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# Efficacy of transdermal diclofenac patch versus intramuscular diclofenac for acute post operative pain

Anaesthesiology

**KEYWORDS:** diclofenac, transdermal patch, pre-emptive analgesia

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## ABSTRACT

*BACKGROUND: We compared the analgesic efficacy of a transdermal diclofenac patch 100 mg and intramuscular diclofenac sodium 75 mg for postoperative analgesia and their associated side-effects.*

*METHODOLOGY:*

*60 patients in the study were randomly allocated to 2 groups of 30 each. The anaesthetic procedure was standardised. A transdermal diclofenac patch 100 mg was applied to the patients in the study group 10-12 hrs before surgery. In the control group, 75 mg of diclofenac sodium was given intramuscularly half an hour before the end of surgery. Pain was assessed postoperatively at 2, 6, and 12-hour intervals using a visual analogue scale (VAS). An injection of Tramadol 2 mg/kg was administered intravenously as rescue analgesia. The study ended when the patients asked for rescue analgesia or when the VAS score was > 5.*

*RESULTS: The mean duration of analgesia was higher in study group (9hrs 45min) than that in the control group ( 7hrs 8 min) which was statistically significant ( p value 0.0001).*

*CONCLUSION : A single application of a transdermal diclofenac patch is as effective as a single dose of intramuscular diclofenac for acute post-operative pain and provides longer duration of analgesia without any significant side-effects.*

**INTRODUCTION:**

Peripheral tissue injury as seen in postoperative patients provokes two kinds of modification in the responsiveness of the nervous system. In peripheral sensitisation, there is a reduction in the threshold of nociceptive afferent peripheral terminals. In central sensitisation, an activity dependent increase in the excitability of spinal neurons occurs. This results in an overall hypersensitivity state in the postoperative period. Prevention and establishment of this hypersensitivity state could lead to reduced postoperative pain. This forms the basis of pre-emptive analgesia. Non-steroidal anti-inflammatory drugs (NSAIDs) exert anti-inflammatory and analgesic effects through the inhibition of prostaglandin synthesis, by blocking the activity of cyclo-oxygenase. Diclofenac sodium is a commonly used non-selective NSAID and is available in various forms to treat pain . The diclofenac transdermal patch is a newly introduced delivery system for postoperative pain management.

**METHOD:**

After obtaining institutional ethical committee clearance, the study was undertaken in 60 patients aged 18-60 years old of either gender, belonging to American Society of Anesthesiologists (ASA) class I and II, and scheduled for elective lower limb orthopaedic & general surgeries, under subarachnoid block. This followed the attainment of written informed consent. The sample size was calculated using the principal variable, the visual analogue scale (VAS) scores for postoperative pain, and considering a difference of 2 cm as clinically significant (estimated mean standard deviation 1.5-2.5 cm). The total sample size was calculated as 60 with a type I error of 0.05, and a statistical power of 95%. Patients with clinical features or a history of renal pathology, bronchial asthma, active peptic ulceration, or any other allergic reactions induced by aspirin or other NSAIDs were excluded. The 60 participants in the study were randomly allocated into two groups of 30 each. A thorough pre-anaesthetic evaluation was performed. On the day of the surgery, an 18-gauge intravenous line was secured, routine monitors were attached, all the patients were administered subarachnoid block in the lateral position, using 0.5% hyperbaric bupivacaine using a 23 gauge Quincke's needle to obtain a sensory level block of T6-T8. Both groups did not receive any intravenous analgesics or sedatives during the surgery. A transdermal diclofenac patch containing 100 mg of diclofenac sodium was applied to patients in the study group 10-12 hrs before the surgery and in the control group 75 mg of diclofenac sodium was given intramuscularly half an hour before the end of surgery. Parameters observed were pain scores postoperatively at 2, 6, and 12 hours using a VAS, hemodynamic changes in pulse rate and blood pressure, duration of analgesia and side effects. At any time during the study, if the VAS was more than or equal to 5 then an injection of tramadol 2 mg/kg was administered intravenously as a rescue analgesic and the study was terminated.

**RESULTS:**

The demographic data with respect to age and gender were comparable between the two groups.

**TABLE 1: Mean Duration of Surgery**

| GROUP | MEAN | STANDARD DEVIATION |
|---|---|---|
| Control group | 1 hour 12 min | 15.6min |
| Study group | 1 hour 20 min | 22.2 min |

The mean duration of surgery in the control group was 1 hour 12 minutes +/- 15.6 minutes and in the study group it was 1 hours 20 minutes +/- 22.2 minutes. The duration of surgery was comparable between the groups (p value= 0.031) and was not significant.

Pain was assessed postoperatively using VAS at 2 and 6 hours in the control group (Table II). If the patient had a VAS of 5 or more IV tramadol 2 mg/kg was given, and the study ended.

**TABLE II: VAS scores of control group**

| VAS | 2 HOURS | 6HOURS |
|---|---|---|
| 0 | 29 | 4 |
| 1 | 0 | 1 |
| 2 | 1 | 13 |
| 3 | 0 | 9 |
| 4 | 0 | 2 |
| 5 | 0 | 1 |

In the control group, at 2 hours postoperatively, 29 of the 30 patients had no pain and 1 patient had a VAS score of 2 (Table II ). At 6 hours postoperatively, 1 patient asked for rescue analgesia whereas 4 patients had a VAS of 0, 13 patients had VAS of 2 and 9 patients had a VAS of 3. All of the remaining patients received rescue analgesia

between the 6 and the 12 hour period. Because patients had already received rescue analgesia, the VAS scores at the 12 hour had no significance.

