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(RESEARCH ARTICLE)

Formulation and evaluation of diclofenac patch

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Abstract

Diclofenac sodium is a nonsteroidal anti-inflammatory drug that effectively manages pain following therapeutic extractions. Post-extraction pain is commonly treated with non-steroidal anti-inflammatory drugs (NSAIDs). In addition to their high bioavailability and long duration of action, transdermal NSAIDS have several other advantages. The review tries to understand and elucidate the use of transdermal patches, here Diclofenac, as a postoperative pain management modality. Drug delivery is one of the essential aspects of drug administration where transdermal patches are to be found equally effective when compared to oral administration of drugs. Various analgesics can be administered as patches, for example, ketoprofen, diclofenac, etc. There are also comparative studies between diclofenac and ketoprofen to see and understand the efficacy of transdermal patches compared with oral administration. Compared to oral administration, transdermal patches offer numerous benefits. These include avoidance of first-pass metabolism, sustained and non-rapid absorption, steady plasma levels that remain for prolonged periods, lack of patient dependence on drugs, prevention of gastric distress, and flexibility of stopping delivery of medications by simply removing the patch. This review aims to examine the diclofenac transdermal patch's effectiveness in reducing postoperative pain after orthodontic extraction.

Keywords: Transdermal; Inflammation; Permeation; Bioavailability; Endurance

1. Introduction

Drug delivery is an essential aspect of drug administration, where transdermal patches are found to be equally effective compared to oral drug administration. Various analgesics can be administered as patches, e.g., ketoprofen, diclofenac, etc. There are also comparative studies between diclofenac and ketoprofen that compare their efficacy in transdermal and oral administration Several routes of administration are available, including oral, transdermal, parenteral, neuraxial, and rectal. Postoperative dental pain can be treated safely with non-steroidal anti-inflammatory drugs (NSAIDs) The WHO pain ladder (Figure 1) describes pain in terms of intensity

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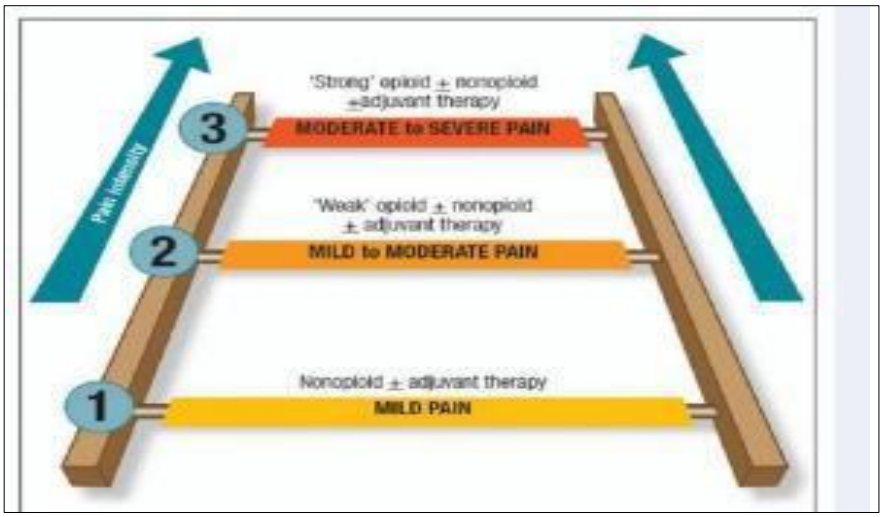

Figure 1 Pain in term of Intensity

In any dental treatment, the dentist's primary goal is to relieve pain as effectively as possible for patients. The experience of pain is a complication involving specific sensations and reactions that occur in response, making it both a physiological and psychological challenge. Monitoring pain relief after surgery using the Visual Analogue Scale (VAS) has become an essential postoperative quality assessment procedure because it offers considerable physiological benefits. The dentist must select an analgesic regimen to help eliminate pain effectively while minimizing side effects. Can manage pain through opioids as well as non-opioid medications. Several routes of administration are available (oral, transdermal, neuraxial, intravenous [IV], and regional). As an alternative method of achieving analgesia, transdermal patches are gaining popularity. Transdermal patches, commonly referred to as transdermal delivery systems, are non-invasive systems for delivering medications into the dermis. This method of drug delivery is a potential alternative to oral ingestion of medications and can improve patient compliance. The first transdermal patch was developed in the 1970s, and the Food and Drug Administration (FDA) approved it as a motion sickness treatment in 1979.

