

## Original Research Article

## A Comparative Study to Determine the Efficacy of a Single Dose of Transdermal Diclofenac Patch versus Intramuscular Diclofenac Injection Postoperatively

Dr. Debashish Borkotoky,<sup>1</sup> and Dr. Joyce Sequeira M.D.S.<sup>2</sup>

<sup>1</sup>Post Graduate, Department of Oral and Maxillofacial Surgery, Yenepoya Dental College Deralakatte, Mangalore, Karnataka – 575018 India.

<sup>2</sup>Professor Department of Oral and Maxillofacial Surgery Yenepoya Dental College Deralakatte, Mangalore, Karnataka – 575018, India.

\*Corresponding Author

Dr. Debashish Borkotoky.

**Abstract: Purpose:** Efficacy of a Single Dose of Transdermal Diclofenac Patch versus Intramuscular Diclofenac Injection Postoperatively. **Methods:** Twelve patients attending our OPD who required open reduction and internal fixation for mandibular fractures were selected and categorized into two groups. Group A received a single dose of a transdermal diclofenac patch 100 mg patch 2 hours before the surgery, while Group B received a single dose of intramuscular diclofenac sodium 75 mg injection half-an-hour before the end of surgery. Post-operative pain relief was assessed at 2, 6, 12, 24 hours respectively using a Visual Analogue Scale (VAS). At any time during this period, if the VAS was more than, or equal to five, then an injection of tramadol 50 mg was administered intramuscularly as rescue analgesia and the time was noted, which marks the termination of the study. **Results:** Group A reported a mean value of 2.33, 0.17, 0.17 and 2.67 while Group B reported a mean value of 1.67, 2.33, 2.33 and 2.67 during the 2<sup>nd</sup>, 6<sup>th</sup>, 12<sup>th</sup>, and 24<sup>th</sup> hour respectively. There was a significant difference noted between Group A and B during the 6<sup>th</sup> hour and 12<sup>th</sup> hour. Rescue analgesia had to be administered in one patient from Group B. No complications were reported by any patients in either group. **Conclusion:** This study clearly exhibits that the use of transdermal diclofenac patch offers several advantages over intramuscular injections as it avoids the need for intravenous or intramuscular drug administration and also has better patient compliance.

**Keywords:** Pain, NSAIDs, Mandibular fractures, Transdermal diclofenac patch, Diclofenac intramuscular injection, Visual analogue scale.

### INTRODUCTION

Pain is the most common symptom for which a patient seeks medical advice. The International Association for the study of pain has defined pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage” (Merskey H *et al.*, 1979). One of the most unique and common form of acute pain is postoperative pain. Many recent studies show that postoperative pain remains poorly treated as about 50-70% of patients complain of moderate to severe pain after surgery. An integral part of postoperative care that helps in transitioning the patient from recovery unit to home is the management of postoperative pain.

Few of the most important drugs used for postoperative analgesia includes narcotics and NSAIDs. As narcotics are known to cause drowsiness, constipation, urinary retention and various other disturbances, NSAIDs are usually preferred. One of the most commonly used NSAIDs is diclofenac. The route of choice in daily practice is oral administration but it becomes impractical post-surgery because of high first pass metabolism and sometimes inability of patient to consume it. Though rare, intramuscular injections of NSAIDs can cause necrosis of tissues and is also quite painful to the patient.

Transdermal drug delivery, a local drug delivery system has gained populace in the recent time. Transdermal patches ensure simple, painless procedure of drug usage even in patients with needle phobia

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(Chaitanya, N. C. *et al.*, 2017). The introduction of the transdermal drug delivery system gives a solution to the question of achieving a therapeutic concentration without producing undesirable side effects. This route of administration differs from the traditional topical administration in that, after penetration of the skin barrier, the drug enters the circulation to be distributed systemically. The purpose of this study is to determine the Efficacy of a Single Dose of Transdermal Diclofenac Patch versus Intramuscular Diclofenac Injection Postoperatively.

**MATERIALS AND METHODS**

Twelve random participants from patients attending Yenepoya Dental College who required open

reduction and internal fixation for mandibular fractures were selected. After obtaining institutional ethical committee clearance and informed consent from the subjects, random allotment of patients was done into two groups comprising of 6 patients each. Group A received a single dose of transdermal diclofenec patch 100 mg (DICOPLAST) (Figure 1.A) while group B received a single dose of intramuscular injection (75 mg) (Figure 1.B). Patients with a history of renal disorders, bronchial asthma, bleeding disorders, patients who were allergic to diclofenac sodium, pregnant and lactating mothers and patients who were suffering from peptic ulcers were excluded. Open reduction and internal fixation for mandibular fracture was done for all the 12 patients.



