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Efficacy of Single Dose of Transdermal Patch as a Pre-Operative Analgesic in Root Canal Treatment – A Randomized Clinical Trial

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Abstract:

Introduction:
Pain is the most common reason for patients seeking root canal therapy, hence, relieving the patients from it is most essential for endodontic success.

Aim:
The aim of the study is to evaluate the efficacy of single dose of transdermal patch as a pre-operative analgesic in root canal treatment and to evaluate pain using visual analogue scale (VAS) at baseline, 4 hrs, 8 hrs & 24 hrs.

Materials & methods:
Fifty patients with symptomatic irreversible pulpitis with VAS score greater than 3 were enrolled in this study. They were randomly assigned to any of the two study groups: Group 1- Diclofenac 50 mg (oral tablet), Group 2- Diclotouch 100mg (transdermal patch).

Results:
To compare between groups Mann Whitney test is applied. SPSS version 22.0 is used to analyse the data. Both the statistical analysis and clinical observation showed that there was gradual decrease in pain in both the groups at baseline, 4 hrs, 8 hrs & 24 hrs.

Conclusion:
The transdermal diclofenac patch seems to be an alternate mode of drug delivery system for the management of mild to moderate pain, with a lower incidence of systemic adverse effects.

Key words: pain, pre-operative analgesic, root canal treatment, transdermal patch.

INTRODUCTION:

According to WHO Pain has been defined as an "unpleasant sensory or emotional experience associated with actual or potential tissue damage".

There is always a significant relationship exists between pre- and post-endodontic pain. Patients with 80 % preoperative pain continue to have mild to severe pain even after root canal treatment.[1, 2] Thus, prevention and management of postoperative endodontic pain plays a vital role in endodontic treatment. Preparing the patients about the expected post-operative pain and prescribing medications prior to treatment can improve their attitude and decrease the fear to overcome endodontic therapy. [3]

Non-steroidal anti-inflammatory drugs (NSAIDs) are the most common group of medications suggested to relieve pain.[4,5,6] Diclofenac is one of the commonly prescribed analgesic to relieve pain as it possess anti-inflammatory, antipyretic and analgesic activity. However, diclofenac as an oral tablet holds some drawback, that is, when taken through oral route, only 50% of the absorbed dose of diclofenac becomes available systematically, due to its first pass metabolism.

Also, due to the high plasma concentrations, oral diclofenac carries risk of adverse reactions, particularly those involving gastrointestinal tract. [7]

Thus, in the recent past Transdermal have been developed as an innovative topical delivery system for diclofenac & other NSAIDs, offering the advantage of sustained drug delivery. [8] They are defined as a "medicated adhesive patch which is placed above the skin to deliver a specific dose of medication through the skin with a predetermined rate of release to reach into the bloodstream".

These patches reduce the incidence of systemic adverse effects due to lower plasma concentrations when compared to oral drugs. [9]

AIM:

The aim of the study is to evaluate the efficacy of single dose of transdermal patch as a pre-operative analgesic in root canal treatment.

OBJECTIVE:

To evaluate pain using visual analogue scale (VAS) at baseline, 4 hrs, 8 hrs & 24 hrs.

HYPOTHESIS

There is no difference between DICLOFENAC as an oral drug and a transdermal patch when used as a pre-operative analgesic in root canal treatment.

ALTERNATE HYPOTHESIS:

There is difference between DICLOFENAC as an oral drug and a transdermal patch when used as a pre-operative analgesic in root canal treatment.

MATERIALS & METHODS

The study proposal was submitted to the scientific review board & the ethical clearance for the study was obtained. (SRB/STPG15/16). 50 patients with symptomatic irreversible pulpitis with VAS score greater than 3 were

enrolled in this study and the subjects belonged to both sexes.

