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Review Article

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BUCCAL PATCHES: AN ADVANCED ROUTE OF DRUG DELIVERY

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ABSTRACT

Buccal patches are just a form of medication preparation that uses a new route of administration for drug delivery through the buccal mucosa. Such patches enable drugs bypass hepatic first-pass metabolism and reach the systemic circulation directly. This form of medication administration is thought to be effective for increasing bioavailability of the drug. The buccal route offers promise benefits as an alternative to other standard methods of systemic drug administration, and this has piqued the curiosity of academics all around the world. This review is a thorough study to apprehend the procedures involved in the assessment of buccal patches and the modern approach towards this type of drug delivery.

KEYWORDS: Buccal patches, Bioadhesive, Administration, Mucosa, Bioavailability.

INTRODUCTION

The Buccal region of oral cavity is an attractive site for the delivery of drugs owing to the ease of administration. Problems such as- first pass metabolism & drug degradation in the harsh gastrointestinal environment can be circumvented by administrating drugs via- the buccal route. Buccal patches are preferred over adhesive tablets in respect of its flexibility & patient comfort. Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been explored for systemic drug delivery of drugs via various pharmaceutical products of different dosage form. Moreover, the oral cavity is easily accessible for self medication & can be promptly terminated in case of toxicity by simply removing the dosage form from buccal cavity. Buccal delivery also enables administering drugs to patients who cannot be dosed orally via this route.[1] Many mucoadhesive buccal films have been formulated to release drugs locally in order to treat fungal infections in the oral cavity such as- oral candidiasis.[2] These dosage forms are usually prepared by casting a solution of the polymer, drug & any excipients such as- Plasticizer ,binder onto a surface & allowing it to dry. Patches can be made 10-15cm² in size but are more frequently 1-3cm² & may present with an ellipsoid shape, so as to fit comfortably onto the centre of the buccal mucosa.[3]

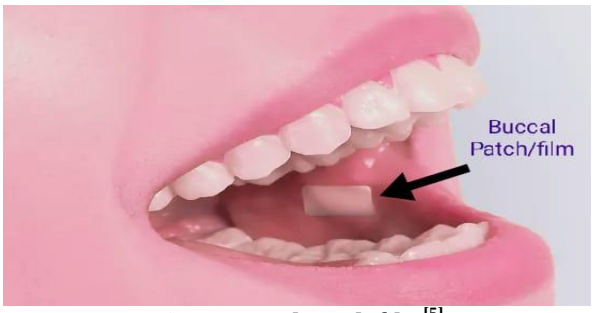

Fig 1: Buccal patch/film[5]

Buccal patches are made with paracetamol, acetaminophen, ibuprofen, aspirin, and naproxen. The majority of Patches are made utilising the Solvent Casting process. Furthermore, because oral gels are rapidly washed away by saliva, a patch can avoid the problem of oral gels having a short residence period on mucosa. By bypassing hepatic first-pass metabolism, the buccal mode of drug administration allows direct access to the systemic circulation via the jugular vein, resulting in excellent bioavailability.[4]

Table 1: Categories of mucoadhesive polymers used in buccal patches[6]

Natural Polymers	Synthetic Polymers
Chitosan	Sodium CMC,HPMC
Sodium alginate	Poly Acrylic acid polymers
Guar gum	Polyhydroxyl ethyl methylacrylate
Xanthan gum	Polyethylene oxide

Soluble starch	Polyvinylpyrrolidone
Gelatin	Polyvinyl alcohol
Tragacanth	Cellulose derivatives(MC,EC,HEC etc)

Advantages[7-11]

• In the event of an emergency, the patient can manage the duration of administration and stop it.
• Rapid absorption due to abundant blood supply and high blood flow.
• Drug is protected from degradation in the acidic environment in the GIT.
• Patient compliance has improved.
• It's simple and painless to use.
• Physical condition, form, size, and surface have more versatility.
• Because it is a passive mechanism for medication absorption, no activation is required.
• For patients experiencing nausea or vomiting, or who are unconscious.
• Increases bioavailability by prolonging the residence period of the dose form at the absorption site.
• Easy to use, with a quick response time.

Limitations[12-13]

- Medication that are unstable at the pH of the buccal cavity cannot be given.
- When compared to the sublingual membrane, the buccal membrane has a modest permeability.
- This method cannot be used to provide drugs that have a bitter or unpleasant taste or irritate the mucosa.
- Only a little amount of the drug can be provided.
- This approach can only be used to give medications that are absorbed by passive diffusion.
- There are restrictions on what you may eat and drink.
- Because of the flushing action of saliva or the intake of foodstuffs, regular dosage may be required.
- Only drugs with a low dosage are suitable.

Types of buccal patches[14]

Buccal patches are in two types-

1. **In matrix type-**The medication is disseminated uniformly in a hydrophilic or lipophilic polymer matrix before being shaped into a drugged disc with a predetermined surface area.
2. **In reservoir type-** The medicine and additives are separated from the adhesive in a buccal patch constructed in a reservoir system. To avoid medication loss, an impermeable backing is put in the mouth.

Method of preparation of buccal patches[15-16]

The buccal patch are prepared by various methods i.e.