It is an alternative to oral administration and could improve acceptance by reducing adverse reactions. It also avoids the pain associated with IV and intramuscular (IM) routes. This form of nonsteroidal anti-inflammatory drugs (NSAIDs), which are applied topically, can be administered systemically in low concentrations. By delivering the medication transdermal, it is possible to reduce the strength of action and the ensuing side effects associated with oral delivery. This article compares the effectiveness of the diclofenac transdermal patch and the need for rescue analgesia within the first 24 hours.

Diclofenac is a NSAIDs that inhibits both cyclooxygenase (COX) -1 and cyclooxygenase (COX) -2 enzymes. NSAIDs inhibit the synthesis of proteinoids (prostaglandin [PG]-E2, PGD2, PGF2, prostacyclin [PGI2], and thromboxane [TX] A2) by binding to COX isozymes. PGE2 is the dominant prostanoid produced in inflammation, and inhibiting its synthesis by NSAIDs is believed to be the primary mechanism of these agents' potent analgesic and anti-inflammatory properties."

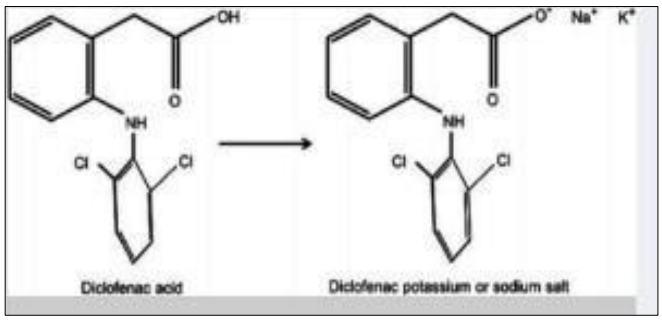

Figure 2 Structure of Diclofenac

The benefits of using transdermal delivery systems - In comparison to oral administration, transdermal patches offer numerous advantages. Among them is the avoidance of first-pass metabolism, sustained and non-rapid absorption, stable

plasma levels for prolonged periods, the absence of drug dependence, the prevention of gastric distress, and the ability to stop drug delivery by simply taking off the patch.

2. Benefits of transdermal patches

- Transdermal patches are a non-invasive, non-painful way of administering medications.
- The transdermal patches deliver a variety of drugs that are absorbed in the small intestine, but not well in the stomach, and they are extensively metabolized in the liver.
- Drugs are delivered through transdermal patches over a long period.
- Transdermal patches allow abrupt termination of medication delivery.
- Compared to oral medications and supplements, transdermal patches have fewer side effects.
- Patients are comfortable using and remembering transdermal patches.
- In therapeutic delivery systems, a reservoir of drugs is present, and its controlled release characteristics allow the active properties of drugs with short plasma half-lives to be prolonged.
- Those who have cognitive disabilities or who are disabled and cannot self-medicate can use transdermal patches as an alternative."

Use of diclofenac as a transdermal patch - One of the many nonsteroidal anti-inflammatory medications used in clinical practice, diclofenac is frequently used to manage postoperative pain. According to Selvi et al., intramuscular Diclofenac and transdermal Diclofenac patches (TDP) effectively provided analgesia following third molar extractions. The study showed that a Diclofenac patch provided adequate analgesia to manage mild to moderate pain following therapeutic extractions Furthermore, Bhaskar et al. compared oral versus transdermal Diclofenac administration. They studied the satisfaction of their study patients with the transdermal patch, which produced analgesia comparable to that of the said supplement

