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TRANSDERMAL PATCH AS A MODALITY OF ANALGESIA IN POST-EXTRACTION PAIN—A PRELIMINARY CLINICAL STUDY

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ABSTRACT
Aim: The aim of this study was to assess the analgesic efficacy of transdermal diclofenac patch in patients undergoing elective intra-alveolar tooth extraction. **Materials and methods:** A preliminary prospective clinical study was conducted among 30 patients selected for elective tooth extraction in either maxillary or mandibular arch. After extraction by a single qualified Oral surgeon, a blinded operator applies a diclofenac transdermal patch following which pain was assessed using a Visual Analog Scale (VAS) and the consumption of rescue analgesia post-operatively. **Results:** The post-operative VAS score to assess pain had a mean ± SD VAS score of 3.5± 2.271. n = 11 (36.66%) patients needed the consumption of rescue analgesia post-operatively among the study population. **Conclusion:** From this study, we conclude that transdermal diclofenac patch is a promising modality to achieve analgesia in patients undergoing tooth extraction with reduced effects of systemic toxicity.

KEYWORDS: Transdermal patch, Drug delivery, Diclofenac, Extraction, Post-operative pain.

INTRODUCTION
Transdermal drug delivery system (TDDS) is a medicated adhesive patch, which is placed on the skin to deliver a medication into the circulatory system.[1] Administering diclofenac orally has a drawback as half of the drug becomes unavailable systemically because of first pass metabolism.[2] The highlights of transdermal route of delivery are controlled, constant administration of the medication. Salient advantages of this system includes good patient compliance due to ease of self-administration. As it by-passes first pass metabolism in the liver, gastric irritation is avoided. The plasma level of the drug is maintained constantly and can also be used in unconscious patient.

Overall therapeutic efficiency of the medication is improved when applied transdermally. Some of the established drugs which have been successfully used by the TDDS includes hormone replacement (estradiol, testosterone), angina (nitroglycerine), motion sickness (scopolamine), smoking cessation (nicotine patches), dermal analgesia (lidocaine), analgesics (diclofenac, buprenorphine).[3,4,5] The principle of the transdermal patch is through the process of diffusion where the drug enters into circulation via the skin. As the concentration of the drug in the patch is high there would be continuous diffusion into the blood stream, thereby constant concentration is maintained.[6] Many trials has successfully confirmed diclofenac sodium as an effective anti-inflammatory drug in various painful conditions such as post-surgical care, odontogenic pain, arthritis and musculoskeletal disorders.[7,8]

The constituents of a transdermal patch are release liner which protects the patch during storage and needs to be removed before application. The drug reservoir contains particles of the drug which is dispersed in the matrix. Thus it constitutes the primary component of the patch. Adhesive layer keeps the components of the patch together and also to adhere the patch to the skin. Backing layer protects the patch from the external environment. The mechanism of transdermal patch involves the release of medicament from the patch membrane which is absorbed by the stratum corneum which is the outermost

layer of the skin and then it penetrates through the epidermis along the lipidic intercellular pathway. Diffusion through the corneal layer is followed by the absorption in the capillaries of papillary layer of dermis.[1,4]

The aim of this study was to assess the analgesic efficacy of transdermal diclofenac patch in patients undergoing elective intra-alveolar tooth extraction.

MATERIALS AND METHODS

The study was conducted among 30 patients requiring an elective extraction of any permanent tooth in either maxilla or mandible. The patients included were from age range of 18 - 60 years, both the genders, ASA class I patients. Patients who were allergic to non-steroidal anti-inflammatory drug (NSAIDs), not willing to sign the informed consent were excluded from the study.

