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A Comparative study of sedative efficacy of anal suppository of tramadol versus diclofenac in reducing acute migraine pain on mental retards in an institution for mentally handicapped

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Abstract: Background: The pupose of our study is to compare the sedative efficacy of tramadol and diclofenac sodium used as a anal suppository and compare the adverse effects of both drugs. **Materials and Methods:** The study design is prospective, randomized, single blind and institutional based. Sixty patients with 19-27 years of age with acute migraine attack on waking up in the morning were eligible in this study and were randomized to receive either anal suppository of tramadol 100mg(n=20) GroupT or anal diclofenac100 mg (n=20), GroupD. Pain measurement was performed usin g visual analoguescale(VAS). Rescue analgesia was given when the VAS was noted>3 in a period of pain up to 6 hours. Adverse effects like nausea, vomiting, were seen during the same period. **Conclusion:** anal suppository of tramadol as well as diclofenac are effective for suppressing migraine pain. Diclfenac is better alternative than tramadol as it is free of nausea and vomiting and have longer duration.
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Key words: sedative efficacy, migraine pain, suppository, tramadol,diclofenac sodium.

INTRODUCTION:

In the U.S., according to AASH, more than 37 million people suffer from migraines. Some migraine studies estimate that 13 percent of adults in the U.S. population have migraines, and 2-3 million migraine suffers are chronic._Almost 5 million in the U.S. experience at least one migraine attack per month, while more than 11 million people blame migraines for causing moderate to severe disability. Because migraines strike during the most productive, working years for sufferers, the pain takes a financial toll. The World Health Organization's disability rating for migraine, ranks migraine as the 19th most common reason for disability. Migraine sufferers use twice the amount of prescription drugs and visit doctors and emergency rooms twice as often as those who don't have the disorder. It is estimated that the loss of productivity in the U.S. to be between $5.6 billion to $17.2 billion per year because of missed work. The average migraine sufferer misses two days of work per year. Some who suffer from persistent migraines work during a migraine attack, which they say lowers productivity. It is estimated that migraines are the reason for 36 million days of bed rest, plus 21.5 million days of restricted activity. Mental pains should be diagnosed on Dimension II of the new American Association on Mental Retardation classification system (Luckasson et al, 1992). The diagnoses are best made by a qualified psychiatrist or clinical psychologist using the Diagnostic and Statistical Manual of Mental Disorders, published by the American Psychiatric Association in 1988.

Many options are available for the treatment of migraine pain including systemic analgesics like opioids and non- opioids like tramadol and ketamine. Mechanism of Tramadol's analgesic activity involves two components: low-affinity binding to opioid receptors and inhibition of monoamine reuptake [1].Tramadol is a synthetic 4-phenyl-piperidine analogue of codeine. Tramadol has a proven analgesic activity for many acute and chronic pain conditions [2–3]. It inhibits serotonin and norepinephrineneuronal reuptake. Tramadol is less likely to cause neonatalrespiratory depression and hence it has been recommended for analgesia. Tramadol is an analgesic with mixed Opioid and non Opioid activities.(5,6) It is increasingly used for the treatment of acute post operative and chronic pain of intermediate or severe intensity.(7) One of the NSAIDS (nonsteroidal anti inflammatory drug)used for acute pain management is diclofenac in suppository form and other steroids have been studied for the same purpose.(8 Many studies have been conducted to compare NSAIDS with opioids,

but there have been no studies to determine the efficacy of suppository diclofenac and Tramadol in reducing acute migraine pain on mental retards.

MATERIALS AND METHODS :

This is prospective, randomized, double blind and hospital based study in Aliakbar institution for mentally handicapped in Birjand, Iran. All mental retards with 19-27 years of age with acute migraine attack on waking up in the morning according to the second edition of the International Headache Society (IHS) criteria for migraine without aura [9] were eligible in this study. The exclusion criteria was – history of bleeding, drug sensitivity to Tramadol or diclofenac.