3. Drug Profile

3.1. Diclofenac Sodium

- **Generic Name** - Diclofenac Sodium
- **Category -** Non-Steroidal Anti-Inflammatory Drug (NSAID)
- Analgesic (Pain reliever), Antipyretic (fever reducer).
- **Chemical Name** - Sodium [2-(2,6-dichloroanilino) phenyl] acetate.
- **Molecular Formula -** $C_{14}H_{10}Clonal_2$
- **Molecular Weight** - 318.13 g/mol.
- **Appearance -** White to slightly yellow crystalline powder**,** Odourless or faint Odor
- **Solubility -** Soluble in water**,** freely soluble in methanol, slightly soluble in ethanol.
- **Mechanism of Action** - Diclofenac sodium inhibits COX-1 and COX-2 enzymes, reducing prostaglandin synthesis. This decreases pain, inflammation, and swelling.
- **Indications / Uses** - Rheumatoid arthritis, Osteoarthritis, Muscular pain, Back pain, Sprain and strain, post-operative pain.
- **Dose Forms Available** – Tablets, Capsules, Injection, Gel, Patch, Suppository.
- **Route of Administration** – Oral, Topical, Intramuscular, Rectal, Transdermal.
- **Half-Life** Approximately 1–2 hours.
- **Side Effects –** Nausea, Headache, Skin irritation (topical/patch), Gastric irritation, Dizziness.
- **Storage -** Store in a cool, dry place, protected from moisture and light.

3.2. Materials Required

- **Drug -** Diclofenac Sodium
- **Polymers (Film forming agents) -** HPMC (Hydroxypropyl Methylcellulose) OR PVA (Polyvinyl Alcohol) OR Eudragit
- **Plasticizer -** PEG-400 OR Glycerine
- **Permeation Enhancer -** Propylene Glycol OR DMSO
- **Solvents -** Distilled Water OR Ethanol OR Methanol (as required)
- **Backing membrane -** Aluminium foil OR Butter paper

4. Method of Preparation

(Solvent Casting Method – Most Common) Step 1: Preparation of Polymer Solution Dissolve required quantity of HPMC or PVA in distilled water. Stir continuously until clear solution forms. Step 2: Drug Solution Dissolve Diclofenac Sodium in small amount of ethanol or water.

- Step 3: Mixing Add drug solution into polymer solution slowly. Add plasticizer (PEG-400) and permeation enhancer. Stir continuously to get uniform mixture.
- Step 4: Casting Pour the mixture into glass mound or petri plate. Spread uniformly.
- Step 5: Drying Dry at room temperature or in hot air oven (40–45°C). Allow solvent to evaporate completely (24 hrs.).
- Step 6: Cutting Remove dried film carefully. Cut into required size patches (e.g., 2×2 cm)

5. Procedure (Step-By-Step)

- **Action of Polymer Solution Prepare -** Dissolve 2 g HPMC in 20 ml distilled water.

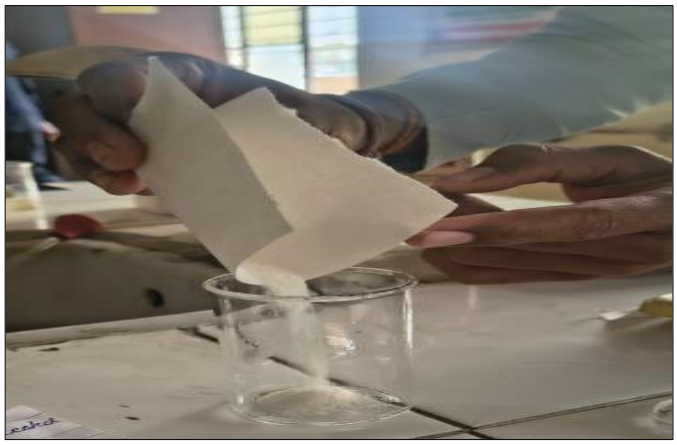

Figure 3 Preparation of Polymer solution

Stir for 1–2 hrs until clear viscous solution forms.

- **Drug Solution** - Dissolve 1 g Diclofenac Sodium in 10 ml ethanol.

Figure 4 Preparation of Drug solution

- **Mixing -** Add drug solution slowly into polymer solution with stirring. Add 0.5 ml PEG-400 (plasticizer). Add 1 ml Propylene Glycol (enhancer). Stir for 30 minutes to get uniform mixture.

Figure 5 Mixing of both Polymer and drug solution

- **Casting -** Pour mixture into glass mould (40 cm^2 area). Cover to avoid dust.

