Original Research Paper

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"Is a Transdermal Diclofenac Patch Better than Oral Diclofenac Tablets": A Randomized Controlled, Trail Clinical.

Abstract:

Aim: This study aimed to compare the analgesic effect of transdermal Diclofenac with oral Diclofenac tablets.

Method: In this randomised controlled clinical trial a total of 80 patients were divided randomly in two groups with one group of patients (N1)were given Transdermal diclofenac patch(200 mg) and other group of patients(N2) were given diclofenac tablets after extraction Patients were assessed for pain at various intervals and the assessment of side effects.

Results: Significant results were seen at 6 hours with higher number of subjects reporting VAS score 0 and 1-3 in group NI, while subjects reported higher VAS score 4-6 and 7-10 in group N2. Also 20 % of the patients in group N2 (Diclofenac tablet group) complains of gastric irritation after 24 hrs. Statistically no significant difference exists in uniformity of pain control and interference in routine activities during past 24 hours among both the groups.

Conclusion: We can conclude that diclofenac patch is more effective in pain control in the early stage after extraction of the tooth and have lesser side effects as compared to diclofeanc tablets.

Keywords: Gastric irritation; Transdermal patch; VAS score.

Introduction:

Pain has been defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. [1]

The most commonly used non-narcotic analgesics in dentistry are aspirin, ibuprofen and paracetamol, all of which are available as 'over the counter' medications.[2]

Diclofenac may also be a unique member of the NSAIDs. Some evidence indicates it inhibits the lipoxygenase pathways, thus reducing formation of the leukotrienes (also pro-inflammatory autacoids). It also may inhibit phospholipase A2 as part of its mechanism of action.

These additional actions may explain its high potency that's why it is the most potent NSAID on a broad basis.[3]

The transdermal diclofenac patch is a relatively new application for pain control in the field of dental therapeutics but has been use in various fields of medicine ranging from anaesthesiology to traumatology.[4]

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Advantages of transdermal drug delivery system.[5]

1. Transdermal medication provides safe, convenient and pain-free self-administration for patients.

2. Transdermal delivery may be useful in those patients who are polymedicated.

Limitations of transdermal drug delivery system:

1. The drug moiety must possesses some physicochemical properties for penetration through Skin and if dose of drug is large i.e. more than 10- 25mg/day transdermal delivery is very difficult. Daily dose of drug preferred less than 5mg/day.

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2. Local irritation at the site of administration such as itching ,erythema and local edema may be caused by drug or the excipients used in the formulations.

Aims & objectives:

The present study was undertaken to compare the analgesic effect of transdermal diclofenac with oral Diclofenac tablets in controlling post extraction pain and to compare the adverse effects of transdermal Diclofenac with oral Diclofenac.

Material and Methods:

A total number of 80 patients with deeply carious, non-tender molar tooth, periodontally uncompromised, deemed unsalvageable, and indicated for extraction has been allocated into the study. In order to control the bias, all the procedures were done by single surgeon which involved the extraction of a single tooth through the closed method of extraction, a time limit of 30 min was given for each patient; any procedure involving any other method other than the standard closed method of extraction or extension of the proposed duration of the procedure was excluded.

Randomization was done using block randomization procedure using block of 10, of which number 1,3,5,7 and 9 assigned to Group I (N1) –Diclofenac as Transdermal patch (fig.1 &2) and number 2,4,6,8 and 0 to Group II (N2) – Diclofenac as tablets.

