TRAMADOL HYDROCHLORIDE IN POSTOPERATIVE ANALGESIA: CLINICAL COMPARISON WITH DICLOFENAC SODIUM

Zahid Ahmad Hashmi,[1] Ghazala Bashir,[2] Shakeel Ahmad Shah[3]

[1]Department of Surgery, [2]Department of Gynecology & [3]Department of Anatomy,
Gomal Medical College, D.I. Khan, Pakistan.

ABSTRACT

Objective: To compare the effectiveness, duration and side effects of Tramadol Hydrocloride with Diclofenac sodium in the first postoperative twenty-four hours.

Setting: District Headquarter Teaching Hospital, D.I. Khan.

Method: A prospective study of 100 patients with moderate to severe postoperative pain, were randomly divided into two equal groups. The post operative pain in group A was controlled with single intramuscular dose of 100 mg Tramadol HCL, while in group B it was controlled with 75 mg of Diclofenac sodium given IM.

Results: Tramadol Hydrochloride when compared with Diclofenac sodium was found to be more effective analgesic (65% compared to 55%). Analgesia in the 4th postoperative hour was significantly higher with Tramadol HCL compared with Diclofenac sodium. There were no significant changes in cardio-respiratory parameters in all patients in our study. Sedation associated with dizziness and muscle relaxation was observed with Tramadol HCL in our study. While in case of Diclofenac sodium GI symptoms like epigastric pain and nausea were recorded. The analgesic effect of 100 mg Tramadol HCL lasted up to 24 hours while that of Diclofenac sodium lasted 6-8 hours, so repeated injections were required to control the pain.

Conclusion: The study shows that Tramadol HCL is a suitable and safe analgesic for the relief of postoperative pain and is more effective than Diclofenac sodium with prolonged analgesia and minimal side effects.

Key words: Tramadol Hydrochloride, Diclofenac Sodium, Postoperative pain.

INTRODUCTION

Tramadol hydrochloride was first introduced into clinical practice in the last seventies as a strong analgesic of opioid profile acting on mu receptors. When given in dose of 100 mg intramuscular injection it gives smooth control of moderate to severe pain in patients for more than 24 hours,[2] but the side effect of opioid analgesics (hypotension and respiratory depression) make it less popular among doctors.

Diclofenac sodium is a non-steroidal anti-inflammatory drug with analgesic and antipyretic activity. It is the most used analgesic in adults. Although it is quite effective in pain control immediately after operation, its action lasts for 6 to 8 hours and repeated intramuscular injection are required for smooth control of pain.

We conducted a study of 100 patients to compare the effectiveness, duration of action, patient compliance and side effects of the two drugs. It will help us to have a better understanding of pain control in postoperative patients.

MATERIAL & METHODS

The study was conducted in the surgical unit of DHQ Teaching hospital D.I. Khan from 1st January 2004 to 30th June 2004. Hundred patients from routine admission were randomly selected for the study. Anesthesia was performed routinely with out opioid premedication and after recovery from anesthesia pain score was taken on a visual analogue scale (VAS). These patients were divided randomly in two groups with 50 patients each for moderate to severe pain. The analgesic in study was injected IM. Another dose of analgesic was given when pain started to reappear.

This was designed as follow:

Group one received Tramadol hydrochloride 100 mg.

Group two receive Diclofenac sodium 75 mg.

Observation for pulse, blood pressure and respiratory rate were performed routinely during the 1st 24 hour.

Sedation was assessed before and during analgesia using five descriptive scores:

Alert	=	0
Sedated	=	1
Drowsy	=	2
Asleep	=	3
Comatose	=	4

This was calculated after every 30 minutes till the 4th hours and then every 2 hourly. Any other side effects were also recorded.[3]

RESULTS

Patients were divided into two groups, Tramadol group and Diclofenac sodium group. Their general characters were:

Table 1: General Characters of the Groups in Study

Groups	Tramadol HCL	Diclofenac Sodium
Sex M /F	26 /24	28 /22
Mean age	38.7	36.2
SURGICAL PROCEDURE:		
Heamorrhoidectomy	12	10
Hysterectomy	8	6
Mastectomy	4	5
Caesarian section	8	9
Splenectomy	9	8
Gastrectomy	7	8
Ovariectomy	2	4
ANESTHESIA:		
General anesthesia	41	38
Epidural & spinal Anaesthesia	9	12

General anesthesia was conducted using Thiopentone and maintained with Halothane, using muscle relaxant Suxamethonium.

Data was obtained from the postoperative observation in the first 24 hours.

Pain relief:

Visual Analog Scale was used in all patients.