Figure 1: A. Transdermal Diclofenac Patch ; B. Vial of Intramuscular Diclofenac Injection

A transdermal diclofenac patch containing 100 mg was applied to the subjects in Group A 2 hours before the beginning of the surgical intervention on non-hair bearing area like the Deltoid region.

Diclofenac sodium injection (75 mg) was given intramuscularly half an hour before the end of the surgical procedure in Group B patients. Using a Visual Analogue Scale (VAS), pain was assessed postoperatively at 2<sup>nd</sup>, 6<sup>th</sup>, 12<sup>th</sup> and 24<sup>th</sup> hours respectively. During this phase, if the VAS score was greater than 5, tramadol HCl 2 mg/kg body weight was administered intramuscularly as rescue analgesic and the time was noted. Patients were also evaluated for side effects such as gastrointestinal disturbances, headache, dizziness and allergic reactions in the immediate postoperative phase.

**RESULTS**

The mean value in Group A was 2.33, 0.17, 0.17 and 2.67 with a range of 2, 1, 1, and 3 during 2<sup>nd</sup>, 6<sup>th</sup>, 12<sup>th</sup>, and 24<sup>th</sup> hour respectively. The mean value in Group B was 1.67, 2.33, 2.33 and 2.67 with a range of 4, 6, 4, and 4 during 2<sup>nd</sup>, 6<sup>th</sup>, 12<sup>th</sup>, and 24<sup>th</sup> hour respectively. Pain was assessed postoperatively at 2, 6, 12 and 24 h respectively using a Visual analogue scale. During this phase, if the VAS score was greater than 5,

tramadol HCl 2 mg/kg body weight was administered intramuscularly as rescue analgesic and the time was noted.

**GROUP A**

**TABLE 1.1**

		2hour	6hour	12hour	24hour
N	Valid	6	6	6	6
	Missing	0	0	0	0
Mean		2.33	.17	.17	2.67
Median		2.00	.00	.00	2.50
Range		2	1	1	3
Minimum		2	0	0	1
Maximum		4	1	1	4

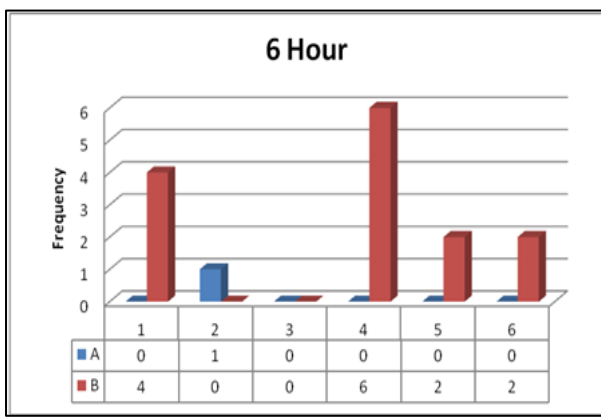
**GROUP B**

**TABLE 1.2**

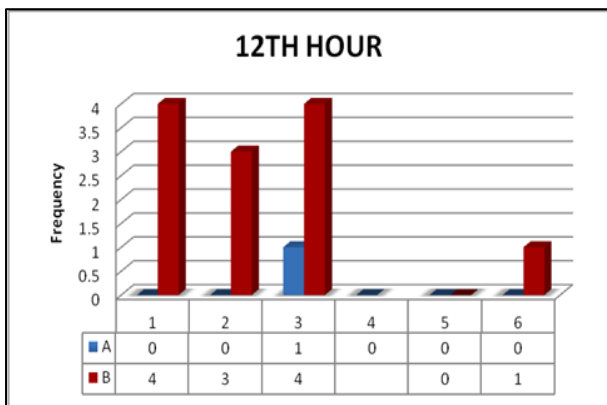
		2hour	6hour	12hour	24hour
N	Valid	6	6	6	6
	Missing	0	0	0	0
Mean		1.67	2.33	2.33	2.67
Median		1.50	2.00	2.50	3.00
Range		4	6	4	4
Minimum		0	0	0	0
Maximum		4	6	4	4

The median value in group A was observed to be 2.00 and 2.50 during the 2<sup>nd</sup> hour and 24<sup>th</sup> hour while in group B the median value consisted of 1.50 during the 2<sup>nd</sup> hour, 2.00 during the 6<sup>th</sup> hour, 2.50 during the 12<sup>th</sup> hour and 3.00 during the 24<sup>th</sup> hour.

