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Original Research Article

Recent Advances in Oral and Transmucosal Drug Delivery Systems for Patients with Dysphagia

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Abstract: Dysphagia is the difficulty or inability to swallow liquids, solids, or medications. It is often observed in older adults. This sensorimotor dysfunction can lead to poor treatment adherence, medication errors, and even treatment failure. It can also increase the risk of pulmonary aspiration. Traditional oral dosage forms, such as tablets and capsules, pose several problems for patients with dysphagia due to their size. Furthermore, some practices used to improve the administration of these dosage forms, such as crushing tablets, can compromise the safety and efficacy of treatment by altering the release mechanism of the active ingredient. Several pharmaceutical approaches have been developed to facilitate the oral administration of medications without requiring conventional swallowing. These technologies generally allow for the rapid dissolution of the active ingredient before swallowing or its absorption in the oral cavity. Examples of these approaches include solid oral dosage forms such as orodispersible, buccal, and sublingual tablets, 3D-printed tablets, oral lyophilisates, and medicated chewing gum. Other systems include mucoadhesive systems and multiparticle systems, as well as other forms such as modified liquids and oral or buccal gels.

Keywords: Dysphagia, Drug Delivery System, Galenic Approach, Swallowing Disorders, Transmucosal, Oral Dosage Forms.

INTRODUCTION

Swallowing is a complex semi-automatic sensory-motor process that safely and quickly moves food, liquids, or medication from the mouth to the stomach, while protecting the airways (Matsuo, K., *et al.*, 2008). On average, a person swallows 1,500 to 2,000 times a day (Clavé, P, *et al*., 2015).

Swallowing disorders, or dysphagia, are defined as the difficulty or inability to swallow liquids, solids, or medications, primarily due to neurological, ear, nose, and throat (ENT), or esophageal conditions (Kirchberger e*t al*., 2012). This sensorimotor dysfunction is common in patients with neurological and cancer conditions, and is very common in the elderly. In fact, dysphagia affects 15% of individuals over 65 years of age living at home Chen, (P. H., *et al*., 2009), 51% of people in long-term care facilities [5], and 73% of hospitalized individuals over 75 years of age (Lin, L. C., *et al*., 2002).

Beyond its nutritional consequences, dysphagia leads to non-adherence to medication and treatment failure (Kirchberger *et al*., 2012). Conventional solid pharmaceutical dosage forms are difficult for patients with dysphagia to swallow. Furthermore, certain practices used to facilitate the administration of solid forms, such as crushing tablets or opening capsules, can alter the mechanisms of release of active ingredients and lead to ineffective treatment.

In this context, developing new dosage forms that are adapted to the specific needs of patients with dysphagia is essential.

This review aims to describe the main pharmaceutical innovations developed to improve medication administration in patients with dysphagia.

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Pathophysiology and Clinical Implications of Dysphagia

Swallowing requires the coordination of 25 pairs of muscles in the oral cavity, pharynx, larynx, and esophagus (Morinière, S., *et al.,* 2013). The process is divided into three phases: oral, pharyngeal, and esophageal, each of which can be disrupted by various pathologies or medications:

- The oral phase, also called the buccal phase, this phase involves the physicochemical transformation of food to facilitate swallowing and transport to the larynx.
- The pharyngeal phase: This phase ensures transport of the bolus into the esophagus while simultaneously protecting the airways.
- The esophageal phase: This phase allows food to migrate to the lower esophageal sphincter through esophageal peristaltic movements. (Forster, A., *et al*., 2013, Lacau St Guily, J., *et al*., 2005).

Dysphagia can occur at any stage and manifests as either oropharyngeal dysphagia or esophageal dysphagia (Robbins, J., *et al*., 2009).