Figure 6 Casting of solution in Petridish

- **Drying -** Dry at 40°C for 24 hours

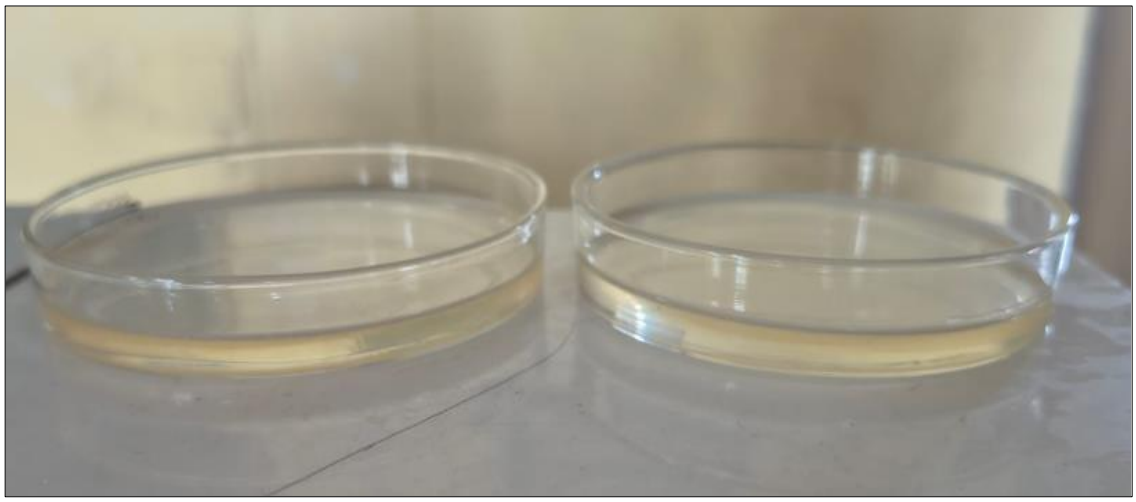

Figure 7 Drying of Casted Solution

- **Cutting -** Remove dried film. Cut into 4 cm^2 patches.

6. Evaluation And Characterization Of Patches

Following tests were performed for the evaluation and characterization of the transdermal patches. These include

- Thickness of patch
- Folding endurance
- Weight Uniformity
- Percentage moisture content
- Percentage moisture uptake

Thickness of patch – To calculate the thickness of patch, we used screw gauge at different positions of the patch and then calculate the average thickness.