One patient in Group B (Intramuscular diclofenac injection) was administered with Injection Tramadol during the 6<sup>th</sup> hour and the results showed a significant difference at 6<sup>th</sup> hour between group A and group B (pvalue = 0.049) as seen in Graph 2.1. There was also a significant difference between Group A and Group B at 12<sup>th</sup> hour (pvalue = 0.016) as seen in Graph 2.2. There was no significant difference between the groups at 2<sup>nd</sup> hour and 24<sup>th</sup> hour. There were no side effects seen in any of the patients in both the groups.



**Graph 2.1 showing the difference of Visual Analogue Scale (VAS) score between Group A and Group B at 6<sup>th</sup> hour.**



**Graph 2.2 showing the difference of Visual Analogue Scale (VAS) score between Group A and Group B at 12<sup>th</sup> hour**

**DISCUSSION**

The result of our study suggests that the efficacy of transdermal diclofenac patch matches the efficacy of intramuscular diclofenac injection in controlling postoperative pain. Transdermal diclofenac patch can be used instead of intravenous or

intramuscular drug administration, and in patients who are unable to swallow oral medications.

Throughout history, various medications have been used to deal with postoperative pain. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) are among the most commonly employed medications used to relieve postoperative pain. NSAIDS when administered systemically have been implicated in various adverse drug events due to their inherent mechanism of inhibiting prostaglandin synthesis thereby disrupting the general physiologic system (Laine, L. *et al.*, 2007).

Topical administration of Non-Steroidal Anti-inflammatory Drugs (NSAIDs) offers the advantage of local enhanced drug delivery to affected tissues with a lower incidence of systemic adverse effects due to reduced plasma concentration (Predel, H. G. *et al.*, 2004). On applying the patch to the skin, a drug concentration gradient is developed and the drug starts to move down the gradient into the skin and is absorbed into the local capillary vasculature and is then transported into systemic circulation (Margetts, L *et al.*, 2007).

In this present study, patients with mandibular fractures were administered diclofenac as an analgesic, both in injection and transdermal form. Diclofenec has been routinely used as an analgesic for managing post operative pain for a long time. The two different formulations used in this study were 75 mg intramuscular diclofenec injections and 100 mg diclofenac transdermal patches. The mode of onset for the diclofenac patch used in this study was 4 hours. Hence, the patch was applied two hours before the surgery, so that the action will start by the time the patient is extubated.

The transdermal diclofenac patch used in this study was found to be as potent as intramuscular injections. These findings are similar to those of (Anisha Perepa *et al.*, 2017) who reported that when used in patients who underwent bijaw surgeries, transdermal diclofenac patch is more effective than intramuscular diclofenac injection in the immediate postoperative phase without any side effects.

(Bhaskar *et al.*, 2010) compared the degree of post operative analgesia between oral diclofenac tablets and transdermal diclofenac patch in patients undergoing multiple premolar extractions and reported that patients

were more comfortable using the transdermal patch as it was a once a day application with lesser systemic adverse effects. (Krishna R *et al.*, 2012) also reported similar results in patients who underwent elective lower limb orthopaedic surgery, under subarachnoid block and stated that Intraoperative application of a single dose of 100 mg transdermal diclofenac patch is as effective as a single dose of intramuscular diclofenac (75 mg) for acute postoperative pain, without any significant side-effects.

The results in our present study showed that patients with diclofenac patch complained of less pain as those with intramuscular injections. And patients in both the group presented no side effects. (Gopal Swaroop Bhargava *et al.*, 2016) compared the analgesic effects of diclofenac transdermal patch (100mg)-Nupatch and diclofenac intramuscular injection (75 mg) in the management of post operative pain in 100 patients undergoing surgery and reported that the analgesic effects of diclofenac diclofenac patch is at par with that of diclofenac intramuscular injections. (Soumya Samal *et al.*, 2013) reported a similar finding when comparing transdermal diclofenac with intramuscular diclofenac for postoperative analgesia in patients undergoing elective laparoscopic, gynaecological & orthopaedic surgeries on limb.

In conclusion, the transdermal diclofenac patch is definitely a promising analgesic modality for the management of postoperative pain following surgery, given the evidence of its established analgesic potency as compared to intramuscular injections. Both formulations have proven to be very effective in pain management with no side effects, although the pain scores and rescue analgesia requirement is less with transdermal diclofenac than intramuscular diclofenac during postoperative analgesia. However as, the number of cases are less in the study, further study is required with large number of cases and at multiple centres to correlate our findings.

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