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A SYSTEMATIC REVIEW ON MUCOADHESION A NOVEL DRUG DELIVERY SYSTEM

Moonmoon Banerjee, Shweta Kumari * and Shruti Rathore

Department of Pharmaceutics, LCIT School of Pharmacy, Bilaspur - 495223, Chhattisgarh, India.

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Correspondence to Author:
Shweta Kumari

Assistant Professor,
Department of Pharmaceutics,
LCIT School of Pharmacy, Bilaspur - 495223, Chhattisgarh, India.

E-mail: Shweta.kumari@lcit.edu.in

ABSTRACT: The phenomenon known as mucoadhesion is characterized by interfacial molecular attractive forces between a natural or synthetic polymer and the surface of a biological membrane. This allows the polymer to stick to the membrane's surface for a prolonged period of time. The idea of mucoadhesion has garnered significant attention in many pharmaceutics sectors during the past forty years. The mucoadhesive buccal drug delivery system has numerous benefits that make it a unique drug delivery method for both local and systemic administration of different medications. The primary benefit of using this route for medication administration is that it avoids the initial metabolic stage of many methods circumvents the first pass metabolism of a number of medications that are susceptible to their first pass metabolism in the liver. Mucoadhesive drug delivery system contacts with mucus layer and generally increases the retention time of the dosage form at the specific site of absorption. The structural characteristics of the mucosa, the mechanism of mucoadhesion, various theories of mucoadhesion, are briefly discussed in this review to provide a brief overview of mucosal drug delivery.

INTRODUCTION:

Mucoadhesive Drug Delivery System: Mucoadhesive Drug Delivery Systems adhere to the mucosa layer and mucin molecules on the epithelial surface of the mucosa in order to increase the duration of time it takes for the medication to reach the absorption site. The drug that is designed for local effect or has the highest absorbency in the gastrointestinal tract requires a longer period of time to remain in the gastrointestinal tract.

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Mucoadhesive dosage forms are effective in enhancing both drug plasma concentration and therapeutic activity. The mucosal membrane is a greatlocation for administering drugs because it is easily accepted and applied. This is particularly valid for drug delivery systems that have mucoadhesive properties, as they release the drug by sticking to the mucous membran.

Initial metabolism in the liver, enzymatic degradation, difficulties with swallowing, and so on. Mucoadhesive delivery systems offer numerous advantages compared to conventional oral controlled release formulations.

Mucoadhesion / Bioadhesion: Early in the 1980s, controlled release medication delivery systems introduced the idea of mucoadhesion.

The process of two materials (at least one of which is biological) being held together for an extended length of time by intermolecular forces is called bioadhesion.

When an adhesive sticks to mucus or the mucous membrane, this process is known as muco-adsorption. Because these delivery systems can maintain a high drug concentration gradient throughout the epithelial system and extend the drug's residence time, they have been thoroughly studied in the pharmaceutical industry. The degree of bonding between the mucus surface and the drug-containing polymer is increased by muco-adhesion.

Advantages of the Mucoadhesive Drug Delivery System:

1. Drugs skip first-pass metabolism, which enhances bioavailability.
2. The drug is easily provided as therapy in an emergency situation.
3. Some medications that are not stable in the acidic environment of the stomach can be supplied by buccal administration.
4. Drug release throughout time.
5. In this system, drugs are absorbed through passive diffusion.
6. Adaptability in actual state, shape, size, and surface.

Mechanism of Mucoadhesion:

Contact Stage: This stage involves the interaction of the mucoadhesive polymer with the mucous membrane, where the formulation spreads and swells, allowing it to deeply engage with the mucus layer.

Consolidation Phase: This stage involves the activation and bonding of mucoadhesive material. The mucoadhesive substances become active when exposed to moisture. The presence of moisture softens the system which enables the mucoadhesive molecules to detach and join together through weak vander waals and hydrogen bonds.

Mucoadhesion Theories: An abundance of theories have been put forth to attempt to explain the mechanism underlying the complex process of muco-adhesion. These theories consist of:

Wetting Theory: The wetting theory is relevant to liquid systems that. Show a current attraction to the surface inorder to cover it. This connection can be identified through the use of measurement methods.

Like the contact angle. Overall, the rule dictates that if the contact angle is decreased, there will be a higher affinity. The contact angle should be zero or very close to zero to ensure sufficient ability to spread easily.

