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(REVIEW ARTICLE)

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Use of transdermal patch insulin in Diabetes Mellitus: A comprehensive review

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Abstract

Diabetes mellitus, a widespread metabolic disorder, necessitates effective glycemic control strategies. Traditional insulin therapies, primarily via subcutaneous injections, present challenges including discomfort, poor compliance, and inconsistent absorption. Transdermal drug delivery systems (TDDS) provide an innovative, non-invasive approach to administer insulin, offering improved patient compliance and controlled release profiles. This review explores the formulation, mechanism, advantages, and limitations of insulin-loaded transdermal patches, current advancements in the field, and future prospects in transforming diabetes management.

Keywords: Diabetes Mellitus; Transdermal Insulin; TDDS; Non-Invasive Delivery; Insulin Therapy; Microneedles

1. Introduction

Diabetes mellitus (DM) is one of the most prevalent chronic diseases globally, with its incidence rising steadily due to lifestyle changes, urbanization, and genetic predisposition. Effective glycemic control is essential to prevent long-term complications such as nephropathy, neuropathy, and cardiovascular diseases. While insulin therapy remains central to managing type 1 diabetes and advanced type 2 diabetes, conventional delivery through injections is associated with compliance issues. The emergence of transdermal delivery systems marks a shift toward less invasive and more acceptable therapeutic modalities.

2. Pathophysiology of Diabetes Mellitus

DM is characterized by impaired glucose metabolism due to insufficient insulin production (type 1), resistance to insulin action (type 2), or both. The chronic hyperglycemia seen in DM leads to oxidative stress, inflammation, and endothelial dysfunction, contributing to its multi-systemic complications. Tight glycemic control is paramount and is achieved through diet, exercise, oral antidiabetic drugs, and insulin.

3. Drawbacks of Conventional Insulin Therapy

Subcutaneous insulin injections, while effective, suffer from several limitations:

- Needle phobia and discomfort
- Risk of infections, especially with repeated use
- Hypoglycemia due to improper dosing
- Inconsistent absorption based on injection site and technique
- Poor adherence to therapy

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These challenges have prompted the exploration of alternative delivery systems that can enhance patient comfort and improve therapeutic outcomes.

4. Overview of Transdermal Drug Delivery Systems (TDDS)

TDDS are designed to deliver drugs across the skin barrier and into the systemic circulation at a controlled rate. The skin, however, presents a formidable barrier, particularly the stratum corneum. Successful transdermal systems employ various methods to enhance permeability, including chemical penetration enhancers, microneedles, iontophoresis, sonophoresis, and the use of nanocarriers. These systems can be categorized into passive and active delivery systems.

5. Insulin-Loaded Transdermal Patches: Formulation and Mechanism

Formulating insulin patches requires careful consideration of insulin's stability and permeability. A typical transdermal patch consists of:

- A backing layer that protects the patch from the environment
- A drug reservoir containing insulin, often embedded in a polymer matrix
- A rate-controlling membrane
- An adhesive to attach the patch to the skin

Upon application, the insulin diffuses through the skin layers, either by passive diffusion or enhanced by physical methods such as microneedles or iontophoresis.

6. Emerging Technologies in Transdermal Insulin Delivery

Several advanced technologies have been developed to overcome the challenges associated with delivering insulin transdermally:

- Microneedle Arrays: These microscopic needles painlessly pierce the stratum corneum to deliver insulin directly into the dermis.
- Nano-carriers: Liposomes, ethosomes, and nanoparticles encapsulate insulin and facilitate its transport across the skin.
- Iontophoresis and Sonophoresis: Utilize electric current and ultrasound respectively to enhance permeability.
- Glucose-responsive Patches: Designed to release insulin in response to elevated glucose levels, mimicking pancreatic function.

7. Advantages of Transdermal Insulin Patches

- Improved patient adherence due to non-invasive application
- Reduced fluctuations in plasma insulin levels
- Minimization of hypoglycemic events
- Lower risk of infections and skin irritation compared to injections
- Enhanced quality of life, especially for pediatric and geriatric populations

8. Challenges and Limitations

- The stratum corneum significantly limits insulin permeability
- High molecular weight of insulin requires enhancement techniques
- Skin irritation or allergic reactions may occur
- High development and manufacturing costs
- Regulatory approval and scalability challenges

9. Preclinical and Clinical Studies

Animal and early human studies have shown promising results in achieving therapeutic insulin levels using transdermal patches. For instance, microneedle patches demonstrated sustained insulin release and effective glucose control in

diabetic rat models. Some human trials with glucose-responsive patches have shown positive results in small cohorts, paving the way for large-scale studies.

10. Future Perspectives and Innovations

Research is ongoing to develop wearable biosensor-integrated patches that can continuously monitor glucose levels and deliver insulin accordingly. Artificial pancreas concepts combining continuous glucose monitors with transdermal insulin systems are under active development. Biodegradable microneedles and personalized patches tailored to individual needs are likely to become available in the near future.

11. Conclusion

Transdermal insulin patches represent a revolutionary step forward in diabetes care. While there are still significant challenges to be addressed, the potential benefits in terms of patient comfort, compliance, and glycemic control are substantial. Continued research and technological refinements are expected to bring these systems into mainstream clinical use.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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