Inclusion criteria

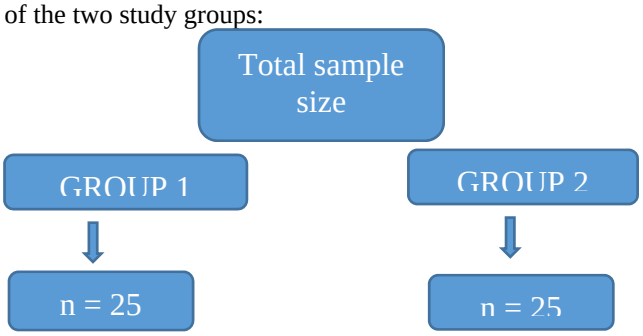
Age range of 18 to 50 years, Healthy periodontal status, none of their teeth being extensively decayed or periapically involved.

Exclusion criteria:

Clinical evidence of allergy to NSAIDs, Those with active peptic ulceration, Subjects undergoing treatment with other NSAIDs or any other analgesics or corticosteroids during the trial period, those with history of systemic diseases

All subjects were informed about the nature of the study and the probable side effects from the drugs being administered and a written informed consent was obtained from all subjects.

The selected patients were randomly assigned (1:1) to any of the two study groups:



Randomization was done using block randomization procedure using block of 10, of which number 1,3,5,7 and 9 assigned to Group I –Diclofenac oral tablets and number 2,4,6,8 and 0 to Group II – Diclofenac as transdermal patch.

SNOSE (Sequentially Numbered, Opaque, Sealed Envelopes) method was implemented for allocation concealment which conceals the sequence until interventions were assigned.

The medicines were prescribed 24 hours prior to the treatment and the pain scores were evaluated at baseline, 4hours, 8 hours & 24 hours.

In case of group 1 (oral diclofenac tablets) patients were asked to take 3 doses per day. In group 2(diclofenac transdermal patch) the patch was placed on the patients arm provides continuous and systemic release of diclofenac and is designed to remain at the site of application for 24 hours.

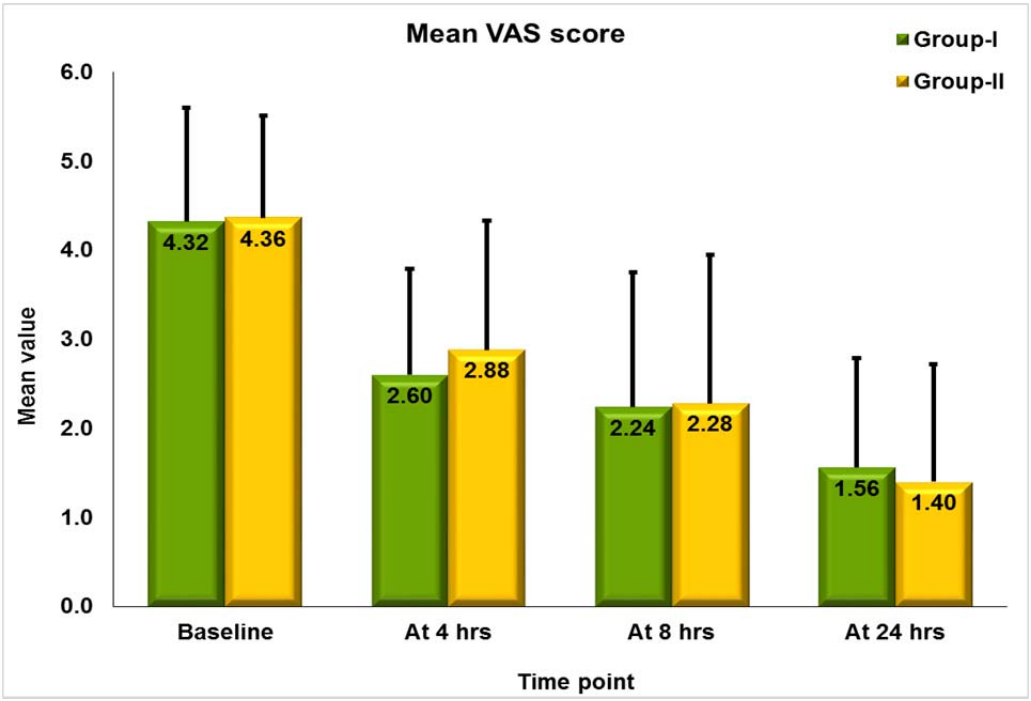
The patients enrolled in the study was given a Visual Analog scale Score Chart for assessing pain intensity at baseline, 4hours, 8 hours & 24 hours (Table 1, Graph 1). The subjects were asked to report after 24 hours with the pain score chart. Later, the patients were asked if they experienced any adverse effects such as gastric discomfort, nausea, vomiting, gastric acidity or burning sensation and dyspepsia, diarrhoea, dizziness, pruritis etc.

