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Sumatriptan Mucoadhesive Buccal Tablet for the Treatment of Migraine

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ABSTRACT

In this review , we assessed a buccal sumatriptan formulation specifically for migraine treatment. This abstract provides a concise overview of the key aspects and applications of mucoadhesive buccal tablets of sumatriptan.

The primary objective of mucoadhesive buccal tablet is to enhance the bioavailability and therapeutic efficacy of drugs by enabling controlled and sustained release directly into the bloodstream.

In this article, we will delve into the concept, development, and applications of mucoadhesive buccal tablet highlighting their key features and benefits in the treatment of migraine.

1. INTRODUCTION

MIGRAINE:

The most prevalent type of vascular headache, which produces a unbearable headache all over the brain, is migraine. This is brought on by the brain's arteries' unusual sensitivity, which produces triggers that frequently cause major developments in nerves diameter leads to a spasm. Causing enlargement as a result, causing excruciating headache pain.[1]

- Migraines are typically accompanied by other symptoms, which can include:
  - Dizziness or Vertigo Migraines may have an important effect on your day's activities. It is not entirely clear why migraines occur, but they are thought to be caused by genetics, environmental factors and the nervous system. It also appears to be associated with fluctuations in brain chemicals, for example serotonin.
- Migraines phases:
  a. *Prodrome*: Subtle warning signs that occur a day or two before the migraine.
  b. *Aura:* Occurs in some people and involves visual disturbances or other neurological symptoms before or during a migraine.
  c. *Attack:* Disturbing visuals, sound, odour.

The actual few hours to up to 72 hours if untreated.

Postdrome: After the headache subsides, individuals may feel drained, confused, or fatigued for up to a day.[2]

Drugs of Migraine:

Treatment for migraines typically involves medications that fall into two main categories:

- ***Drugs for the Acute (abortive) treatments of migraines*** to relieve symptoms during an attack, and Acute Treatment:

A. **NSAIDs *(Analgesics)***:

Mild to moderate migraine attacks can be treated with non-specific medications such as pain relievers and rapidly absorbed anti-inflammatory **drugs such as aspirin, ibuprofen, paracetamol, acetaminophen & naproxen.**

Mechanism of Action

NSAIDs suppress prostaglandin production. NSAIDs reversibly inhibit COX 1 and 2. NSAIDs that block prostaglandin E2 synthesis are beneficial for managing acute migraine attacks. Aspirin works as an irreversible COX I and 2 inhibitor.[3]

B. **Anti-*emetics:***

Compounds with antiemetic properties, like metoclopramide and domperidone, can accelerate the emptying of the stomach, potentially enhancing the absorption of other medications when taken at the onset of a migraine. The use of aspirin in combination with metoclopramide has shown great efficacy in treating migraines.

a. Dopamine antagonists: Domperidone

b. Phenothiazines: Promethazine

c. 5-HT3 Antagonists: Ondanesetron , Granisetron

d. H1 Antagonist: Meclizine, Diphenyhydramine

Mechanism of Action

Metoclopramide is a benzamide that inhibits the D2 receptor in low dosages and 5HT-3 in high doses. Prochlorperazine and chlorpromazine are dopamine antagonists (D2 receptors) that have antiemetic and migraine relief properties.[4]

C. Ergotamines:

For many years, ergot alkaloids such as ergotamine and dihydroergotamine have been the main drugs for immediate migraine relief. However, their efficacy has not been conclusively proven in controlled clinical trials. These drugs function by constricting blood vessels and reducing perivascular inflammation in animal models. They have digestive issues, dry mouth, restlessness, and chest discomfort. Overdosing or prolonged use of ergotamine, and to a lesser degree dihydroergotamine, can lead to ergotism—a serious condition characterized by extensive vasospasm, which can cause cyanosis, tissue necrosis, and heart or brain infarctions .[5]

Ergot-dependent headaches are more likely to develop when ergots are used more frequently than once per day each week (Ferrari et al., 1998). The high incidence of side effects is likely due to ergotamine and dihydroergotamine targeting a wide array of receptors, including alpha- HT1D, 5-HT1B, 5-HT1A, and 5-HT2 receptors (T felt et al., 1999). These drugs have low bioavailability when taken orally or rectally, and their clinical effectiveness does not correlate with their plasma concentration (Martin et al., 1995). This discrepancy is attributed to the slow release of these compounds from their receptor sites (Martin et al., 1995).[6]

Mechanism of Action

Ergotamines, like triptans, are highly effective 5-HT 1b/1d receptor agonists. They work by constricting the postulated pain-producing intracranial extracerebral blood arteries at 5-HT1B receptors and inhibiting trigeminal neurotransmission at both peripheral and central 5-HT1D receptors. They also work with additional serotonin, adrenergic, and dopamine receptors. They restrict the peripheral and cerebral blood arteries.

D. The Triptans

Compared to the ergot derivatives, the triptans offer specific benefits such as selective pharmacology, straightforward and reliable pharmacokinetics, and prescription guidelines based on evidence, proven effectiveness through well-planned trials, manageable side effects, and a well-documented safety history (Welch et al, 2001). The primary drawbacks of the triptans include their higher price and limitations on their usage when cardiovascular disease is present.

***Triptans*: Sumatriptan, Zolmitriptan, Rizatriptans**

Recently, several new triptans such as zolmitriptan, naratriptan, and rizatriptan have been introduced to the market, and there are expectations for the introduction of others like eletriptan, almotriptan, and frovatriptan in the near future.