Diffusion Theory: According to diffusion theory, the strength of the adhesive force rises in proportion to the depth of penetration of the polymer chains. The rate of penetration is contingent upon factors such as the diffusion coefficient, flexibility, characteristics of the muco-adhesive chains, mobility, and duration of contact. The extent to which polymer and mucinchains can penetrate can be determined using the following equation

$$1 = (tDb)1/2$$

Where t is the contact time and Db is the diffusion coefficient of the muco-adhesive material in the mucus.

Mecanical Theory: According to mechanical theory, adhesion results from a mucoadhesive liquid filling in the imperfections on a rough surface. Furthermore, this kind of roughness expands the interfacial region that is accessible for interactions, therefore helping to dissipate energy and is arguably the process's most significant phenomenon.

Electronic Theory: In this theory, both mucoadhesive and biological components have opposite electrical charges and due to this when both materials come into contact electron transfer to form a double electronic layer which indicate the strength of mucoadhesive bond.

Adsorption Theory: According to the adsorption theory, the mucoadhesive device binds to the mucus layer by hydrogen bonds results in complete mucosal adherence.

Fracture Theory: This is the most widely recognized explanation based on mechanical measurements of mucosal adherence. It defines the link between the forces required to separate polymers from mucus and the strength of the adhesive bind. Work fracture is observed to be great when network strands are longer, or cross-links are weak.

Factors Affecting of Mucoadhesion: There are following types of factors are affect on muco-adhesion**:**

1. Polymer Related Factors:

A. Molecular weight

B. Concentration of active Polymer

C. Spatial confirmation

2. Environment Related Factors:

A. pH

B. Applied strength

C. Initial contact time

D. Selection of model substrate

3. Physiological Variables:

A. Mucin turnover

B. Disease status

Mucoadhesive Dosage Forms:

Tablet: Small, flat, and oval, tablets typically have a diameter of around 5–8 mm. Mucoadhesive tablets, unlike traditional tablets, allow for drinking and talking without causing significant discomfort, as they soften, adhere to the mucosa, and remain in place until they dissolve or release their contents. Generally, mucoadhesive tablets have the potential for use in controlled release drug delivery. However, combining mucoadhesive properties with tablets offers additional benefits, such as efficient absorption and improved bioavailability of drugs.

The high surface to volume ratio allows for closer contact with the mucus, making mucoadhesive tablets suitable for adherence to various mucosal tissues, including those in the stomach. This provides opportunities for both localized and systemic controlled release of drugs. Applying mucoadhesive tablets to the mucosal tissues of gastric epithelium is a common method for administering drugs for localized effects. Mucoadhesive tablets are popular due to their extended drug release, which reduces the frequency of drug administration and enhances patient compliance. However, a major limitation of mucoadhesive tablets is their lack of physical flexibility, which can result in poor patient compliance for long-term and repeated use.

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Patch: Patches are laminates made up of an impermeable backing layer, a drug-containing reservoir layer that releases the medicine in a regulated manner, and a mucoadhesive surface for attachment. Patch systems are comparable to those used for transdermal medicine delivery. Solvent casting and direct milling are two processes for preparing adhesive patches. The intermediate sheet from which patches are punched is made using the solvent casting process, which involves casting a solution of the drug and polymer(s) onto a backing layer sheet and then letting the solvent evaporate. The direct milling process involves homogeneously mixing formulation elements and compressing them to the required thickness before cutting or punching out patches of a particular size and shape.

Gels and Ointments: Semisolid dose formulations, such as gels and ointments, offer the benefit of being easily dispersed throughout the oral mucosa. Semisolid dose forms may not provide accurate

drug dosing compared to pills, patches, or films. Poor gel retention at the place of application. has been overcome with the use of mucoadhesive compositions. Certain mucoadhesive polymers, such as sodium carboxymethylcellulose, carbopol, hyaluronic acid, and xanthan gum, undergo a phase transition from liquid to semisolid. This shift increases viscosity, resulting in the sustained and regulated release of medicines. Hydrogels are also a viable dose option for buccal medication administration. Polymers are hydrated in an aqueous environment and entrap drug molecules for delayed release through diffusion or erosion. Mucoadhesive gels offer long-lasting oral retention, effective medication penetration, and excellent patient acceptance. Adhesive gels are commonly used for delivering medicinal ingredients to treat periodontitis, an inflammatory condition.

Mucoadhesive Polymers: The Greek words "poly," which means numerous, and "meros," which denotes components or molecules, are the sources of the word polymer. Due to their special qualities, polymers compounds with large molecular weights made up of "monomers" are utilized in new drug delivery systems (NDDS). Polymers are the primary tool utilized in new drug delivery systems (such buccal drug administration systems) to control and prolong medication dose release.

