

COMPARISON OF ANALGESIC EFFICACY OF TRAMADOL HYDROCHLORIDE WITH DICLOFENAC SODIUM IN DENTO-ALVEOLAR SURGERY

¹IRFAN SHAH, ²KHALID ZAEEM, ³MOHAMMAD WASIM IBRAHIM,
⁴IFTIKHAR HUSSAIN, ⁵AYUB HASSAN

ABSTRACT

The purpose of this study was to find a safe and effective analgesic alternative to non-steroidal anti-inflammatory drugs (NSAIDs) for patients undergoing dento-alveolar surgery who could not tolerate NSAIDs. We have compared on a double blind, randomized basis the efficacy of Tramadol hydrochloride with Diclofenac Sodium. Sixty patients undergoing third molar surgery were divided into two groups. One group was given tramadol hydrochloride 50 mg three times daily and the second group diclofenac sodium 50 mg three times daily for three days. Pain control was measured using a 0 to 10 numerical scale.

The analgesic efficacy of the two drugs was equal except on day one when tramadol did better than diclofenac. Tramadol can be used safely for post operative analgesia after dento-alveolar surgery especially in situations where NSAIDs are contraindicated.

Key words: *Wisdom Teeth, Analgesics, Tramadol*

INTRODUCTION

Tramadol Hydrochloride is a narcotic analgesic that produces its effects through central actions. It relieves moderate to severe pain by combining synergistically weak opioid and monoaminergically mediated anti-nociceptive mechanisms^{1,2}. It is of intermediate potency. Its efficacy lies between that of morphine and codeine. Tramadol is preferred because of the relative lack of some of the serious side effects such as respiratory depression seen with other opioids of comparable efficacy^{3,4}. It causes minimal dependence and tolerance and has a very low abuse potential^{5,6}. Tramadol also lacks the prostaglandin mediated adverse effects of the non-steroidal anti inflammatory drugs (NSAIDs).

Non steroidal anti inflammatory drugs are currently the first choice of analgesics after dento-alveolar surgery⁷. In some patients, however, especially those having the history of asthma, peptic ulcer or renal disease, their use is inappropriate or contraindicated. In such patients, there is an ever present need of a safe and potent analgesic to control post operative pain.

This study compares on a double blind randomized basis, the analgesic efficacy of oral tramadol hydrochloride with that of diclofenac sodium in patients undergoing dento-alveolar surgery under local anesthesia. The aim of the study is to find an effective alternative to NSAIDs for patients who can not tolerate the later drugs due to their medical conditions.

¹Assistant Professor (Oral Surgery) AFID / AM College (NUST), Rawalpindi

²Classified Anesthesiologist, CMH, Muzaffar Abbad

³Classified Oral Surgeon, AFID, Rawalpindi

⁴Classified Anesthesiologist, PNS Hafeez, Islamabad.

⁵Assistant Professor AFID / AM College (NUST)

Correspondence: Dr. Irfan Shah, BDS, FCPS, Assistant Professor, Department of Oral & Maxillofacial Surgery, AFID / AM College (NUST), Rawalpindi, 0300 5972646, Shahgi121@hotmail.com

METHODOLOGY

This study was conducted on 60 patients, who underwent surgical removal of one of their impacted mandibular third molars in the department of oral and maxillofacial surgery, Armed Forces Institute of Dentistry (AFID), Rawalpindi. All the patients were healthy and free of any systemic illness. Patients currently receiving any potent analgesic or those having the history of asthma, peptic ulcer, chronic opiate abuse or any other contraindications to NSAIDs or opiates were excluded from this study. The purpose, methods and risks of the study were explained and informed consent obtained at the preoperative visit. All the impacted teeth were of equal surgical difficulty (mesioangular, Pell & Gregory class 2, Position B) and were removed by one surgeon under local anesthesia. The preoperative interviews, subsequent observations and recordings after the operation were collected by an independent observer.

Patients (n = 60) were divided into two groups. Group-I (n=30) patients were given capsule Tramadol hydrochloride 50 mg (Campex® Akhai Pharmaceuticals) orally and group II (n = 30) patients were given capsule diclofenac sodium 50 mg (Voren® Continental Chemical Co.) orally 30 minutes before the operation.

Neither the patient nor the observer was aware of the drug given. All the teeth were removed using the same standard envelop incision, bone removal and wound closure. Subsequently, group I patients were started with tramadol 50 mg orally and group II patients diclofenac sodium 50 mg orally, two hours after the surgery. Both the drugs were given three times a day for three days.

All the patients were asked to mark the level of their postoperative pain on a 0 to 10 numerical scale, where 0 meant no pain, 1-3 meant mild, 4-6 moderate, 7-9 severe and 10 meant the worst imaginable pain.