- Oropharyngeal dysphagia: This is the most common form in elderly individuals and patients with neurological disorders [10]. It is defined as difficulty initiating the swallow and transferring the food or medication bolus from the mouth to the throat. It most often results from neuromuscular dysfunction affecting the muscles involved in the oral or pharyngeal phase.
- Esophageal dysphagia: Difficulty progressing the food bolus through the esophagus to the stomach, generally due to structural or functional disorders of the esophagus (Robbins, J., *et al*., 2009).

Dysphagia is not limited to simple difficulty swallowing; it can lead to serious complications such as the risk of aspiration and pulmonary aspiration, which can be fatal for the elderly and patients with neurological disorders (Baijens, L. W. J. *et al*., 2021). Furthermore, reduced food intake due to dysphagia can lead to malnutrition or even undernutrition (Cichero, J. A. Y. *et al*., 2020). From a therapeutic and pharmaceutical standpoint, dysphagia can lead to poor treatment adherence because it complicates regular intake and can even result in discontinuation of treatment. It also increases the risk of medication errors.

Limitations of Conventional Oral Dosage Forms

Conventional solid dosage forms, such as tablets and capsules, are difficult to administer to patients with dysphagia. One of the main limiting factors is tablet size. Several studies have shown that patients report feelings of obstruction or discomfort when swallowing large tablets (Liu, F., *et al*., 2014). Furthermore, crushing tablets is a common and sometimes unavoidable practice for patients with dysphagia. Given the potential risks involved, the decision to modify a drug's formulation should not be taken lightly. One study showed that 42% of crushed medications had a formulation that contraindicated crushing (Verger, P. 2013). Crushing certain formulations, such as extended-release, enteric-coated, and multilayer tablets, can lead to the rapid and uncontrolled release of the active ingredient, thus increasing the risk of adverse effects (Verger, P. 2013). Also, when tablets or capsule contents are dispersed in water or crushed, the bitter taste of some active ingredients may decrease patient acceptance of the treatment.

Pharmaceutical Strategies for Dysphagic Patients

Several innovative pharmaceutical alternatives have been developed over the past few decades to facilitate the oral administration of medications to patients with swallowing disorders. These include orally disintegrating tablets, buccal tablets, sublingual tablets, oral lyophilisates, orally disintegrating films, multiparticle systems, 3D-printed tablets, oral gels, chewing gum, and mucoadhesive systems (Figure 1).

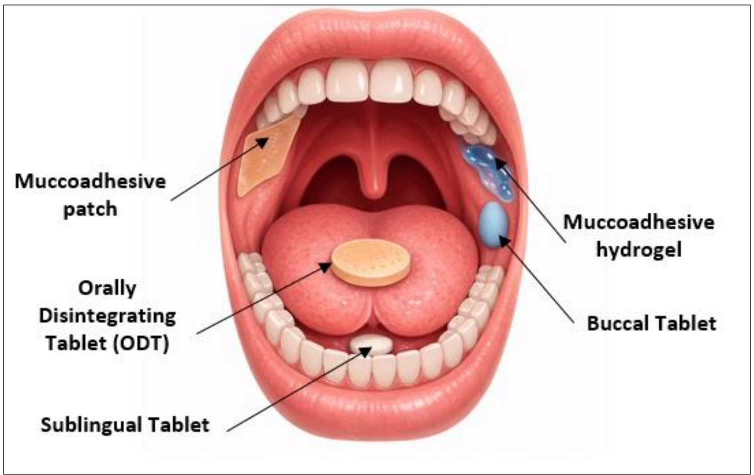

Figure 1: Oral and Transmucosal Drug Delivery Systems

Orally Dispersible Tablets (ODTs)

These dosage forms are administered orally and are designed to be placed in the mouth, where they disperse rapidly before being swallowed. ODTs disintegrate quickly in the oral cavity upon contact with saliva and do not require water. This rapid disintegration is due superdisintegrants, which quickly break down the tablet matrix. The most commonly used disintegrants in ODT formulations are crospovidone, croscarmellose sodium, and sodium starch glycolate. Other excipients that can be used in ODT formulations include mannitol, which is highly soluble, and certain types of hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC) Preis, M. (2015, Visser, J. C., al. 2020).