In the study group, at 2 hours, 29 patients had no pain and 1 patient had a pain score of 2 (Table III). At the end of 6 hours, 7 patients had no pain and 15 had a score of 2, whereas 3 patients had a score of 5. At 12 hours, only 1 patient had a score of 4, and the others had received rescue analgesia.

**TABLE III : VAS scores in study group**

| VAS | 2HRS | 6HRS | 12HRS |
|---|---|---|---|
| 0 | 29 | 7 | 0 |
| 1 | 0 | 2 | 0 |
| 2 | 1 | 15 | 0 |
| 3 | 0 | 3 | 0 |
| 4 | 0 | 0 | 1 |
| 5 | 0 | 3 | 0 |

At 2 hours postoperatively, the VAS was comparable between the groups, and was not statistically significant (p value 0.32). At 6 hours postoperatively when the VAS was compared between the two groups were comparable and was statistically not significant ( p value 0.21). At 12 hours postoperatively, only 1 patient in the study group had a score of 4 without
rescue analgesia.

The duration of analgesia in the control group was 7 hours 8 minutes +/- 28 min and in study group it was 9 hours 45 minutes +/-1 hour 18 min (Table IV). Both the groups were comparable and when analysed using an unpaired t-test they were found to be statistically significant ( p value 0.0001).

**TABLE IV : Duration of analgesia**

| GROUPS | DURATION OF ANALGESIA |
|---|---|
| CONTROL GROUP | 7Hrs 8 Min +/- 28min |
| STUDY GROUP | 9Hrs 45 Min +/- 1Hr 18 Min |

Side-effects in patients receiving intramuscular diclofenac included abdominal pain (gastritis) in 2 patients whereas those in the study group were none.

**DISCUSSION :**

Post-operative pain may result in psychological, physiological, neuroendocrine, respiratory and cardiovascular problems, ultimately increasing the risk of post-operative morbidity and mortality. The aim of good postoperative analgesia is to produce a long lasting, continuous effective analgesia with minimum side effects.

The results of our study suggest that when applied at the beginning of surgery a transdermal patch of diclofenac is as effective as intramuscular diclofenac in prolonging the requirement of postoperative opioids. The transdermal drug delivery offers several advantages as it avoids the need for intravenous or intramuscular drug administration and is an option in patients who are unable to swallow oral medications. Transdermal drug administration also bypasses first-pass metabolism in the liver and overcomes concerns regarding drugs that are poorly absorbed in the gastrointestinal tract. An important concern with regards to transdermal drugs is their prolonged duration of onset and offset, typically 12-24 hours unlike the intravenous or the intramuscular routes. Currently, regimens consisting of a combination of analgesics (multimodal analgesia) are recommended for the management of postoperative pain. Adjunctive techniques, such as wound infiltration with local anaesthetics, the use of NSAIDs or corticosteroids and epidural administration of opioids have been recommended to treat postoperative pain. Of these, the NSAIDs have gained increasing popularity in treating postoperative pain.

The mean duration of surgery was comparable between the two groups. The duration of surgery has a bearing on the postoperative analgesic requirement as prolonged duration of tissue handling increases the local production of inflammatory substances and oedema, hence increasing the requirement for analgesics.

In a study conducted by Krishna et al. the analgesic efficacy of transdermal diclofenac patch 100 mg was compared to intramuscular diclofenac sodium 75mg for post-operative analgesia in patients undergoing elective orthopaedic lower limb surgeries. They assessed the duration of analgesia and adverse effects in both the groups. The mean duration of analgesia was 7 hours 28min in the control group and in 8hours 6min in the study group respectively. They observed a prolonged duration of analgesia with transdermal diclofenac when compared to IM diclofenac without any adverse side effects.

Soumya et al, compared the efficacy of transdermal diclofenac patch with intramuscular diclofenac for post-operative analgesia in patients who underwent elective laparoscopic, gynaecological and orthopaedic surgeries. The dosage of the transdermal diclofenac patch was 200 mg in their study. They observed for pain intensity, changes in vital parameters, & adverse effects. The mean pain score as measured by VAS was high in IM diclofenac group than the transdermal diclofenac group in the above study and there was no significant changes in the vital parameters and there were no significant side effects which were concurrent with that of our study.

**CONCLUSION :**

Application of a single 100 mg transdermal diclofenac patch is as effective as a single dose of intramuscular diclofenac (75 mg) for acute post-operative pain and provides longer duration of analgesia without any significant side-effects.

**REFERENCES:**

1. Hepner DL. Preemptive analgesia: what does it really mean? Anesthesiology. 2000;93(5):1368.
2. Ong CKS, Lirk P, Saymour R. The efficacy of preemptive analgesia for acute postoperative pain management: a metanalysis. Anesth
Analg. 2005;100(3):575-573.
3. Guidelines for the use of non-steroidal anti-inflammatory drugs in the perioperative period. The Royal College of Anaesthetists;1998.
4. Shang AB, Gan TJ. Optimising postoperative pain management in the ambulatory patient. Drugs. 2003;63(9):855-867.
5. Hitesh B. A prolonged release parenteral drug delivery system. International Journal Pharmaceutical Sciences Review and Research. 2010;3:1-11.
6. Krishna et al - "Efficacy of a single dose of a transdermal diclofenac patch as pre-emptive postoperative analgesia: a comparison with intramuscular diclofenac." Southern African Journal of Anaesthesia and Analgesia 18.4 (2012): 194-197.
7. Soumya et al - "Postoperative analgesia with transdermal diclofenac versus intramuscular diclofenac–a comparative study." J Evol Med Dent Sci 2.19 (2013): 3367-3376.