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THE EFFICACY OF TRANSDERMAL PATCHES OF DICLOFENAC SODIUM WITH ORAL DICLOFENAC SUSTAINED RELEASE (SR) IN PATIENTS OF OA KNEE BY USING NRS PAIN SCORE AND VAS SCORE

Orthopaedics

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ABSTRACT

Introduction: Osteoarthritis (OA) affects 37.4% of adults over 60 and costs the US economy over $60 billion a year. The onset of OA is linked to genetics, aging, joint misalignment, and obesity. The progression of osteoarthritis is associated with joint deterioration, stiffness, narrowing, and persistent pain. Even though the basic mechanism underlying the advancement of OA and the discomfort it produces is not entirely known, inflammation plays a crucial role in the degradation of afflicted joints over time. **Methods:** The present study were conducted in the department of Orthopaedic surgery of SRMS-IMS, Bareilly from 1st February 2021 to 31st June 2022 in all the patients having Osteoarthritis of Knee coming to OPD, after obtaining approval from Institutional Ethics Committee. Either a pill of diclofenac SR or a transdermal patch was administered to the qualified patients. A visual analog scale was used to measure pain at two and four weeks. Unfavorable incidents were noted. **Results:**There was no significant difference in complete blood count between the group (P>0.05). We observed there was a significant decrease in pain in both groups. However, the pain was significantly lower in Transdermal Diclofenac Patch. **Conclusion:** Our findings indicate that a transdermal diclofenac diethylamine patch is equally efficacious as an oral dose of diclofenac sodium SR in treating patients with chronic MSK discomfort. Compared to oral diclofenac sodium SR, transdermal diclofenac diethylamine patch treatment exhibited a significantly decreased percentage of gastrointestinal side effects in this study.

KEYWORDS

Osteoarthritis, VAS Score, NRS Scale

INTRODUCTION

In persons over 60, osteoarthritis (OA) affects 37.4% of the population and costs the US economy about $60 billion annually.[1]Joint misalignment, aging, genetics, and obesity are associated with the development of OA.[2,3]Joint degeneration, stiffness, narrowing, and chronic pain are all linked to the advancement of OA.[4–6]Inflammation contributes significantly to the deterioration of impacted joints over time, even if the fundamental mechanism of OA progression and the pain it causes is not fully understood. The only options for treating osteoarthritis (OA) are pain control, joint stiffness reduction, improved function, range of motion, and the patient's quality of life despite the condition.[7]Weight loss, exercise, physical therapy, acupuncture, therapeutic ultrasonography, hyaluronic acid injection, systemic or topical administration of nonsteroidal anti-inflammatory medications (NSAIDs), and surgery are among the current symptomatic treatments for osteoarthritis (OA). Many of these therapies have long-term negative side effects or procedural risk, only temporarily relieve pain, and compromise the integrity of the skin.[8–10]

For many years, nonsteroidal anti-inflammatory medications (NSAIDs) have been a staple in the management of pain associated with osteoarthritis (OA). Long-term use of systemic NSAIDs have adverse effects on the kidney, liver, and gastrointestinal system,[11,12] while the topical application of NSAIDs has limited penetration through the skin.[13]Recent meta-analyses have demonstrated that diclofenac is more effective than other NSAIDs including ibuprofen, celecoxib, and ketoprofen.[14,15]The effectiveness of diclofenac penetration through the skin has been studied utilizing a variety of techniques, including iontophoresis, sonophoresis, electroporation, and skin penetration enhancers.[16,17]

Topical NSAIDs, including gels and transdermal patches, are well-liked for their benefits, which include a lower risk of GI adverse events, and are also used to treat OA knee pain. Since they may have a better safety profile than oral NSAIDs, transdermal NSAIDs appear to be a desirable substitute.[18,19]Diclofenac sodium patch outperformed placebo in a double-blind, randomized, placebo-controlled treatment of myofascial pain of the upper trapezius, decreasing visual analog ratings and enhancing functional results while posing no appreciable side effects.[20] The present study was aimed to evaluate the efficacy of transdermal patches of diclofenac sodium with oral diclofenac sustained release (SR) in patients of OA knee by using NRS pain score and vas score.