The patients were randomly selected from the outpatient department who reported for tooth extraction. All the tooth extractions were performed atraumatically using forceps or elevator under strict aseptic precautions by a single qualified Oral Surgeon. Regular post-operative instructions were given. A single transdermal diclofenac patch (Nupatch, Zydus Cadilla, 200 mg) was applied over the biceps region immediately after tooth extraction. All the patients were instructed not to remove the patch for 24 hours post-operatively. A 10 point Visual analogue scale (VAS) was used to access the pain in the post-operative phase in the first 24 hours. If required, rescue analgesic of tablet diclomol (Diclofenac 50 mg + Paracetamol 500 mg, Win-Medicare) was administered after a telephonic follow up by a single blinded research assistant and the number of rescue analgesia was noted.

DATA COLLECTION AND STATISTICS

All the data were collected by the blinded research assistant and analyzed using SPSS software. Student's t test was used with significance of *p* was considered at 0.05.

RESULTS

All the 30 patients included in this study were between age range of 18 – 60 years. Among the study population, n = 19 (63.3%) were males and n = 11 (36.66%) were females. n= 11 (36.66%) were between 15-25 years of age, n = 7 (23.33%) were between 26-35 years of age, n = 2 (6.66%) were between 36-45 years of age and n = 10 (33.33%) were between 46-55 years of age. The post-operative VAS score to assess pain had a mean ± SD of 3.5 ± 2.271. n = 11 (36.66%) patients needed the consumption of a single dose of rescue analgesia post-operatively. No complications were observed in any patients post-operatively.

DISCUSSION

TDDS is found to be an effective method to relieve post-operative pain. It is often known as patches is a non-invasive way to deliver medications across the skin surface. It is a potent alternative to administer drugs other than conventional routes. It delivers the drug at a pre-determined rate across the skin to receive a local effect. Patches were first used for systemic delivery of scopolamine to treat motion sickness. The success of nicotine patches popularized the transdermal patch usage for other applications as well.[1,3,4]

The results of the present study shows that diclofenac transdermal patch is effective in managing post-operative analgesia following atraumatic extraction of maxillary and mandibular teeth. Few patients had the requirement for rescue analgesia post-operatively. This could be attributed to the fact that pain tolerance is different in every patient. Literature evidence suggests that transdermal patch is effective in achieving analgesia post-operatively after various minor and major surgical procedures with any major adverse effects and reduced systemic complications as compared to the oral route of drug administration.

Bhaskar H et al.[2] conducted a cross over efficacy between transdermal and oral diclofenac in patients undergoing orthodontic extractions. He observed that patients who received both oral and transdermal diclofenac had relief from pain but those with transdermal diclofenac were more comfortable as it needs to be applied once a day with less systemic adverse effects. He concluded that transdermal diclofenac was equally potent as compared to the oral route of drug administration. Similar results were observed by Bachalli PS et al.[9] in their study where they compared the efficacy of transdermal diclofenac patch to that of oral diclofenac after extraction of mandibular third molar tooth. They observed that transdermal patch was effective in achieving post-operative analgesia following mandibular third molar extraction. However they found that there may be requirement to consume diclofenac orally in the initial post-operative period as the peak efficacy of patch is initiated after few hours of application.

Selvi UGP et al.[10] conducted a cross over efficacy trial in patients undergoing extraction of mandibular third molars by comparing the analgesic efficacy of transdermal diclofenac patch to that of intramuscular diclofenac injection and observed that diclofenac administered as transdermal patches or intramuscular injections has similar effectiveness. Patients who received transdermal patch showed better compliance without the need for oral medications. The author concluded that transdermal diclofenac patch is a promising modality to achieve analgesia to manage mild to moderate pain after dental extractions.

CONCLUSION

Effective post-operative pain management depends not only on a profound knowledge of drugs but also pharmacokinetics and the route of drug administration. The clinician plays a major role in deciding the dosage

and the route of administration for a particular drug. From this study, we conclude that TDDS can be effectively used to relieve post-operative pain following dental extraction.

COMPLIANCE WITH ETHICAL STANDARDS

Funding: Nil.

Conflict of Interest: None.

Ethical approval: Obtained. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from the patients involved in this study.

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