Buccal Tablets

They are placed in the oral cavity and dissolve slowly, usually between the cheek and gum. This dosage form allows the medication to be absorbed through the oral mucosa, which reduces the difficulty of swallowing and the risk of aspiration. The dissolution, release, and absorption of the medication in the mouth are primarily due to mucoadhesive excipients, which ensure that the tablet adheres to the oral mucosa through physicochemical interactions, thereby prolonging contact with the epithelial tissue. The most commonly used excipients are polymers, such as chitosan, carbopol, hydroxypropyl methylcellulose, polycarbophil, and sodium alginate. Other excipients, such as mannitol, lactose, or sorbitol, are often added to improve solubility. (Shojaei, A. H. (1998, Khairnar, G. A., *et al*., 2010).

Sublingual Tablets

These solid dosage forms are designed to be placed under the tongue, where they rapidly dissolve to allow absorption of the active ingredient through the sublingual mucosa. The sublingual area allows for rapid release and diffusion of the active ingredient due to its high vascularization and thin epithelium. Sublingual tablets are designed to disintegrate quickly due to the presence of superdisintegrants, such as crospovidone, croscarmellose sodium, and sodium starch glycolate. These superdisintegrants promote the rapid penetration of saliva and the rupture of the compressed matrix (Preis, M. 2015, Patel, V. F., *et al*., 2011).

3D-Printed Tablets

Three-dimensional printing is an innovative pharmaceutical technology that enables the manufacture of customized tablets for patients. For patients with swallowing difficulties, 3D-printed tablets can be designed with high porosity to disintegrate in seconds in the oral cavity for oral absorption. Alternatively, they can be designed with optimized geometries to facilitate swallowing. Several scientific studies have shown that 3D-printed tablets can improve medication acceptability and ease of administration. (Norman, J., *et al*., 2017, Scoutaris, N., *et al*., 2018).

Oral Lyophilisates (Lyocs)

Also known as orally disintegrating lyophilisates, these compact, porous, lyophilized masses can be chewed, sucked, or dispersed in water before administration. They are obtained by lyophilizing a solution or suspension that contains the active ingredient and excipients. Their porous nature allows for extremely rapid disintegration upon contact with saliva, followed by the rapid release of the active ingredient (Visser, J. C., al. 2020, Borges, A. F., *et al*., 2015, Maheshwari, R. K., *et al*., 2018).

Mucoadhesive Systems

These are pharmaceutical formulations designed to adhere to mucous membranes, such as the oral mucosa. This prolongs contact time between the active ingredient and the mucosa. This promotes absorption, prolongs the release of the active ingredient, and consequently reduces the frequency of administration.

Mucoadhesive Systems

Exist in various dosage forms, such as tablets, films, gels, and oral patches. They are generally formulated with hydrophilic polymers, such as chitosan, carbopol, polycarbophil, hydroxypropyl methylcellulose (HPMC), or sodium alginate. These polymers adhere through mechanisms of hydration, swelling, or electrostatic interactions with the mucus layer covering the epithelium. (Patel, V. F., *et al.,* 2011).

Orodispersible Films (ODFs)

These forms are solid, thin, flexible polymer matrices designed to be placed on the tongue or oral mucosa. These films dissolve or disintegrate rapidly upon contact with saliva. Their thinness and large surface area promote rapid disintegration in less than one minute without water absorption.

From a pharmaceutical standpoint, ODFs are primarily formulated with hydrophilic, film-forming polymers that create the matrix of the film, such as hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA), and carboxymethylcellulose. To improve flexibility and mechanical strength, plasticizers such as glycerol, propylene glycol, and polyethylene glycol (PEG) are added. To improve patient acceptance, flavorings and sweeteners such as mannitol and aspartame may be added. However, their limited drug loading capacity may restrict their use for certain medications requiring high doses. (ser, J. C., *et al*., 2020, Musazzi, U. M., *et al*., 2020). (Figure 2).