TABLE 1: AGE & SEX DISTRIBUTION OF PATIENTS

DRUG USED	Mean Age (Years)	GENDER		Total
		Males	Females	
Group I (Tramadol HCl)	34.6	15	15	30
Group II (Diclofenac Sodium)	34.4	17	13	29
Total	34.5	32	28	

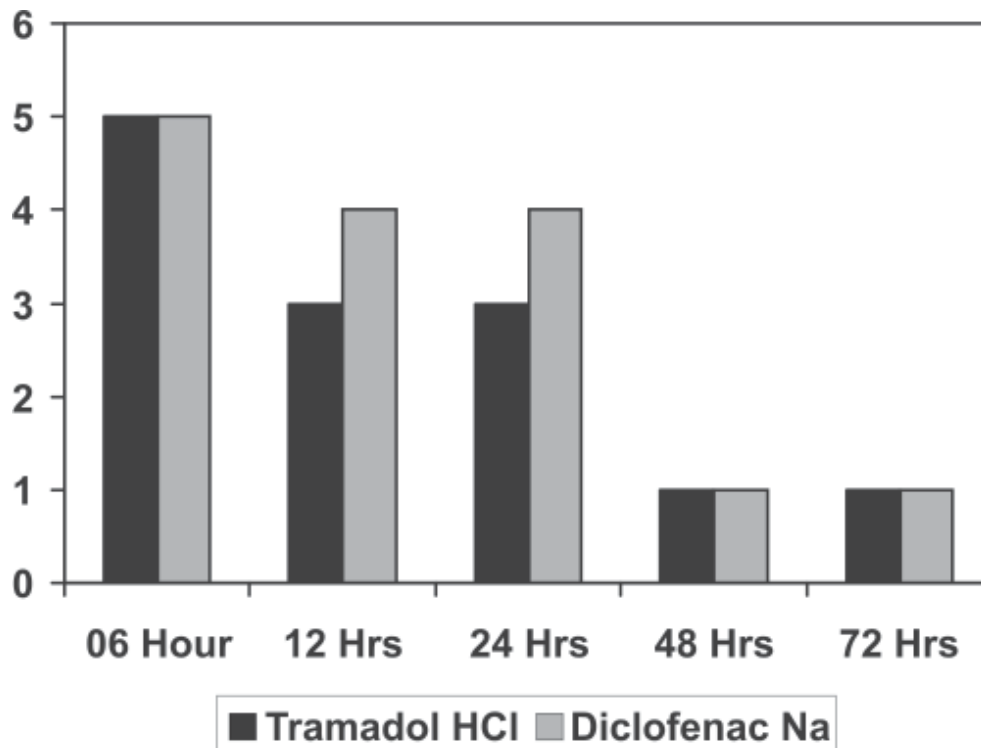


Fig. 1: Pain relief scored on numerical scale showing better pain relief by Tramadol in the first 24 hours.

Such recordings were made at 06, 12, 24, 48 and 72 hours after the surgery. The patients were also asked to notify side effects of the drug, if any.

RESULTS

Out of the 60 patients 32 were males and 28 females. The age range was from 21 to 48 (mean = 34.5) years. The mean ages of both groups were nearly identical (Group – I = 34.6 years and group – II = 34.4 years). At the conclusion of the trial, records of one of the patients from group-I were incomplete and was therefore excluded from the study (Table – 1).

The results of pain relief are summarized in Fig 1. As is evident from the figure, the pain relief was similar in both groups except on day 1 when tramadol did slightly better as analgesic than diclofenac. In group-I, three patients and in group-II, two patients required additional doses of analgesics on the first postoperative day. In group-I two patients complained of nauseating feelings whereas one patient from group-II registered the complaint of dyspepsia or gastric upset.

DISCUSSION

Tramadol was developed in the early 1960s by a German pharmaceutical company. Since then it is widely used as an analgesic for relieving mild to moderate pain. It is structurally related to morphine. It is a non-control drug and its world-wide availability provides the clinician with a useful analgesic for short and long term use in the hospital and community settings. Tramadol has a low potential for abuse and psychological dependence^{5,6}. In different studies tramadol has proved itself to be an effective analgesic that is well tolerated by adult and pediatric patients^{8, 9, 10, 11}. It has a good safety profile with lack of respiratory depression, tolerance and constipating effects.

After dento-alveolar surgery patients feel moderate to severe pain for which dental surgeons mostly prescribe NSAIDs. In Pakistan, clinical experience of tramadol in dental practice is either less or not documented. The clinicians are reluctant to prescribe narcotic analgesics because of the adverse event profile of these agents. Tramadol, as noted in this and other studies may be a good alternative to NSAIDs for post operative pain after dento alveolar surgery especially

in those cases where the use of NSAIDs is inappropriate or contra indicated⁹.

The analgesic efficacy of tramadol was found equal, if not superior to diclofenac sodium and patient satisfaction was slightly better with tramadol. As far as the adverse events profile is concerned, the dose of tramadol that was used in this study is very safe and well tolerated.

Other studies have shown that combination of narcotic and non-narcotic analgesics may give better results than tramadol alone^{13,14,15}. If, however the NSAIDs are contra indicated due to any reason, tramadol alone can give acceptable analgesia, as is demonstrated in this study. One more important point noted in this study was that when tramadol was given as pre medicament before tooth extraction, it not only provided pre-emptive analgesia but also the patient remained relatively calm and quite while receiving local anesthetic injection and during extraction of the tooth.

CONCLUSION

Tramadol can be used safely for post operative analgesia after dento-alveolar surgery. It can be used in a regimen of 50 mg three to four times daily. If more profound analgesia is required then the dose can be increased up to a maximum of 400 mgs per day in divided doses. Its use is especially more appropriate in patients who are allergic to NSAIDs or those with a history of peptic ulcer, congestive heart failure and renal disease. It can also be used as a pre medicament in apprehensive patients.

DISCLAIMER

The authors have no commercial interest in any of the products used in this study.

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