Mechanism of Action

Triptans are serotonin receptor agonists with a strong affinity for 5-HT1B and 5-HT1D receptors but a variable affinity for 5-HT1F receptors. The theorized mechanism of action involves binding to postsynaptic 5-HT1B receptors on smooth muscle cells in blood vessels and presynaptic 5-HT1D receptors on trigeminal nerve terminals and dorsal horn neurons.[7]

- ***Preventive (prophylactic) treatments***.

Here's a brief overview of the drug classifications used in these treatments:[8]

Preventive Treatment:

A. *Anti-epileptic*: Topiramate, Valproic acid

B. *Tri-cyclic antidepressants:* Amytriptyline, Nortriptyline

C. *Beta-blockers*: Propronolol, Metoprolol

Bioadhesion/Mucoadhesion:[9]

The phenomenon of bucco-adhesion sticks within buccal membrane cells for an extended duration due to interfacial forces . This complex process of mucoadhesive bond formation involves several suggested steps. The initial step involves attachment. Following this, there a, creating enhancement within tissue.

Developing mucoadhesive systems benefit the most from hydrogen bonds and hydrophobic interactions.[10]

Mechanism of Mucoadhesion:

It is facilitated by various to fulfill their orbitals. A weaker bond also helps within mucoadhesion.

The "electronic theory," which contends that upon contact electron transfer may, leading to applicable energy, asserting for adhesion to occur.

The liquid splatter onto a surface on its own. adsorption theory, the primary driving force of the adhesive contact is necessary. According to interdiffusion of chains over an adhesive contact, which is accelerated by a concentration gradient.[11] The mechanical theory and the fracture theory are further hypotheses put out for mucoadhesion. The medication reaches the bloodstream after adhesion.

Advantages of Oral Mucoadhesive Drug Delivery Systems:

1. **Prolonged Residence Time**
    - Mucoadhesion allows the dosage form to stay longer at the absorption site, enhancing drug absorption and **increasing bioavailability**.
2. **Excellent Accessibility and Rapid Onset of Action**
    - Easy access to the oral mucosa and its permeability leads to a **faster therapeutic effect**.
3. **Rapid Absorption**
    - The oral mucosa has a **rich blood supply and high perfusion rate**, enabling quick drug uptake into systemic circulation.
4. **Protection from Gastrointestinal Degradation**
    - Drugs administered via the oral mucosa **bypass the acidic environment of the gastrointestinal tract (GIT)**, protecting acid-sensitive drugs from degradation.
5. **Improved Patient Compliance**
    - Non-invasive, **painless administration**, ease of use, and no need for water contribute to better adherence, especially in pediatric and geriatric patients.[12]

➢ **Known Mucoadhesive marketed formulations :[13]**

S.No.	Marketed Product	Active Ingredient	Bioadhesive Agent	Dosage Form	Company/Manufacturer
1	Buccastem	Prochlorperazine	Xanthum gum	Buccal Tablet	Reckitt
2	Suscard	Glyceryl trinitrate	Hypromellase	Tablet	Forest Laboratories
3	Coreg	Carvedilol	HPMC	Buccal Tablet	Glaxosmith Kline
4	Loramyc	Micanazole	Corn Starch	Buccal Tablet	Bioalliance Pharma

➢ **Sumatriptan Buccoadhesive Tablet Formulation:**

- Sumatriptan, similar in structure to serotonin, functions as a 5-HT agonist. It particularly targets the ID subtype 5-HT receptors, likely at presynaptic sites, causing selective narrowing of nerves. This medication is a 5-HT1 receptor agonist used to treat migraines. Its oral bioavailability is quite low at about 15% and varies among individuals, but it is not

influenced by food intake.[14] The typical oral dosage ranges from 50mg (Tmax) occurring roughly 2 hours after ingestion. This peak can be slightly delayed by food or an acute migraine.

- Sumatriptan's pharmacokinetics are linear within a 25-200 mg dose range, except for its absorption rate. The liver extensively metabolizes the drug, primarily through MOA type A, and it is mainly excreted in the urine as inactive indoleacetic acid and its glucuronide. The total plasma clearance is 1160 ml/min, with 20% of this through the kidneys, and the drug has an elimination half-life of about 2 hours.[15]
- Creating an buccal mucoadhesive long-acting formulation of sumatriptan succinate can enhance its therapeutic efficacy and bioavailability by allowing the drug to bypass rapid metabolism and reaches into body via the internal jugular vein. This study aims to develop such a mucoadhesive tablet using various polymer combinations to avoid first-pass metabolism, prolong the drug's effect, and improve patient compliance by achieving better therapeutic outcomes.[16]

2. CONCLUSION

The current study effectively developed a sumatriptan buccal mucoadhesive tablet. The development and evaluation of Sumatriptan mucoadhesive buccal tablets have demonstrated promising results in improving the delivery and efficacy of migraine treatment. The formulation's mucoadhesive properties ensure prolonged retention and consistent release of Sumatriptan in the buccal cavity, leading to enhanced bioavailability.[17] This delivery system bypasses gastrointestinal degradation and hepatic first-pass metabolism, offering a significant advantage over conventional oral tablets.

Studies confirmed the tablet's excellent mucoadhesion, appropriate release profile, and effective therapeutic outcomes.

Overall, Sumatriptan mucoadhesive buccal tablets represent a viable alternative for migraine management, offering enhanced efficacy, improved patient compliance, and potentially faster relief. validate these findings and explore the long-term benefits and safety of this innovative delivery system.[18]

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