, have the possibility to be delivered transdermally at therapeutic levels than was possible just a decade ago. Of course, the use of a TDD technology for any drug must be clinically beneficial.

Factors Affecting Transdermal Drug Delivery

Apart from minor factors such as individual variations, age, site of application, occlusion, temperature, race, and disease states, there are other physical related factors that affect the permeation of drugs through the skin as described in the Fick's equation:

$dQ/dt = ÞCDA/l$

Where, dQ/dt is the rate of drug penetration, Þ is the partition coefficient between stratum corneum and vehicle, C is the concentration of drug in the vehicle, D is the average diffusion coefficient, A is the surface area of application of the drug, l is the thickness of the skin barrier.

(a) Partition Coefficient: For an individual drug, this is measured as the octanol-water ratio (or log P). It is a measure of lipophilicity verses hydrophilicity. In skin permeation studies, the steady-state rate of permeation across the skin can be expressed by the equation below:

$dQ/dt = Ps(Cd-Cr)$

Where *Cd* and *Cr* are, respectively, the concentration of drug in the donor compartment and in the receptor compartment and *Ps* is the permeability coefficient of the skin defined by the equation below:

$Ps = Ks.Ds/h$

Where *Ks* is the partition coefficient for the interfacial partitioning of the drug from the device (vehicle) to the skin, *Ds* is the diffusivity of the drug through the skin, h is the thickness of the skin.

(b) Diffusion

This is the process by which a substance moves from one area to another. It is driven by thermal agitation and requires a concentration gradient. In other words, the area that a substance is going to must have a lower concentration of the drug than the area it is coming from. Lipophilic substances diffuse easily through stratum corneum lipids, but have much more difficulty with the aqueous layers below. If transport slows too much in any layer of tissue (example, stratum corneum, epidermis, dermis) diffusion slows, causing a build up in the outer layers.

(c) Concentration

This is the amount of substance per unit volume of vehicle. The importance of solubility is the reason a solvent carrier is typically used despite its reduction in partition coefficient. For example, corticosteroid's partition coefficient is reduced twofold by the addition of 50 % ethanol to saline, but its solubility is increased 100 fold, giving a 40 fold penetration enhancement. The solubility issue can become a problem if the vehicle evaporates before the drug has fully partition into the skin, causing precipitation. Thus, it is necessary to also incorporate a small amount of a less volatile solvent such as fatty acid, terpenes, isopropyl myristate into a transdermal formulation.

(d) Surface Area

Large surface area of contact between the drug formulation and the stratum corneum exposes more drug molecules to the lipid skin layer and so increases the rate of drug permeation.

Types of Transdermal Patches

1. Single-layer drug –in-adhesive
2. Multi-layer drug-in-adhesive
3. Drug reservoir-in-adhesive
4. Drug matrix-in-adhesive

Basic components of transdermal systems

1. Polymer matrix
2. Rate controlling membrane
3. Adhesive
4. Release liners
5. Backing laminate
6. Penetration enhancers
7. Drug
8. Plasticizers and solvents

Benefits of transdermal drug delivery systems

1. Provides safe, convenient and pain less self administration systems for patients
2. Beneficial for patients on polymedication
3. Provide constant rate of drug release
4. Bypass metabolic problems like presystemic metabolism thereby improves therapeutic efficacy
5. Decreases dosing frequency of the drug
6. Very helpful in long term treatment regimes

Method of Transdermal drug delivery

(a) Use of Chemical Enhancers

The enhancement of skin has been tested with water, surfactants, essential oils, dimethyl sulfoxide (DMSO), and alcohols. Barry and coworkers proposed the lipid-protein partitioning (LPP) theory to describe how enhancers affect skin permeability. By disrupting the intercellular bilayer lipid structure and interacting with intracellular proteins of the stratum corneum, chemical enhancers improve the partitioning of a drug, coenhancer, or cosolvent into the stratum corneum.