Additionally, mucoadhesive polymers are employed in matrix devices, in which the medicine is placed within a polymer matrix that regulates the drug's release time. The core layer or the rate-controlling layer of the mucous membrane then allows the medicine to be released. One of the most crucial steps in creating a bucco-adhesive dosage form is choosing and analyzing the ideal bioadhesive polymer for the formulation. The oral drug administration is greatly enhanced by the use of bioadhesive polymers that cling to mucin and are effective.

Characteristics of an ideal muco-adhesive polymer:

- The polymer and its degradation products should be non-toxic.
- It should adhere quickly to moist tissue surface.
- The polymer must not decompose on storage or during the shelf life of dosage form.
- The polymer should be economic and easily available in the market.
- It should be inert and compatible with environment.
- It should form a strong non-covalent bond with the mucin-epithelial cell surfaces.

Advantages of Muco-adhesive Polymers:

- Provide prolong duration of action
- Reduce side effects
- Improve patient compliance
- Decrease dose frequency
- Localized delivery

Disadvantages of muco-adhesive polymers:

- Exhibit dose dumping effect
- Non-uniform distribution
- Cost effective

Mechanism of drug release from polymer:

Degradation: Biodegradable polymers undergo degradation as a natural biological process within the body. Following the release of the active components, the body removed them without altering bodily functions.

Diffusion: When a drug diffuses, it moves from the polymer matrix into the surrounding environment, which is the body.

Swelling: When dried polymers containing drugs are immersed in bodily fluids, the polymers swell and release the medication.

Classification of Mucoadhesive Polymers:

Based on Origin: Polymers of cellulose, polymers of acrylic acid, polymers of hydroxyethyl methylacrylate, polymers of ethylene oxide, polymers of vinyl pyrrolidone, and polymers of vinyl alcohol. Natural mucoadhesive polymers include chitosan, tragacanth, guar gum, Xanthan

gum, Sodium alginate, soluble starch, gelatin, pectin, and guar gum.

Based on Nature: This category's polymers are soluble in water. These polymer-developed matrices swell when placed in an watery media with the matrix dissolving later on. Greater mucoadhesive property is extended by the polyelectrolytes. For mucoadhesive qualities, other materials such as poly(vinyl alcohol), poly (vinyl pyrrolidone), hydroxypropyl methyl cellulose, and methyl cellulose have also been employed.

Polysacchrides and its Derivatives: Xanthan gum, gellan gum, guar gum, carrageenan, methyl cellulose, hydroxy propyl methylcellulose, hyaluronic acid, and several other polysaccharides and their derivatives have been used in ocular mucoadhesive delivery systems. It has been observed that cellulose and its derivatives possess surface active properties in addition to their ability to form films. In ocular administration systems, cellulose derivatives with lower surface acting properties are typically selected because they cause less irritation to the eyes. Sodium carboxymethyl cellulose has been discovered to have the best ocular mucoadhesive properties among the several cellulose derivatives. To create sustained delivery systems, cationic cellulose derivatives, such as cationic hydroxyethyl celluloses, have been combined with a variety of anionic polymers.

Hydrogels: Hydrogels are composed of polymer chains that are cross linked in three dimensions and possess the capacity to retain water due to their porous structure. The fundamental reason hydrogels can hold water is because they include hydrophilic functional groups, such as carboxyl, amino, and hydroxyl groups. Besides the drug targeting, mucoadhesive hydrogel-based formulations are used to increase the medication's bioavailability that is poorly soluble in water. This was explained by the delivery system's longer retention period in the digestive tract.

Impact of Physicochemical Properties on the Clinical Stability and Efficacy of Microemulsions: The stability of parenteral emulsions is crucial for their safe administration into the body. Instabilities in these emulsions, such as droplet aggregation and separation, are significantly influenced by their physicochemical properties. These properties include the composition and concentration of hydrophilic and hydrophobic components, surface tension, pH, degree of dissociation, droplet size, and the electrical charge on the droplet surface, along with their interactions.

The zeta potential, which reflects the surface electrical charge of the emulsifier, plays a key role in emulsion stability. A higher zeta potential increases electrostatic repulsion between droplets, thereby enhancing stability. Conversely, lower zeta potential can lead to instability. Additionally, high surface tension indicates a well-dispersed emulsion with stable oil droplets. Among these factors, droplet size is particularly critical; larger droplets pose risks such as embolism and reduced stability in the bloodstream, making them undesirable.

