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Research Article

Preparation and Characterization of Transdermal Patches for Osteoarthritis

Muskan Das[1], Harish Sharma[2], Gyanesh Kumar Sahu[2*]

[1]*Rungta Institute of Pharmaceutical Sciences (C G).*
[2]*Rungta Institute of Pharmaceutical Sciences and Research (C G).*

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ABSTRACT

Pain can last a short time and go away when you heal (acute pain). Or it can also last for months or years (chronic pain). The elderly population comprises the fastest growing segment of the world's population. As patients age, the incidence and prevalence of certain pain syndromes increase. Pain may be underreported as some elderly patients incorrectly believe that pain is a normal process of aging. A comprehensive pain assessment includes a thorough medical history and physical examination, review of systems and pertinent laboratory results, imaging studies, and diagnostic tests. The result includes good physicochemical properties such as thickness, weight uniformity, folding endurance and mixture content. These were found to be stable and hence there is scope for further pharmacokinetic and pharmacodynamic evaluation. Thus, it can be concluded that the pain can be treated by Aceclofenac topically in the form of transdermal patch.

INTRODUCTION

Everyone feels some kind of pain from time to time. Pain is the most common symptom of potentially thousands of injuries, diseases, disorders and conditions you can experience in your lifetime. It can also result from treatments for conditions and diseases. (1) Pain can last a short time and go away when you heal (acute pain). Or it can also last for months or years (chronic pain). The elderly population comprises the fastest growing segment of the world's population. (2) As patients age, the incidence and prevalence of certain pain syndromes increase. Pain may be underreported as some elderly patients incorrectly believe that pain is a normal process of aging. A comprehensive pain assessment includes a thorough medical history and physical examination, review of systems and pertinent laboratory results, imaging studies, and diagnostic tests. (3) Pain physicians should have a broad range of understanding of the pharmacologic and

***Corresponding Author:** Gyanesh Kumar Sahu
Address: *Rungta Institute of Pharmaceutical Sciences and Research (C G)*
Email : gyanesh.sahu23@gmail.com
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physiological changes that occur in the geriatric population. The present review on pain management in the elderly focuses on relevant information for the pain clinician. Included are appropriate pain assessment, physical examination, pathophysiologic changes in the elderly, pharmacokinetic and pharmacodynamic changes, and present pain management modalities. (3,4) Elderly patients present with increased fat mass, decreased muscle mass, and decreased body water, all of which have important ramifications on drug distribution. Hepatic phase I reactions involving oxidation, hydrolysis, and reduction appear to be more altered by age than phase II conjugation such as acetylation, glucuronidation, sulfation, and glycine conjugation. There is a predictable age-related decline in cytochrome P-450 function and, combined with the polypharmacy that much of the elderly population experiences, this may lead to a toxic reaction of medications. One of the newer opiates, oxymorphone, has recently been studied as it is metabolized in a non-cytochrome P-450 pathway and therefore bypasses many of the drug-drug interactions common to the elderly. (4)

PAIN MANAGEMENT

Anyone with pain can benefit from a pain management plan. A comprehensive plan can help people manage pain that lasts a few days (such as after an injury or surgery). It can also help people who have long-term pain from disease or chronic health conditions. The purpose of pain management is to evaluate, diagnose and treat different types of pain. There is 2 main type of OTC medicine:

1. Acetaminophen (Tylenol)
2. Non-steroidal anti-inflammatory (NSAIDs)
    - Aspirin
    - Diclofenac
    - Ibuprofen
    - **Aceclofenac**

Pain is the main symptom of a wide range of injuries, infections and diseases. Cancer pain can result from nearly every type of cancer. (5,50,55,63) One of the first signs of a heart attack is often chest pain that may move to your arms, back or jaw. Some of the most common conditions that cause pain include:

Arthritis and muscle and joint injuries: Several types of arthritis, including osteoarthritis and gout, cause severe pain in the joints. Orthopedic injuries (such as frozen shoulder) limit mobility and lead to pain and stiffness.

Autoimmune disorders: Lupus, Crohn's disease and other autoimmune disorders cause your immune system to attack the body.

Back injuries: Herniated disks, sciatica and other back problems are common causes of pain and limited mobility.

Chronic pain disorders: There are several disorders that can lead to widespread pain all over your body. These include fibromyalgia, complex regional pain syndrome (CRPS) and central pain syndrome.

Endometriosis: This painful condition causes the lining of the uterus to grow outside of the uterine walls. Endometriosis causes abdominal pain and irregular periods.

Facial pain: Several conditions can cause pain in your face, including trigeminal neuralgia (TN), an abscessed tooth and other dental problems.

Headaches: Migraine headaches and cluster headaches cause pain in the head and neck.

Kidney stones and urinary tract problems: Kidney stones can cause severe pain when they pass through your body with urine (pee). Interstitial cystitis (painful bladder syndrome) causes pelvic pain and pressure.