METHODS

The present study were conducted in the department of Orthopaedic surgery of SRMS-IMS, Bareilly from 1st February 2021 to 31st June 2022 in all the patients having Osteoarthritis of Knee coming to OPD, after obtaining approval from Institutional Ethics Committee Patients must be ≥18–65 years old, of any gender, and have a pain score of ≥4 on an 11-item numeric rating scale (NRS), which is a numeric version of the visual analog score (VAS). The patient must also have an independent radiological confirmation of primary OA of the knee or hand and must be experiencing pain associated with other MSK conditions, such as soft-tissue rheumatism, cervical and lumbar back pain, and fibromyalgia, in addition to their pain.Exclusions from the study included a history of secondary OA, NSAID-related allergies or asthma, severe or uncontrolled renal, hepatic, and hematologic abnormalities found through laboratory investigations, a history suggestive of cardiovascular or neurologic disease, patients taking any NSAID other than diclofenac sodium, and mothers who were pregnant or nursing.

Patients with chronic osteoarthritis (OA) knee pain as determined by an orthopedician were informed about the trial if they met the inclusion criteria. All potential participants received patient information sheets, and patients who agreed to participate provided signed informed consent in plain language. Throughout the whole investigation, subject confidentiality was preserved. Following enrollment, the case record form was filled out with information on the patient's age, gender, diagnosis, course of treatment, and initial clinical laboratory tests.

RESULTS

Baseline characteristics

In our study, there was no significant difference in age group between the transdermal diclofenac patch and oral diclofenac Na SR (0.778). Mean age also showed a non-significant difference between the transdermal diclofenac patch and oral diclofenac Na SR (P=0.557). In transdermal diclofenac patch group, 64% of patients' sere male and 36% of patients were female while in oral diclofenac Na SR group, 60% of patients were male and 40% of patients were female. Gender showed a non-significant difference between transdermal diclofenac patch and oral diclofenac Na SR group. The right side was most common in each group.

Complete blood count

There was no significant difference in complete blood count between

the group (P>0.05).

Numerical rating score

In our study, we observed there was a significant decrease in pain in both groups. However, the pain was significantly lower in Transdermal Diclofenac Patch.

Visual analog (VAS) scores

In our study, we observed there was a significant decrease in pain in both groups. However, the pain was significantly lower in Transdermal Diclofenac Patch

DISCUSSION

Chronic knee pain caused by OA continues to be a widespread problem, despite recent advancements in treatment. OA knee pain can result in significant disability and is frequently associated with decreased activity, sleep disturbances, fatigue, and mood swings. People who experience chronic pain frequently find themselves caught in a "vicious circle" of problems. Anxiety and depression are brought on by the pain, and they may make the pain worse.[21] There are a variety of treatment options available for chronic arthritic knee pain, including nonsteroidal anti-inflammatory drugs (NSAIDs) such as diclofenac, ibuprofen, paracetamol, and aspirin, opiates, opioids, and other pharmacologic agents such as antidepressants and seizure medications. Some of the methods that nonsteroidal anti-inflammatory drugs (NSAIDs) can be administered are orally, parenterally, rectal, and topically. The oral route of administration is the most common form of administration; however, this strategy has been associated with significant side effects, including difficulties with the gastrointestinal tract, cardiovascular system, and renal system.[22] To address the problem that is caused by oral NSAIDs, there are a number of topical NSAID treatments that are available. These treatments come in the form of gels and transdermal patches. Both the diclofenac epolamine patch and the diclofenac diethylamino patch are transdermal patches that contain diclofenac salts and are approved for use in the treatment of pain.