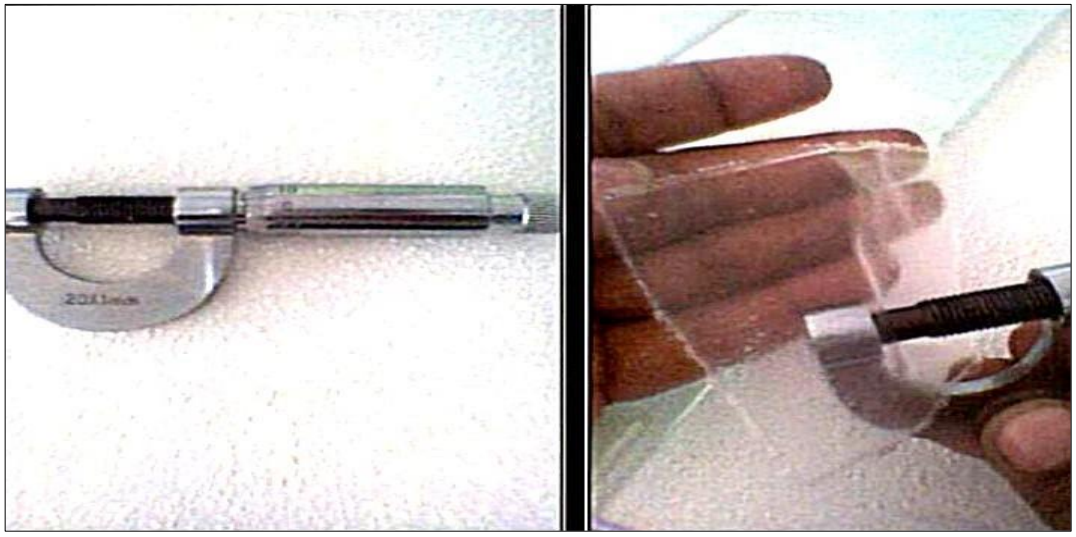

Figure 8 Measurement of Thickness of Patch through screw gauge

- **Folding Endurance -** Evaluation of folding endurance involves determining the folding capacity of the films by subjecting them to frequent folding. This involves repeatedly folding the film at the same place until it breaks. The number of times the films could be folded at the same place without breaking is gives the value of folding endurance. To calculate folding endurance, a patch of 2em radius was cut evenly and repeatedly folded at the same place till it broke. The number of times the film was folded at the same place without breaking was the value of folding endurance.

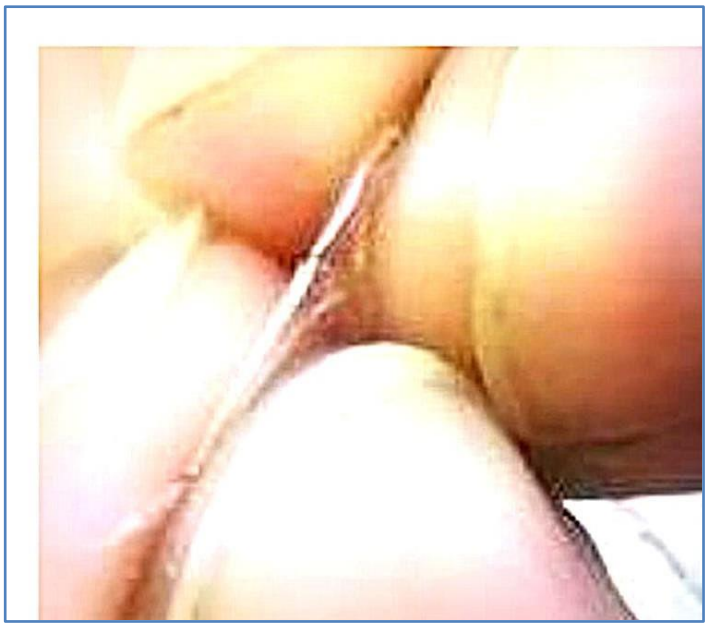

Figure 9 Evaluation of Folding Endurance

- **Weight Uniformity -** Weight uniformity of patch was calculated by cutting the patch into equal sizes of 2cm. The weights of ten different patches were taken and weight variation was calculated. The individual weight should not deviate significantly from the average weight.
- **Percentage Moisture Content -** To calculate percentage moisture content, the patch containing film was weighed and then kept in a desiccator for 24hrs containing calcium chloride at room temperature. After 24hrs, the patch was reweighed and percentage moisture content was calculated from the formula. The percent moisture content was calculated using following formula.

% Moisture content = ((Initial Weight-Final weight/ final weight)) X 100

- **Percentage Moisture Uptake -** To calculate percentage moisture uptake, the patch containing film was weighed and then kept in a desiccator for 24hrs containing saturated solution of potassium chloride. After 24hrs, the patch was reweighed and percentage moisture uptake was calculated from the formula.

% moisture uptake = ((Final weight - initial weight / initial weight)) X 100

Figure 10 Weighing % of Moisture content

- **Flatness test -** A transdermal patch should possess a smooth surface and should not constrict with the passage of time. This can be tested with flatness study. For flatness test, one strip was cut from the center and two from each

side of patches; from the right and the left side. The length of each strip was measured and variation in length was measured by determining percent constriction. Zero percent constriction is equivalent to 100 percent flatness.

% constriction = 11 12 X 100

Were

- 12 = Final length of each strip
- 11 = Initial length of each strip
- **Percentage elongation break test -** The percentage elongation break was determined by noting the length just before the break point, the percentage elongation was determined from the below mentioned formula.

Elongation percentage = ((L1-L2)/L2)) x 100

Were

- LI is the final length of each strip, and
- L2 is the initial length of each strip.

