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Assessment of efficacy of diclofenac sodium in oral and transdermal patch in the management of postoperative pain following surgical removal of impacted mandibular third molars

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***Abstract*---**Background: Pain is one of the most commonly experienced symptoms in surgery and as such is a major concern to the surgeon. The present study was conducted to assess analgesic efficacy of diclofenac sodium in oral and transdermal patch in the management of postoperative pain following surgical removal of impacted mandibular third molars. Materials & Methods: 80 patients with bilateral impactions of mandibular third molar of both genders were divided into 2 groups of 40 each. In group I, patients received diclofenac sodium 100 mg once a day for 3 days on one side and in group II, diclofenac sodium transdermal patch 100 mg once a day for 3 days on second side. The postoperative pain was recorded on visual analog scale (VAS) at 2 hours, 4 hours, 8 hours, 12 hours and 24 hours postoperatively. Results: Out of 80 patients, males were 35 and females were 45. VAS on day 1 in group I and II at 2 hours was 4.6 and 5.3, at 4 hours was 4.3 and 4.7, at 8 hours was 3.2 and 4.1, at

12 hours was 2.7 and 4.0 and at 24 hours was 2.4 and 3.2 respectively. At day 2 was 2.6 and 3.1, 3.2 and 2.9, 2.1 and 2.6, 1.9 and 2.3 and 1.4 and 2.1. At day 3 was 1.3 and 1.7, 1.3 and 1.5, 1.2 and 1.3, 1.1 and 1.2 and 1.0 and 1.1 at 2 hours, 4 hours, 8 hours, 12 hours and 24 hours respectively. The difference was non- significant (P>0.05). Conclusion: Transdermal diclofenac is an excellent alternative method to oral route of drug administration in pain control in patients undergoing mandibular third molar impaction.

***Keywords*---**Transdermal diclofenac, pain, mandibular third molars

Introduction

Pain is one of the most commonly experienced symptoms in surgery and as such is a major concern to the surgeon. It is often spoken of as a protective mechanism, since it is usually manifested when an environmental change occurs that causes injury to responsive tissue.[1] One of the most important aspects of the practice of dentistry is the control or elimination of pain. In the past, pain has been so closely associated with dentistry that the words pain and dentistry have become almost synonyms.[2]

The transdermal delivery system has gained importance over the last decade. Initially introduced to circumvent the gastric side effects of the oral and injectable forms, it has emerged as a patient-friendly alternative to the latter.[3] It can overcome the pharmacokinetic barriers of oral and parenteral routes by bypassing the hepatic first-pass metabolism, maintaining a steady-state plasma concentration over a prolonged time and minimizing inter- and intrapatient variability.[4] Its reduced dosage frequency compared to the oral route, non-invasiveness, ease of administration and termination also results in better patient compliance. Transdermal administration has the advantages of being a very easy, simple route of administration without the disadvantages of the routes mentioned above and also comparatively fewer side effects and complications.[5] The present study was conducted to assess analgesic efficacy of diclofenac sodium in oral and transdermal patch in the management of postoperative pain following surgical removal of impacted mandibular third molars.

Materials and Methods

The present study comprised of 80 patients with bilateral impactions of mandibular third molar of both genders. The consent was obtained from all enrolled patients. Data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 40 each. In group I, patients received diclofenac sodium 100 mg once a day for 3 days on one side and in group II, diclofenac sodium transdermal patch 100 mg once a day for 3 days on second side. The surgical procedure was carried out as per protocol following aseptic steps under local anaesthesia by administering an inferior alveolar nerve block on two different occasions with a minimum interval of 1 week in-between the procedures. The postoperative pain was recorded on visual analog scale (VAS) at 2 hours, 4 hours, 8 hours, 12 hours and 24 hours postoperatively. On the second and third

days, the repeat medication was administered at that reference time and recordings taken at the same intervals for a total of 3 days. Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

Results

Table I
Distribution of patients

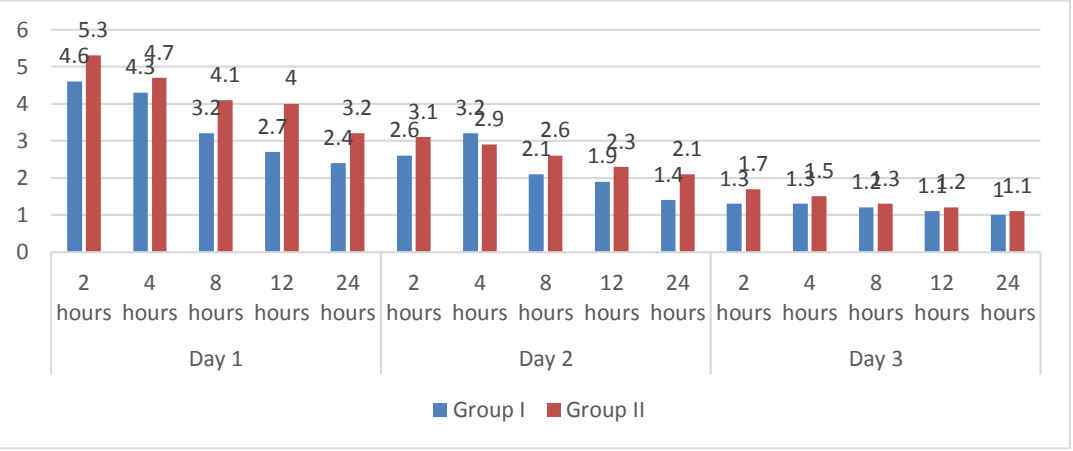
Total- 80		
Gender	Males	Females
Number	35	45

Table I shows that out of 80 patients, males were 35 and females were 45.