One of the safest and most widely used chemical enhancer to increase permeation is water. It is hypothesized that the increased hydration of the skin may lead to swelling and to the opening of the structure which can increase permeation. Other types of enhancers have shown increase in permeability by disordering the lipid structure of the stratum corneum. The diffusion coefficient of the drug is increased as microcavities are formed in the lipid bilayers. In other cases, enhancers can create permeable "pores" that provide less resistance for polar molecules. Penetration of chemical enhancers has also been found to interact with the keratin in the corneocytes. The surfactants interact and bind with keratin to disrupt the order within the corneocytes thereby diffusion coefficient. One of the major side effects of chemical enhancers is irritation to the skin at potent levels, which is not surprising since the chemicals disrupt organized lipid structures, cell membranes, and their components. The toxicity associated with many enhancers have limited their usefulness in clinical applications, however there has been a move towards investigating potential generally regarded as safe (GRAS) enhancers by the FDA, such as essential oils and terpenes.

(b) Iontophoresis

This method of transdermal drug delivery involves low level electric current applied either directly or indirectly to the skin in order to enhance its permeation. The electrical charge primarily drives drug molecules through the skin via sweat ducts since they provide less electrical resistance than the stratum corneum. The reason for the increased permeation can be attributed to one or all of the following: electrophoresis (for charged solutes), electro-osmosis (for uncharged solutes), and electropertubation (for both charged and uncharged solutes). Electrophoresis drives charge molecules across the skin by direct interaction with the applied electric field, therefore small highly charged particles are delivered more rapidly. In electroosmosis, the delivery of molecules occurs as they are dragged by the electrically induced solvent flow. The flow of the solvent is induced by the net flux of cations from the anode to the cathode. The electroosmotic flow of water is generated by the preferential movement of mobile cations in the cells (i.e. Na+) instead of fixed anions proteins in the skin.

Typically, a few milliamperes of current are applied to a small area of the skin, generating no pain beyond mild erythema. The PhoresorTM was the first iontophoretic system approved by the FDA in the late 1970s as a therapeutic device. Currently, iontophoretic systems are approved for administering drugs into the body for specialized medical purposes, such as diagnosis of medical conditions and glucose monitoring. Despite the straight forward application, many parameters can affect the design of an iontophoretic device, including but not limited to electrode type, current intensity, pH of system, and competitive ion effect. Currently, there are many requirements for a successful iontophoretic device. For example, the device must: (1) be sufficiently high powered to provide desired delivery rate; (2) not produce any permanent harmful effects on skin permeability; (3) establish proportionality between flux and

applied current/voltage; and (4) maintain constant current/voltage over time. In addition, iontophoresis is limited by the electric current that can be used on humans (regulated at 0.5mA/cm2)

(c) Electroporation

This method of transdermal delivery is similar to iontophoresis, in which it uses electrical current to aid the delivery of drug molecules through the skin. In the case of electroporation, extremely high voltage pulses, rather than milliamperes of current, are used to induce skin perturbation. The high voltage creates transient pores which may account for the skin permeability. The increased skin permeability is related to the electroporation process, which is the formation of aqueous pathways across the lipid bilayer by a pulsed electric field. This technology can enhance the skin permeability to molecules of greater hydrophilicity and sizes compared to other methods. High voltages (≥100 V) over short durations (milliseconds) are normally applied. The pulses can be administered painlessly using closely spaced electrodes to minimize the electric field in the nerve-free stratum corneum. With the application of high voltages, transdermal transport can be reduced to a few seconds opening opportunities for rapid-response delivery systems. Transdermal transport has been shown to increase by orders of magnitude with partial to full reversibility within minutes to hours. However, with the use of high voltage, there is a greater chance of cell damage if the pulses duration or intensity is too great. In addition, electroporation requires specialized and cumbersome equipment.

(d) Microneedles

This method of transdermal drug delivery involves piercing the skin with very short needles. Solid microneedles (~50-100µm) encapsulated or coated with drug formulations for controlled or rapid release. Microneedles increase permeability and delivery of drugs transdermally by creating micron-scale pathways into the skin, driving drugs into the skin as coated cargo. Their effects are targeted in the stratum corneum, although they do pierce across the epidermis and into superficial dermis. Microneedles treatment have been reported to be painless by volunteers and generally well tolerated. This technique has great promise because they appear to be capable of delivering a broad range of drugs. A notable limitation is the diffusion rate of large compounds through micron-scale pathways. When rapid delivery is required, it may be necessary use an additional force to drive the drugs into the skin.

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