Figure 11 Flatness testing of patches

7. Result and Discussion

The formulated Diclofenac Sodium transdermal patches were found to be clear, smooth, and flexible. Thickness and Weight: The patches exhibited uniform thickness (0.21 \pm 0.02 \text{mm}) and weight, indicating the efficiency of the solvent casting method. Drug Content: The percentage of drug content was found to be within the range of 98.5% to 99.2%, which is highly satisfactory.

Release Profile: The in-vitro release studies showed a controlled and sustained release of Diclofenac Sodium, following zero-order or Higuchi kinetics. The diclofenac sodium transdermal patch was prepared successfully by the solvent casting method using suitable polymer, plasticizer, and permeation enhancer. The selected polymer formed a smooth and flexible film, while the plasticizer improved elasticity and prevented brittleness of the patch. Diclofenac sodium was uniformly dispersed in the polymeric matrix, which helped in obtaining consistent drug content throughout the patch. The permeation enhancer was useful in improving the penetration of drug through the skin membrane. The prepared patch showed satisfactory physical characteristics such as uniform thickness, smooth surface, good folding endurance, and acceptable surface PH. In- vitro drug release studies indicated a controlled and sustained release pattern, which is beneficial for prolonged pain relief. Overall, the formulation demonstrated that diclofenac sodium can be effectively delivered through transdermal route, reducing frequent dosing and minimizing gastric side effects associated with oral administration.

8. Conclusion

The study successfully demonstrates that Diclofenac Sodium can be effectively formulated into a transdermal patch using various grades of polymers. The formulation provides a controlled release of the drug, which can significantly improve patient compliance by reducing the frequency of dosing. Furthermore, this transdermal delivery system bypasses the hepatic first- pass metabolism and avoids the gastrointestinal side effects commonly associated with oral Diclofenac administration. These patches remain stable and provide a consistent therapeutic effect, making them a viable alternative to conventional dosage forms.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

References

[1] Chaitanya NCSK, et al. A comparative evaluation of diclofenac sodium transdermal patch, oral diclofenac sodium with intramuscular injections. Int J Pharm Investig. 2017;

[2] Gschwend MH, et al. Determination of the transdermal bioavailability of a newly developed diclofenac sodium patch. Arzneimittelforschung. 2005;

[3] Diwan V, et al. Comparative evaluation of transdermal diclofenac patch with oral diclofenac sodium after periodontal flap surgery. Indian J Dent Res. 2019;

[4] Sa'adon S, et al. Electrospun nanofiber and cryogel of PVA transdermal patch containing diclofenac sodium. Pharmaceutics. 2021;

[5] Sa'adon S, et al. Preparation and physicochemical characterization of a diclofenac sodium dual-layer PVA patch. Polymers. 2021;

[6] Taguchi T, et al. Systemically acting diclofenac sodium patch for control of low back pain. Pain Ther. 2023

[7] Perepa A, et al. Diclofenac transdermal patch: A potential ingress to maxillofacial surgery. J Maxillofac Oral Surg. 2017;

[8] Taguchi T, et al. Combined efficacy of systemically acting diclofenac sodium patch in chronic low back pain. Pain Ther. 2023.

[9] Kothai P, et al. Study to evaluate analgesic efficacy of transdermal diclofenac sodium patch. Indian J Forensic Med Toxicol. 2021.

[10] Nurmalia Z, et al. Comparison of in- vitro penetration of transdermal patch containing diclofenac sodium nanoparticles. Asian J Pharm Res Dev. 2020.

[11] Kriplani P. Formulation and evaluation of transdermal patch of diclofenac sodium. Global J Pharm Pharm Sci. 2018.

[12] Barry BW. Dermatological Formulations. Routledge.

[13] Allen LV. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems. Lippincott.

[14] Remington. Remington: The Science and Practice of Pharmacy. Pharmaceutical Press.

[15] Jain NK. Controlled and Novel Drug Delivery. CBS Publishers.

[16] Brahmankar DM, Jaiswal SB. Biopharmaceutics and Pharmacokinetics. Vallabh Prakashan.

[17] World Health Organization. Guidelines on pharmaceutical preparations.

[18] Food and Drug Administration. Guidance for topical and transdermal delivery systems.

[19] European Medicines Agency. Quality guidelines for transdermal patches.

[20] International Council for Harmonisation. Stability testing guidelines (Q1A).