RESULTS:

To compare between groups Mann Whitney test is applied. SPSS version 22.0 is used to analyse the data. No statistically significant difference were seen in both groups in relation to pain reduction.

Table 1: Mean score values

TIME PERIODS	GROUP I	GROUP II
BASELINE	4.32	4.36
4 Hrs	2.60	2.88
8 Hrs	2.24	2.28
24 Hrs	1.56	1.40



Graph 1: Variation in the mean pain score from baseline to 24 hrs:

DISCUSSION:

Various researches are going on in developing drugs with better formulation replacing the obsolete ones. Non-steroidal anti-inflammatory drugs works by inhibiting the prostaglandin synthesis by decreasing the activity of the enzyme, cyclooxygenase (Cox) 1 and 2, thereby, reducing dental pain.[10] However, they carry the risk of first pass metabolism with significant amount of the drug being lost before it's systemically absorbed.[11]

Transdermal systems for NSAIDs are an innovative delivery mechanism replacing oral and other traditional forms of drug administration. The drug in the transdermal patch enters the body through skin and ultimately diffuses into capillaries for systemic delivery. [12]

The major components of transdermal patch are:

Liner -which protects the patch during storage and is removed prior to use , Drug – containing the drug solution in direct contact with release liner ,Adhesive - Serves to adhere the components of the patch together along with adhering the patch to the skin., Membrane - Controls the release of the drug from the reservoir and multi-layer patches. Backing - Protects the patch from the outer environment. [11]

The two formulations of diclofenac used in this study were oral Diclofenac 50 mg tablets which was taken thrice a day and 100 mg transdermal Diclofenac patch, which is designed to remain at the site of application for 24 hours. The 50-sq. cm patch used in the study contains 100 mg of Diclofenac Diethyl amine as its active agent which permits sustained release of the drug.

Patients were also questioned if they experienced any adverse reactions of which, In Case of group 1 (diclofenac tablets) 4 patients reported with gastric acidity and in group II (Diclofenac transdermal patch) 2 patients complained of lack of adhesiveness of patch.

In the studies done by Prithvi S Bachalli et al [13] and Hemant Bhaskar et al [14], diclofenac transdermal patch were used post-operative analgesic following tooth extraction. The results showed that both the oral and transdermal patch form showed similar analgesic efficacy.

Similarly, in our present study, both the form of drugs showed pain reduction from baseline to 24 hours when used as a pre-operative analgesic.

LIMITATIONS:

Use of transdermal patch is not been investigated on the effect of anaesthetic efficacy.Also has not been evaluated as post-operative analgesics in endodontics.

FUTURE SCOPE

Future studies have planned to check these effects

CONCLUSION:

In the present study, there was no statistically significant difference in pain reduction in both the groups.

Thus, transdermal diclofenac patch can be used as an alternate method for the management of mild to moderate pain, for patients suffering from systemic side effects like GIT disorders, etc.

However, longer clinical trials with a larger sample need to be conducted before the real scope of the transdermal diclofenac patch can be clearly defined.

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