1. **Direct milling-** Patches are made without using solvents in direct milling. Without the use of liquids, the drug and excipients are mechanically combined by direct grinding or kneading. The resulting material is placed on a release liner until it reaches the appropriate thickness. After that, the backing material is laminated as mentioned earlier. While there are very small or no changes in patch effectiveness between patches made by the two techniques, the solvent-free method is preferable since there are no leftover solvents and no associated complications.
2. **Solvent casting method** All patch excipients, including the medicine, are co-dispersed in an organic solvent and layered onto a release liner sheet in this process. After the solvent has evaporated, a thin layer of impermeable protective coating is bonded to the coated release liner sheet, resulting in a laminate that can be die-cut into patches of the specified size and shape**.**
3. **Solid dispersion extrusion-** Immiscible components are extruded with the medication, followed by solid dispersions. Finally, dies are used to mould the solid dispersions into films.
4. **Semisolid casting-**A solution of water soluble film forming polymer is created initially in the semisolid casting procedure. The resultant solution is mixed with an ammonium or sodium hydroxide solution of acid insoluble polymer (cellulose acetate phthalate, cellulose acetate butyrate). The necessary amount of plasticizer is then applied, resulting in a gel mass. Finally, heatcontrolled drums are used -to cast the gel into films or ribbons. The film is around 0.015-0.05 inches thick. The acid insoluble producing polymer should be used at a 1:4 ratio.
5. **Rolling Method-** A solution or suspension holding medication is rolled on a carrier in this rolling process. Water and a combination of water and alcohol are the principal solvents. On rollers, the film is cured and cut into the required forms and sizes.
6. **Hot melt extrusion-** The medication is initially combined with carriers in solid form in this approach.The mixture is melted in an extruder with heating. Finally, dies form the melt into films. Hot melt extrusion has a number of advantages.

Evaluation parameters of buccal patches[17-20][6]

1. **Surface pH.** Buccal patches are put to the surface of previously prepared agar petri plate for 1 hour, and pH is evaluated by using litmus paper on the surface of the swelled patch.
2. **Thickness measurements** Vernier callipers with a count of at least 0.001nm are used to measure the patch thickness. The width regularity is measured five times and the average value is taken.
3. **Swelling study** The buccal patch is weighed and incubated at 37±1°C in a 1.5 percent agar gel plate. The patch is taken from the petri dish and extra surface water is gently desiccated using the filter paper every one hour time intermissions up to three

hours. The swelling index is calculated after reweighing the swollen patch.

4. **Folding endurance:** The patch's folding durability is tested by repeatedly folding it in the same spot until it breaks. The value of folding endurance is determined by the number of times the patch may be folded at the same location without breaking.
5. **Drug content uniformity:** The homogeneity of drug concentration is tested by dissolving a 1cm2 patch in 100 ml of phosphate buffer pH 6.8 with 5% methanol, then shacked for 24 hours at 25-30^{0}C. A UV spectrophotometer is used to examine the solution, which is filtered via what man filter paper no.42..
6. **Water absorption study:** On the surface of agar plates, patches are allowed to swell. Phosphoric acid is used to raise the pH to 6.7. The sample is stored at 37ºC ±0.5ºC in an incubator. Samples are weighed and dried for 7 days at room temperature at a specific time interval. After drying, the final constant weights are recorded. The following equation is used to calculate water uptake (percent).

Water uptake(%)= (Ww – Wi)/Wf ×100

Where,

Ww is the wet weight and Wf is the final weight.

7. **In-vitro drug release studies** Paddle equipment was used to release patches in vitro. The dissolution media is phosphate buffer pH 6.8, with the temperature maintained at 37ºC±0.5ºC and the paddle rotating at 50 rpm. The patch backing layer is attached with adhesive material. The disc is assigned to the dissolution vessel's bottom. Fresh medium was replaced with previously obtained sample after predefined time intervals. After dilution, the samples are tested for drug content.
8. **Permeation evaluation of buccal patch:** The receptor chamber is filled with phosphate buffer pH 6.8 for permeation testing, and the velocity of the fluid in the compartment are maintained by stirring with a magnetized bead at 50rpm. At predefined intervals, samples are taken and analysed for drug content.
9. **Ex-vivo bioadhesion method** The mouth of a sheep was detached and rinsed in phosphate buffer (pH 6.8). In the open mouth of a glass vial filled with phosphate buffer, a piece of gingival mucosa is knotted (pH 6.8). The mucosal surface was merely contacted by this glass vial, which was snugly fitted into a glass beaker loaded with phosphate buffer (pH 6.8, 37°C). A cyano acrylate adhesive is used to adhere the patch to the lower surface of a rubber stopper. A 5-g weight is balanced in two pans of the balance. The 5-g weight was taken from the pan on the left side, which was loaded with the patch over the membrane. This position is maintained for 5 min of contact time. The water is gently poured to the rightmost pan at a rate of 100 drops per minute until the patch separates from the mucus layer. The weight required to remove the patch from the mucous membrane was used to determine mucoadhesive ability.
10. **In-vivo techniques for buccal patches**: In order to determine buccal patches in vivo, the following methods are used:

(1) Use of radioisotopes
(2) Use of gamma scintigraphy
(3) Use of pharmacoscintigraphy
(4) X-ray studies
(5) Isolated loop techniques.

CONCLUSION

Buccal patches provide a number of benefits over traditional medication administration methods. The mucosa has ample vascular and lymphatic drainage, allowing it to bypass first-pass metabolism. The adhesion of bioadhesive drug delivery devices to mucosal surfaces increases the drug concentration gradient at the absorption site, improving systemically administered medication bioavailability. In addition, buccal adhesive dose forms have been utilised to address local problems at the mucosal surface (e.g., mouth ulcers) in order to reduce total dosage requirements and avoid adverse effects associated with systemic medication delivery. Buccal medication administration is a promising avenue for future study into systemic distribution of pharmaceuticals that are ineffective when taken orally. Patients can safely employ buccal medication administration since the medicine is withdrawn if side effects emerge. Buccal patches are expected to become one of the most important dosage forms in the healthcare and pharmaceutical industries in the next years.

Conflict of Interest

The authors declare that the review was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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