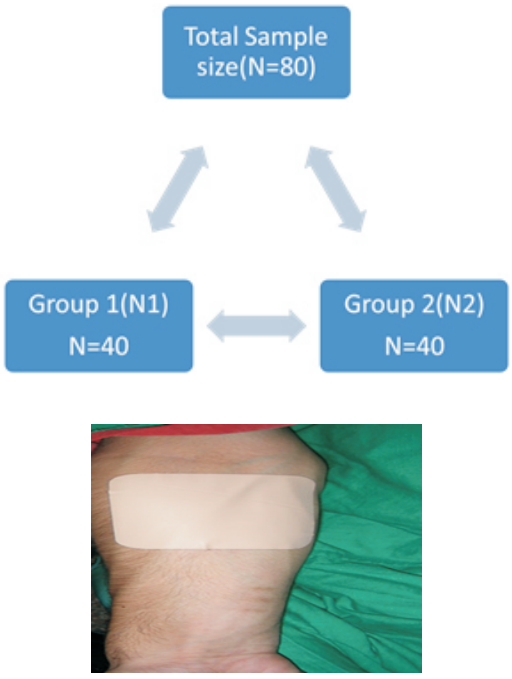

Fig 1: Transdermal Diclofenac Patch applied on forearm of subject.

Fig 2: Commercially available Transdermal Diclofenac Patch (Nu Patch).

Pain assessment and follow-up:

Before discharge, the operating dental surgeon provided the subject with a visual analogue pain scale chart in which the patient had to make an entry of the pain intensity during the 6th, 12th, and 24th hour following the dental extraction. An evaluator receives the patient after a period of 24 h and obtained the completed visual analogue pain scale, completes the questionnaire, and maintained a record of the data for evaluation.

Complications:

Each patient was evaluated for complications like gastric irritation, vomiting, nausea, chest pain or any skin irritation or itching at the site of application of patch after 24 hours.

Results:

In the present study mean age of patients in N1 group was 27.52 ±7.82 years while mean age of patients in N2 group was 30.65 ±9.76 years.

Out of 40 patients in group N1 23 (57.5%) were male while 17(42.5%) were female and in group 2 out of 40 patients 21 (52.5%) were male and 19 (47.5%) were females.

The distribution of VAS score was compared after 6 hours, 12 hours and 24 hours among two groups. Significant results were seen at 6 hours with higher number of subjects reporting VAS score 0 and 1-3 in group NI, while subjects reported higher VAS score 4-6 and 7-10 in group N2 at 6 hours ($p=0.032<0.05$). No Significant results were seen at 12 & 24 hours among both the groups in VAS score ($p>0.05$). (Table 1) No significant difference was found in the study population according to uniformity of pain control during past 24 hour

Distribution of study population according to assessment of side effects after 24 hour:

None of the patients in N1 group complains of any side effects like vomiting, gastric irritation or itching but 8 out of 40

patients in group 2 (20%) complains of gastric irritation after 24 hours.(Table: 2)

categories of VAS score		6 hour		12 hour		24 hour	
		N1	N2	N1	N2	N1	N2
0	N	3	0	4	1	2	2
	%	7.5	0	10	2.5	5	5
1-3	N	28	20	28	22	30	25
	%	70	50	70	55	75	62.5
4-6	N	8	19	7	16	8	12
	%	20	47.5	17.5	40	20	30
7-10	N	1	1	1	1	0	0
	%	2.5	2.5	2.5	2.5	0	0
Chi square value		8.815		6.042		3.055	
P value		0.032		0.110		0.383	

CHI SQUARE TEST, level of significance at $P < 0.05$

Table 1: Distribution of study population according to assessment of VAS score.

		Vomiting	Uneasiness /Burning sensation in stomach	Burning sensation/chest pain	Allergic Reaction
N1	N	0	0	0	0
	%	0	0	0	0
N2	N	0	8	0	0
	%	0	20	0	0

Table 2: Distribution of study population according to Assessment of side effects after 24 hrs.

Discussion:

The present study was carried out to compare and evaluate the post-operative analgesia, adverse events, patient tolerability and compliance with the use of oral diclofenac sodium tablets and the diclofenac transdermal patch (following extraction of grossly decayed molar tooth) which is incorporated with diclofenac diethyl amine, which releases the medication in sustained doses over a period of time, hence effective in pain control.