Research has demonstrated the relationship between physicochemical properties and the clinical performance of microemulsions. For example, stable emulsions of paclitaxel were successfully prepared using lecithin-sodium deoxycholate with polyethylene glycol further enhancing stability in plasma. Lecithin concentration was shown to improve emulsion stability, affecting both zeta potential and droplet size. The choice of emulsifiers and their impact on droplet size, influenced by pH, has also been explored, revealing important correlations between these properties and emulsion performance. Studies on phosphatidylcholine emulsions with purified egg yolk lecithin have highlighted the importance of droplet size in maintaining stability.

Future Directions: Microemulsions have diverse applications including targeted drug delivery, sustained and controlled drug release, enzyme immobilization, enhancing bioavailability, and taste masking. Since hydrophilic drugs can be unstable in the gastrointestinal tract, there is a need to explore biocompatible materials for targeted drug delivery. Additionally, water-in-oil (W/O) microemulsions can protect water-soluble drug molecules from metabolism. By converting W/O microemulsions into oil-in-water (O/W) microemulsions, it is possible to selectively release active pharmaceutical ingredients in targeted

regions of the gastrointestinal tract, enhancing therapeutic efficacy.

RESULT AND DISCUSSION: On this review we found that the recent global picture, scientists are finding various ways to develop buccal adhesive dosage form to improve the bioavailability of low oral bioavailability drugs. The research in this area continues to develop very quickly with more than hundred new papers being published each year. The current efforts in this area are focused on the design of mucoadhesive polymers with improved performance, development and validation of new physical techniques to study mucoadhesion and formulation of novel dosage forms for mucosal administration. Currently solid dosage forms, liquids and gels applied to oral cavity are commercially successful. The future direction of buccal adhesive drug delivery lies in vaccine formulations and delivery of small proteins/peptides.

Since, the introduction of Orabase in 1947, when gum tragacanth was mixed with dental adhesive powder to apply penicillin to the oral mucosa; the market share of bioadhesive drug delivery systems is increasing. The growth rate for transmucosal drug delivery systems is expected to increase 11% annually through 2007. Worldwide market revenues are at $3B with the U.S. at 55%, Europe at 30% and Japan at 10%.

Based on our current understandings of biochemical and physiological aspects of absorption and metabolism, many drugs, cannot be delivered effectively through the conventional are subjected to pre systemic clearance extensively in liver, which often leads to a lack of significant correlation between membrane permeability, absorption and bioavailability.

Exciting challenges remain to influence the bioavailability of drugs across the buccal mucosa. Many issues are yet to be resolved before the safe and effective delivery through buccal mucosa. Successfully developing these novel formulations requires assimilation of a great deal of emerging information about the chemical nature and physical structure of these new materials.

CONCLUSION: The main aim of buccal drug delivery of the drug as potential therapeutic agent is their instability in acidic environment, extensive first pass metabolism and low bioavailability of drug results an inadequate oral absorption. The buccal mucosa is rich in blood supply and relatively permeable. Mucoadhesive drug delivery systems or buccal drug delivery systems are gaining popularity day by day in the global pharma industry and a burning area of further research and development. This review presents the mucoadhesive or bioadhesive polymers, both conventional and substituted or conjugated emphasizing their mechanism of mucoadhesion. It can be concluded from the current study that research with conventional MDDS with conventional polymer is already a past trend. The reason is the maximum mucoadhesion occupancy with a single conventional polymer is already being achieved or studied. It is found from the current study that use of composite material, combined polymer systems, substituted or conjugated polymers are more popular to design a MDDS with desired criteria. Buccal drug delivery holds a great promise for systemic delivery of orally inefficient drugs as well as a feasible and attractive alternative for non-invasive delivery of potent peptide and protein drug molecules**.**

At the current global scenario, scientists are finding ways to develop buccal adhesive systems through various approaches to improve the bioavailability of orally less/inefficient drugs by manipulating the formulation strategies. Polymeric science needs to be explored to find newer mucoadhesive polymers with the added attributes of being biodegradable, biocompatible, non-toxic, mucoadhesive for specific cells or mucosa, and which could also function as enzyme inhibitors for the successful delivery of proteins and peptides. However, the invention of new biomaterials, tailor-made copolymers, has excellent potential for mucoadhesive drug delivery, but the formulations based on them still have to go a long way to find their path in actual clinical practice. Recently researchers facing many more challenges in development of such formulation and it requires a multidisciplinary approach.

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