Table II
Comparison of VAS score in both groups

Day	VAS	Group I	Group II	P value
Day 1	2 hours	4.6	5.3	0.05
	4 hours	4.3	4.7	
	8 hours	3.2	4.1	
	12 hours	2.7	4.0	
	24 hours	2.4	3.2	
Day 2	2 hours	2.6	3.1	0.09
	4 hours	3.2	2.9	
	8 hours	2.1	2.6	
	12 hours	1.9	2.3	
	24 hours	1.4	2.1	
Day 3	2 hours	1.3	1.7	0.12
	4 hours	1.3	1.5	
	8 hours	1.2	1.3	
	12 hours	1.1	1.2	
	24 hours	1.0	1.1	

Table II, graph I shows that VAS on day 1 in group I and II at 2 hours was 4.6 and 5.3, at 4 hours was 4.3 and 4.7, at 8 hours was 3.2 and 4.1, at 12 hours was 2.7 and 4.0 and at 24 hours was 2.4 and 3.2 respectively. At day 2 was 2.6 and 3.1, 3.2 and 2.9, 2.1 and 2.6, 1.9 and 2.3 and 1.4 and 2.1. At day 3 was 1.3 and 1.7, 1.3 and 1.5, 1.2 and 1.3, 1.1 and 1.2 and 1.0 and 1.1 at 2 hours, 4 hours, 8 hours, 12 hours and 24 hours respectively. The difference was non-significant (P>0.05).



Graph I. Comparison of VAS score in both groups

Discussion

Analgesic drugs can be administered in a variety of routes, including oral, parentral, inhalation as well as transdermal.[6] Oral route carries the risk of first pass metabolism and loss of substantial quantities of the drug before it is absorbed systemically. Parentral administration of drugs can be extremely painful and sudden increase in drug concentration in the plasma could lead to certain adverse effects.[7,8] Although there have been several studies on the effect of transdermal diclofenac usage in fields like acute muscle spasm, sports injuries, laparoscopic surgeries, its impact on pain control in oral surgical procedures is less known, making surgeons depend on the more familiar oral and parenteral routes.[9] The present study was conducted to assess analgesic efficacy of diclofenac sodium in oral and transdermal patch in the management of postoperative pain following surgical removal of impacted mandibular third molars.

We found that out of 80 patients, males were 35 and females were 45. Samal et al[10] evaluated transdermal diclofenac in terms of analgesic efficacy, safety, compliance and cost-effectiveness and to compare it with oral tablets and intramuscular (IM) injections following surgical removal of impacted mandibular third molars. The study included 90 participants, 30 in each group. Participants received the standard once daily (OD) dosages of diclofenac in each group for three post-operative days and were advised to consume paracetamol 500 mg as rescue analgesics if the pain was not alleviated. Outcome measures such as demographics, duration of surgery, post-operative pain, the number of rescue analgesics taken, adverse drug reactions experienced and overall global assessment for three post-operative days were recorded by the participants on a questionnaire. Transdermal and oral forms achieved similar analgesia on all 3 days. Injectable diclofenac had significantly better pain control on the second and third postoperative days compared to tablets and on the third day compared to transdermal diclofenac. A higher number of rescue analgesics was consumed in oral group on day 1. Gastritis and vomiting were seen in 36.66% and 10% cases, respectively, in oral group. 100% of those in IM group had pain on injection. 6.6%

complained of dry skin due to patch, while 3.33% had rash and pruritus. Transdermal group had better overall global assessment by patients with 16.67%, 46.67% and 20% participants reporting excellent, very good and good pain control, respectively. The cost in INR was maximum for the transdermal group.

We observed that VAS on day 1 in group I and II at 2 hours was 4.6 and 5.3, at 4 hours was 4.3 and 4.7, at 8 hours was 3.2 and 4.1, at 12 hours was 2.7 and 4.0 and at 24 hours was 2.4 and 3.2 respectively. At day 2 was 2.6 and 3.1, 3.2 and 2.9, 2.1 and 2.6, 1.9 and 2.3 and 1.4 and 2.1. At day 3 was 1.3 and 1.7, 1.3 and 1.5, 1.2 and 1.3, 1.1 and 1.2 and 1.0 and 1.1 at 2 hours, 4 hours, 8 hours, 12 hours and 24 hours respectively. Bachalli PS et al[11] assessed subjectively the analgesic efficacy of oral diclofenac sodium against diclofenac sodium transdermal patch in the management of postoperative pain following surgical removal of impacted mandibular third molars. Twenty healthy subjects belonging to both the sexes in the age group of 18–40 years with bilateral mesioangular impactions of mandibular third molar teeth underwent surgical removal under local anaesthesia by administering an inferior alveolar nerve block on two different occasions with a minimum interval of 1 week in-between the procedures. The postoperative pain was recorded on visual analog scale, a verbal rating scale, a pain relief scale and a pain intensity scale. Readings were taken at 2 hours, 4 hours, 8 hours, 12 hours and 24 hours postoperatively, taking the time at which the surgery was completed as a reference. On the second and third days, the repeat medication was administered at that reference time and recordings taken at the same intervals for a total of 3 days. Patients received the study medication i.e. Diclofenac Sodium 100 mg once a day for 3 days after performing surgery on one side and the same patients were given Diclofenac Sodium Transdermal Patch 100 mg once a day for 3 days after performing surgery on the contralateral side. Both the statistical analysis and clinical observation showed that on the first postoperative day diclofenac sodium administered orally has slightly more significant efficacy when compared to the drug administered transdermally. However, on the second and third postoperative days there was no statistical or clinical difference in the pain control by either route of administration.

Conclusion

Authors found that transdermal diclofenac is an excellent alternative method to oral route of drug administration in pain control in patients undergoing mandibular third molar impaction.

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