Drug	Tramadol	Diclofena Sodium
Initial score	77.5 (+8.8)	77 (+9.1)
On 1st hour	42.5 (+22.2)	30 (+24.5)
On 2nd hour	32.5 (+16.3)	30.7(+17.4)
On 3rd hour	42.5 (+27.5)	32.4 (+22.4)
On 4th hour	43.2 (+20.3)	39 (+19.4)
On 5th hour	35 (+16.7)	32.6 (+15.4)
On 6th hour	32.5 (+17.6)	30.8 (+22.3)
On 12th hour	34.6 (+19.6)	___
On 18th hour	42.2 (+19.6)	
On 24th hour	43.4 (+20.3)	

Tramadol's analgesic effect was maintained for 24 hours as compare to Diclofenac sodium, which was only for 6-8 hours.

Cardio respiratory changes:

Monitoring of vital signs like pulse, blood pressure and respiratory rate in the early postoperative period was done hourly for 6 hours.

The results show no significant clinical variation except in diastolic blood pressure for one reading after Diclofenac sodium dosing, as well and in the 1st reading in the respiratory rate in both drugs.

Side effects:

The side effects resulting from Tramadol hydrochloride and Diclofenac sodium were recorded.

Over sedation was evident with Tramadol (25%) with some dizziness (20%) and muscle relaxation

Side effects	Tramadol	Diclofena Sodium
Over sedation	25 %	0 %
GI symptoms: (Nausea, diarrhoea, vomiting)	7 %	50 %
Dizziness	20 %	0.5 %

(10%). GI symptoms like epigastric pain, nausea, diarrhea (50%), and headache is more evident with Diclofenac sodium.

DISCUSSION

Analgesia: Opioid drugs are regarded as strong analgesics. Tramadol hydrochloride is an analgesic with an opioid profile, its analgesic character mimics morphine, including its ability to relieve thermal pain.[4] Naloxone pretreatment do not prevent Tramadol toxicity.

Diclofenac sodium is a non-steroidal, anti-inflammatory agent that possess analgesic actions, it acts by inhibiting the synthesis of prostaglandins.[5]

Tramadol hydrochloride provides analgesia for postoperative pain patients with greater efficacy than Diclofenac sodium. It has prolonged action i.e. 24 hours. Only 25% of the patients had booster injection in the 1st 24 hours when compared with Diclofenac sodium.

The long-term effects of Tramadol may be explained on the view that by-product metabolites of Tramadol produce an active metabolite (0-demethyl Tramadol) which is an active analgesic while the by-product of Diclofenac sodium is pharmacologically inactive.[6]

Tramadol does show some changes in the cardiovascular parameters. It was observed in some cases that it increased heart rate and caused some drop in blood pressure.

In our study there was change in respiratory rate in the 1st hour. These changes started to return towards the original in the 2nd hour. The respiratory rate in all the patients was above the normal rates, due to the influence of surgery and anesthesia. Over sedation was more evident in case of Tramadol. Dizziness was significantly higher as well as muscle relaxation. GI symptoms, like nausea, vomiting and diarrhea were observed in case of Diclofenac sodium.

CONCLUSION

The overall study profile proved that Tramadol was a suitable and safe analgesic for relief of post-operative pain and is more effective than Diclofenac sodium with a long sustained analgesic action. The percentage of side effects was minimal.

REFERENCES

1. Lee CR, McTavish D, Sorki EM. Tramadol: A preliminary review of its pharmacodynamic and pharmacokinetic properties and therapeutic potential in acute and chronic pain states. Drugs 1993; 46: 313-340.
2. Bonica J. Postoperative pain. In: The management of pain, 2nd edn: Philadelphia: Lea and Febiger, 1990: 461-480.
3. Vickers MD, O'Flaherty D, Szekely SM, Read M, Yoshizumi, J. Tramadol: Pain relief by an opioid without depression of respiration. Anasthesia 1992; 47: 291-296.
4. Abel SR. Tramadol: An alternate analgesic to traditional opioids and NSAIDs. J Pharm Care Pain Symptom Control 1995; 3: 5-29.
5. Striebel HW, Hackenberger J. O Vergleich einer Tramadol /Metamizol-Infusion plus ibuprof en-suppositorien zur postoperativen Scherztherapie nach Hysterektomien. Anathesist 1992; 41: 354-360.
6. Raffa RB, Friderichs E, Reimann W, Shank RP, Codd EE, Vaught JL. Opioid and non-opioid components independently contribute to the mechanism of action of tramadol, an 'atypical' opioid analgesic. J Pharmacol Exp Ther 1992; 260: 275-285.

Address for correspondence:

Dr. Zahid Ahmad Hashmi
Assistant Professor Surgery
Department of Surgery
Gomal Medical College,
D.I. Khan, NWFP, Pakistan