Written informed consent was obtained from all the patient. Using block randomization method, the patients were randomly divided into either of two groups –

Group T : patients receiving Tramadol 100 mg rectal suppository

Group D: patients receiving Diclofenac 100 mg rectal suppository.

Assessment of pain was done using Visual Analogue Scale (VAS), that is graded ruller ranging from 0 -10 showing the minimal and maximum pain score respectively. The monitoring anesthesiologist and all the patients were explained about pain assessment process by using VAS score. The score was assessed post operatively at 1,2,3, hrs in isolation room. If the patient had pain during this period (i.e. VAS score > 3) inj. Pentazocine0.4 mg /kg i.v. was given as rescue analgesia. During this period vital parameters like pulse, blood pressure, respiration and side effects like nausea,vomiting , heart burn were monitored.

Table1. Comparison of Mean Age, and weight in both groups.

Sr.No.	Parameters	Diclofenac Group		Tramadol Group	
		Mean	SD	Mean	SD
1.	Age (yrs)	23.60	3	22.57	2.64
2.	Weight (Kgs)	Weight (Kgs)	50.33	50.37	2.74

Table 2. Distribution of patients with nausea and vomiting.

Sr. No.	Nausea and Vomiting	Diclofenac Group	Tramadol Group	Total
1.	Yes	0 (0.00)	1(3.33)	01
2.	No	30 (100)	29 (96.66)	59
	Total	30 (100)	30 (100)	60

DISCUSSION and CONCLUSION:

The analgesic regimen needs to meet the goals of providing safe,effective analgesia, with minimal adverse effects for patients. (10,11). However, new technologies are not available in many hospitals since they are expensive and require trained personnel and special equipments (12,13).

It thus seems that tramadol may be suitable to treat pain; however after intravenous and oral administration, peak concentrations are reached rapidly and this has been associated with nausea and vomiting. Rectal administration of Tramadol may be an alternative in this situation. It is convenient to use and is the established treatment for reducing pain in adults(14). A rectal dose of 1.5 – 2.0 mg / kg Tramadol is therapeutic. (15) Therefore a dose of 100 mg was used in our study as suppository. After suppository absorption of active ingradient was rapid but its metabolism quickly transformed the parent drug to high levels of N-desmethyl-tramadol(M2) and N.Odidesmethyl Tramadol (M5).

Studies are not available showing the duration of analgesia after tramadol suppository. In our study, it was shown that, at 7 hours after waking up 60% patients needed first rescue analgesia in tramadol group.At 4 hours mean VAS score 2.53 and at 6

hours it was 2.93 , after that rescue analgesia was given. In our study only one patient had nausea and vomiting. This low incidence of vomiting after tramadol could be because of the suppository used rectally. NSAID inhibit prostaglandin biosysnthesis by bloking the cyclooxygenaseenzyme, which catalyses the coversion of arachidoonic acid to prostaglandin. By reducing the production of these agents,the feeling of pain may decrease in the peripheral nervous system. On other hand NSAIDs have no effect on CNS or cause no drowsiness.

Rescue treatment rates for different agents have been reported to be between 11% and 33% [17,18 , 16,4].

In our study, we compared diclofenac suppository with tramadol suppository. In diclofenac group at 4 hours mean VAS score 2.1, at 6 hours it was 2.63 and at 8 hours mean VAS was 2.07 , after that rescue analgesia was given. When we compared diclofenac suppository with tramadol suppository, it was found mean VAS was less in diclofenac group and this difference was statistically significant. Also no side effect was found in diclofenac group. Thus, rectal suppository of diclofenac is better alternative for analgesia in reducing acute pain of migraine as compared to tramadol. There are few limitations of our study. First of all, we had 2 groups and study lacked a 3rd group of control patients to compare the effects of placebo with each of the two groups. Also the number of patients included in our resaerch was small, so further study with large number of patients is required.

Rectal suppository of diclofenac and tramadol can be used for pain relief in acute migraine.

Tramadol has side effects like nausea and vomiting. It seems that, diclofenac suppository is better alternative to tramadol because it has shown better effect on pain reduction.

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