Nerve damage (neuropathy): Damaged nerves can lead to pain, stinging and tingling. Carpal tunnel syndrome is a common type of neuropathy. (4,63)

Pain

Some types of pain result from a disease or accident. Other pain may linger or come back after treatment. Sometimes, pain results from treatments (such as pain after surgery). Some pain has no known cause. The types of pain include:

1. Acute: This type of pain is sharp and often results from an injury. Acute pain gets better when providers treat the injury or disease that's causing the pain. This type of pain can result from a bone fracture, muscle spasms, a burn or other kind of accident. Some illnesses and disorders, such as appendicitis and shingles, cause acute pain.

2. Chronic: Providers call pain that lasts more than six months chronic pain. This type of pain can result from an untreated injury or disease. It can also result from conditions like arthritis, fibromyalgia or nerve damage (neuropathy). Low back pain is another type of chronic pain.

3. Nociceptive: Nerve cell endings (nociceptors) send pain signals to your brain when you have an injury. Nociceptive pain happens when you break a bone, bump your head or pull a muscle. The pain can be sudden and short-lived or long-lasting. It can affect your internal organs (visceral pain) or your musculoskeletal system (somatic pain).

4. Neuropathic: Problems with the nervous system cause neuropathic pain (nerve pain). It happens when nerves fire pain signals to the brain by mistake, even when they aren't damaged. Diabetes, multiple sclerosis (MS) and HIV commonly cause this type of pain. (4,6,51-55)

Osteoarthritis

Osteoarthritis is the wide most common joint disorder diseases in all over the globe. This disease is very common among older age people around 60-80 age and approximately 10% of male and 13% of female is suffering from osteoarthritis in United states. (7,8) In India the percentage of osteoarthritis are found to be 22% in males and 39% in females. Basically, the number of people affected by osteoarthritis is likely to increase due to the aging and obesity epidemic. The percentage of getting infected by this disease is more in females as compared to male, but the prevalence increases dramatically with age. Pain from OA is a key symptom in the decision to seek medical care and is an important antecedent to disability.(11,61-64) Because of its high prevalence and the frequent disability that accompanies disease in major joints such as the knee and hip, OA accounts for more difficulty with climbing stairs and walking than any other disease.(10)OA is also the most common reason for total hip and total knee replacement.(10) The rapid increase in the prevalence of this already common disease suggests that OA will have a growing impact on health care and public health systems in the future.(9)Osteoarthritis (OA) can be classified into two categories: primary osteoarthritis and secondary osteoarthritis. Classically, OA presents with joint pain and loss of function; however, the disease is clinically very variable and can present merely as an asymptomatic incidental finding to a devastating and permanently disabling disorder. This activity reviews the etiology, presentation, evaluation, and management of osteoarthritis and reviews the interprofessional team's role in evaluating, diagnosing, and managing the condition. (12) Pathological changes in the late stage of OA include softening, ulceration, and focal disintegration of the articular cartilage. Synovial inflammation also may occur(13,14) Typical clinical symptoms are pain, particularly after prolonged activity and weight-bearing; whereas stiffness is experienced after inactivity(13,55-60) It is probably not a single disease but represents the final end result of various disorders leading to joint failure.(13,15) It is also known as degenerative arthritis, which commonly affects the hands, feet, spine, and large weight-bearing joints, such as the hips and knees.(15)

Symptoms of Osteoarthritis

The symptoms of osteoarthritis often begin slowly and usually begin with one or a few joints. The common symptoms of osteoarthritis include:

- Pain when using the joint, which may improve with rest. For some people, in the later stages of the disease, the pain may be worse at night. Pain can be localized or widespread.
- Joint stiffness, usually lasting less than 30 minutes, in the morning or after resting for a period of time.
- Joint changes that can limit joint movement.
- Swelling in and around the joint, especially after a lot of activity or use of that area.
- Changes in the ability to move the joint.
- Feeling that the joint is loose or unstable.

Causes of Osteoarthritis

Osteoarthritis happens when the cartilage and other tissues within the joint break down or have a change in their structure. This does not happen because of simple wear and tear on the joints. Instead, changes in the tissue can trigger the breakdown, which usually happens gradually over time.

Certain factors may make it more likely for you to develop the disease, including:

- Aging.
- Being overweight or obese.
- History of injury or surgery to a joint.
- Overuse from repetitive movements of the joint.
- Joints that do not form correctly.
- Family history of osteoarthritis.

Structural Changes in OA

The signature pathologic feature of OA is articular cartilage loss which is typically recognised on plain radiographs as a reduction in joint space. Loss of cartilage and joint disruption is linked with attempts at repair with new bone formation occurring and the development of subchondral sclerosis and osteophytes. With the advent of more detailed imaging studies, particularly magnetic resonance imaging (MRI), OA is now widely recognised as a disease involving the whole joint including ligaments, menisci, synovium (synovitis), and joint capsule.(21) MRI studies also show evidence of abnormal bone structure at the subchondral boundary with cysts and bone marrow lesions (BMLs)—the latter best visualised on MRI as hyper-intense areas using fat-suppressed T2-weighted or proton density-weighted imaging (22,23,41-45).