The principal motivation behind this examination was to compare the pain at 6hrs, 12hrs, and 24hrs, interference with routine activities during past 24 hour, the uniformity of pain control during past 24 hour and the assessment of side effects (like gastric irritation, nausea, and itching). Significant results were seen at 6 hours with higher number of subjects reporting VAS score 0 and 1-3 in group NI, while subjects reported higher VAS score 4-6 and 7-10 in group N2 which accepts the alternate hypothesis. No Significant results were seen at 12 & 24 hours in subjects reporting VAS score. Also, there was no significant difference exists in both the groups in terms of uniformity of pain control in past 24 hr or in interference with routine activities during the past 24 hr which leads to acceptance of null hypothesis. 8 out 40 patients (20 %) in group N2 (Diclofenac Tablet group) were reported with side effects like gastric irritation but none of the patients in group N1 (Diclofenac Patch group) reported with any side effects which is a quite significant result which also proves the alternate hypothesis.

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.

The transdermal diclofenac patch 200mg was found to be as potent as oral diclofenac for post dental extraction analgesia. Moreover, with the use of transdermal diclofenac patch not a single patients had complained of side effects like gastric irritability or any allergy, but out of 40 patients who were given oral diclofenac 8(20%) had complained of gastric irritability.

These findings are similar to Funk et.al., who reported that when used in patients with post-operative shoulder pain, both oral and transdermal diclofenac had similar analgesic efficacy.

Operative shoulder pain, both oral and transdermal diclofenac had similar analgesic efficacy.[6]

Various studies have been reported where certain additional agents can be applied onto the patch or site of placement of patch that may enhance the absorption of the drug systemically, hence increasing the plasma concentration and also hastening the time of action of the drug.[7]

Prithvi S Bachalli et.al. conducted a study to evaluate subjectively the analgesic efficacy of Oral Diclofenac Sodium against Diclofenac Sodium Transdermal patch in the management of postoperative pain following extraction of teeth. Their study concludes that transdermal diclofenac sodium can be used as an alternative form of pain control following removal of teeth.[8]

Predel et.al.[9] conducted a clinical study to evaluate clinical efficacy and safety of diclofenac patch in the topical treatment

of blunt injuries and concluded that diclofenac patch was significantly more effective, and Alessandri et.al. compared pain management of standard analgesic and standard analgesic plus transdermal patch in patients who undergo laparoscopic gynecologic surgery and reported that diclofenac transdermal administration seems a valid help to standard analgesic treatment in prospective pain control.[10] Naedal et.al. [11] demonstrated that because of low systemic concentrations, topical NSAIDs have a reduced risk of upper gastrointestinal complications, such as gastric and peptic ulcers, and gastrointestinal nuisance symptoms, such as dyspepsia the results of this study correlated with our study as not a single patient who has been applied diclofenac patch, is reported to have any such complications.

Transdermal diclofenac therapy may have a role to play in post-traumatic pain, perhaps with an increased strength of analgesic drug in the transdermal patch. However, longer clinical trial with a larger sample needs to be conducted before the real scope of transdermal diclofenac patch can be clearly defined.

Conclusion:

Though statistically no difference exists in uniformity of pain control and interference in routine activities during past 24 hours among both the groups, significant results were seen at 6 hours with higher number of subjects reporting VAS score 0 and 1-3 in group N1. in group N2(Diclofenac tablet group) complains of gastric irritation after 24 hrs so we can conclude that diclofenac patch is more effective in pain control in the early stage after extraction of the tooth and have lesser side effects as compared to diclofeanc tablets. However more comprehensive study, with larger number of samples and follow up for longer duration ,need to be conducted before the real scope of transdermal diclofenac patch can be clearly defined.

"Compliance with Ethical Standards"
* Disclosure of potential conflicts of interest: All the authors declare that they have no conflict of interest.

* Research involving human participants and/or animals: 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 all individual participants included in the study.
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