After only two weeks of applying a transdermal diclofenac dimethylamine patch, patients who suffered from chronic pain in their musculoskeletal system showed signs of recovery, according to the primary finding of our research. After the first two weeks of treatment, the transdermal diclofenac dimethylamine patch (100 mg) led to a drop in the numerical rating scale for pain that was statistically and clinically significant. This was the outcome of the patch.[23] These results confirm findings of study conducted by P. Brühlmann and Michel[24] in OA of knee joint. Diclofenac patch resulted in a statistically significant reduction ($P < 0.01$) in VAS compared to control patch in a study by Hsieh et al.[13] in myofascial pain syndrome of upper trapezius.[20]

When the two groups in our study were evaluated for efficacy, it was found that the transdermal diclofenac diethylamine patch (100 mg) once daily was just as effective as the tablet diclofenac sodium SR (100 mg) once daily in terms of reducing pain by NRS at the end of two weeks and continued until four weeks. This was the case even though the patch was applied once daily. In the course of this clinical research, the group that received the transdermal diclofenac dimethylamine patch had an overall reduction in pain of 45.03%, whereas the group that received the tablet diclofenac SR demonstrated an overall improvement in pain of 46.38%. The maximum level of patient impression of improvement was shown to correspond with a reduction in pain intensity of fifty percent, according to a study conducted by Farrar and colleagues.[23] The search for literature was exhaustive; nevertheless, there were no head-to-head comparative studies found between the transdermal diclofenac dimethylamine patch and the tablet diclofenac sodium SR for the treatment of chronic pain in the musculoskeletal system. As a result, it is challenging to compare our findings with those of previously published papers. Numerous studies, on the other hand, have compared the transdermal diclofenac patch to the tablet diclofenac sodium SR in the treatment of postoperative pain and acute pain, such as the pain that is caused by the extraction of a tooth. Following the excision of mandibular impacted third molars on the second and third postoperative day, Prithvi S. Bachali and colleagues conducted a study in which they found that the transdermal diclofenac dimethylamine (100 mg) patch group gave analgesia that was comparable to that of oral diclofenac (100 mg) SR. This was determined by measuring the pain on the visual analogue scale (VAS).[18]

CONCLUSION

According to the findings of our study, a transdermal patch containing diclofenac diethylamine is equally as effective as an oral dose of diclofenac sodium SR in treating patients who suffer from chronic pain in the musculoskeletal system. The percentage of gastrointestinal (GI) adverse events that were linked with the transdermal application of diclofenac diethylamine patch treatment was significantly lower in this experiment compared to the oral administration of diclofenac sodium SR. It is necessary to conduct studies over a longer period of time in order to evaluate the safety of the transdermal diclofenac diethylamine patch.

Table 1: Baseline characteristics

Baseline characteristics	Transdermal Diclofenac Patch (n=25)	Transdermal Diclofenac Na SR (n=25)	P Value
Age group			0.778
≤30 years	5	6	
31-40years	11	9	
41-50years	2	4	
51-60 years	4	2	
>60years	3	4	
Mean age (years)	49.56±8.56	51.23±11.26	0.557
Gender			0.770
Male	16	15	
Female	9	10	
Side Involved			0.135
Right side	19	14	
Left side	6	11	

Table 2: Complete blood count

Complete blood count	Transdermal Diclofenac Patch (n=25)	Transdermal Diclofenac Na SR (n=25)	P Value
Hemoglobin (g)	11.46±2.56	12.67±3.45	0.566
TLC (/mm^3)	5460.67±1754.89	6134.23±1978.32	0.230
Platelet count (/mm^3)	267.54±87.76	249.87±83.79	0.450
Blood urea (mg/dL)	23.45±4.67	22.23±3.24	0.387
5Sr. Creatinine (mg/dL)	0.80±0.19	0.73±0.16	0.198
SGOT (IU/L)	22.34±6.76	23.50±8.54	0.054
SGPT (IU/L)	20.24±6.65	23.15±7.14	0.065

Table 3: Numerical rating score

Numerical rating score	Transdermal Diclofenac Patch (n=25)	Transdermal Diclofenac Na SR (n=25)	P Value
Baseline	8.23±2.12	7.45±2.45	0.812
3 weeks	4.67±1.12	6.01±1.56	0.001
6 weeks	2.87±0.89	4.01±1.01	0.001

Table 3: Numerical rating score

visual analog (VAS) scores	Transdermal Diclofenac Patch (n=25)	Transdermal Diclofenac Na SR (n=25)	P Value
Baseline	8.15±2.38	7.78±2.70	0.787
3 weeks	5.54±1.76	7.01±1.98	0.007
6 weeks	2.90±0.97	3.98±1.12	<0.001

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