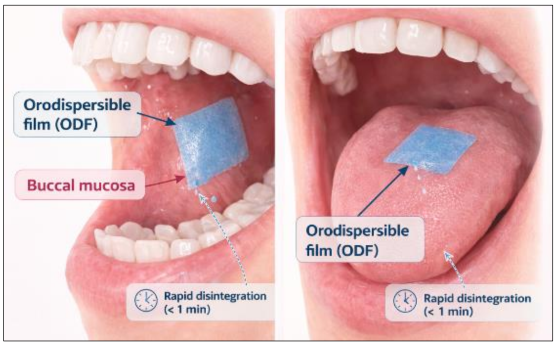

Figure 2: Orodispersible films

Multiparticulate Dosage Forms

These are pharmaceutical dosage forms composed of small, discrete solid units generally less than a few millimeters in size. Examples include pellets, granules, microgranules, and mini-tablets. They can be administered together to deliver the desired therapeutic dose. These systems are easy to swallow due to their small size and can be dispersed in thickened liquids, gels, or texture-modified foods. This characteristic reduces the sensation of obstruction during swallowing for dysphagic patients and decreases the risk of aspiration. Multiparticulate systems can be produced by various processes, including extrusion-spheronization, granulation, fluidized bed pelletization, and mini-tablet compression. (Visser, J. C., *et al.,* 2020, Borges, A. F., *et al*., 2015, Lopes, C. M., *et al*., 2006).

Microparticles and Nanoparticles

These are among the multiparticle systems that allow the encapsulation of an active ingredient within polymeric, lipid, or hybrid matrices. This modifies the drug's biopharmaceutical and galenic properties. Frequently used polymers in the formulation of these systems include PLGA, alginate, chitosan, and solid lipids. (Mitchell, M. J., *et al*., 2021).

Modified Liquid Formulations

Viscous liquid forms are a good alternative to solid forms for oral administration. They slow the flow rate, which facilitates swallowing control. In contrast, low-viscosity liquid forms can increase the risk of aspiration in patients with dysphagia. Viscosity can be increased by adding thickening agents, such as cellulose derivatives, gums (e.g., xanthan gum), and certain starch derivatives. (Cichero, J. A. Y., *et al*., 2017, Hanson, B., *et al*., 2021).

Oral Gels

These gels are an appealing alternative to traditional solid forms. They offer easy oral administration and a texture tailored to the needs of patients with dysphagia. Their cohesion and viscosity facilitate bolus formation and propulsion in the oropharynx. They are generally made from hydrophilic gelling polymers, such as hypromellose (HPMC), carbomer, xanthan gum, sodium alginate, and pectin. These polymers provide a stable, mucoadhesive texture that is easily swallowable (Allen, L. V. 2014).

Medicated Chewing Gum

This solid form is designed to be chewed, allowing for the slow release of the active ingredient in the oral cavity. These newer forms consist of an insoluble elastomeric gum matrix that ensures controlled drug release through diffusion into saliva. Chewing gum is popular because it is easy to administer. Formulations generally include gum, elastomers, plasticizers (such as glycerol), sweeteners (such as sorbitol, xylitol, or aspartame), and flavorings to improve taste. (Aslani, A., *et al*., 2015, Khanna, R., *et al*., 2010).

Conclusion

Dysphagia poses a significant obstacle to medication administration, especially among vulnerable populations. Conventional solid dosage forms are often unsuitable for patients with swallowing difficulties.

Fortunately, new technologies offer solutions that allow patients with dysphagia to avoid swallowing, reduce the risk of aspiration, and improve treatment adherence.

Advances in nanotechnology and pharmaceutical printing may lead to new, more effective dosage forms that better suit the needs of patients with dysphagia.

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