Nociception Within the Joint

Within the joint, there are pain-sensing afferent neurons (nociceptors) in many of the anatomic tissues affected by OA including the periosteum and subchondral bone (16), soft tissues including ligament insertions (16), menisci (17,18) and synovium (17,46-50). Although cartilage loss is an important structural feature, it is not innervated and therefore cannot be a direct source of pain in mild to moderate disease. In-vivo studies corroborate this. For example, in a study in which an orthopaedist underwent arthroscopy with only the soft tissues around the joint anaesthetised, probes inside the joint suggested that probes of the cartilage were not painful (19). In more severe disease, neurovascular invasion at the osteochondral junction may occur and potentially contribute to pain (20). Also, in mild and moderate disease, microscopic cartilage debris can be phagocytosed by cells lining the synovium, triggering inflammatory responses and pain from synovitis. (19,20,23,35-40)

MATERIALS AND METHODS

Aceclofenac was received as a gift sample from Atulya Medlink, Haryana. Hydroxyl propyl methyl cellulose, Propylene glycol and Polyethylene glycol 400 were purchase from Sigma Aldrich. Other materials used in the study (methanol, glycerol) were of analytical grade. Double distilled water was used throughout the study.

Preparation of transdermal patch

Transdermal patch of aceclofenac were prepared by solvent casting technique. (Table no.1) A petri dish with total area of 44.15cm2 was used. Polymer were accurately weight and dissolved in 10ml of water, methanol (1:1) solution then kept aside to form clear solution. Drug was dissolved in above solution and mixed until the clear solution was obtained. Polyethylene glycol 400 (30% w/w of total polymer) was used as plasticizer and propylene glycol (15% w/w of total polym0er) was used as a permeation enhancer. Magnetic stirrer is used to mix all the solution properly. The resulted uniform solution then cast on petri dish before that petri dish was lubricated with glycerol and then the uniform solution is dried at room temperature for 24h. An inverted funnel was placed over the top of perti dish to avert fast evaporation of the solvent present. After 24h, the dried patch were taken out and stored in a desiccators for further studies.

Figure no.01 Transdermal patch with Aceclofenac drug

Table 1: Formulation table of transdermal.

S.No.	Ingredients	Formulation Batches					
		F1	F2	F3	F4	F5	F6
1.	Aceclofenac (mg)	50	50	50	50	50	50
2.	HPMC (mg)	167	170	175	175	175	175
3.	Propylene glycol (mg)	-	-	-	100	150	200
4.	Polyethylene glycol 400 (ml)	0.4	0.4	0.4	0.4	0.4	0.4
5.	Methanol (ml)	5.5	5.5	5.5	5.5	5.5	5.5

Thickness of the patch

The thickness of the drug loaded patch was measured in different points by using a digital micrometer and determines the average thickness and standard derivation for the same to ensure the thickness of the prepared patch. (24,25)

Figure no. 02a measuring the thickness of patch using micrometer

Weight uniformity

The prepared patch was dried at 60 degree Celsius for 4hrs before testing. A specific area of patch was cut in different part of the patch and weight in digital balance. The average weight and standard deviation values are to be calculated from the individual weight. (26,27)

Figure no.02b Patches dried at 60°*c* in hot air oven

Folding endurance

A patch of 2cm radius (4cm diameter) was cut evenly and repeatedly folded at the same place till it breaks. The number of times the film was folded at the same place without breaking give the value of the folding endurance. (28)

Percentage moisture content

The prepared films were weighed individually and kept in a desiccator containing fuse calcium chloride at room temperature for 24h. After, the films were reweighted and determined the percentage moisture content from the mentioned formula. (20,30)

Figure No. 3 Moisture content of patch

RESULTS AND DISCUSSION

The method of preparation of transdermal patch of Aceclofenac is prepared by using HPMC, propylene glycol, polyethylene glycol. The evaluation parameters showed promising results. The result includes good physicochemical properties such as thickness, weight uniformity, folding endurance and mixture content. These were found to be stable and hence there is scope for further pharmacokinetic and pharmacodynamic evaluation. Thus, it can be concluded that the pain can be treated by Aceclofenac topically in the form of transdermal patch.

Table no.02 Properties of transdermal patches containing ACF

Formulation code	Thickness (mm) ± S.D	Weight uniformity(mg)	Folding endurance± *S.D*	Moisture content (%)± S.D
F1	0.154± 0.0076	96 ±130	45± 2.5	2.32± 0.56
F2	0.173±0.0080	105± 3.08	72± 3.5	2.92± 0.69
F3	0.233±0.0043	110± 2.50	5.1± 3.0	4.04 ±0.89
F4	0.198±0.0090	116 ±3.08	39± 4.4	1.96± 0.39
F5	0.145±0.0091	125± 2.029	57± 1.9	1.78± 0.33
F6	0.249±0.0080	135± 3.51	45± 2.1	1.64 ±0.31

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