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DOI: 10.46903/gjms/22.01.1329

ORIGINAL ARTICLE

COMPARISON OF EFFECTIVENESS OF GABAPENTIN AND SODIUM VALPROATE IN PATIENTS WITH MIGRAINE

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ABSTRACT

Background: Migraine causes patients' disability so that these patients are either absent from work and study, or even if they attend, they do not have the necessary efficiency for learning or working. Objectives of the study was to compare the effects of gabapentin (GBP) and sodium valproate (VPA) on patients with migraine headaches.

Materials & Methods: In this clinical trial, patients suffering from migraine were included in the study and received preventive treatments of migraine in two groups: GBP (n=35) and VPA (n=35). In this study, headache impact test (HIT6) and Migraine Disability Assessment Scale (MIDAS) were used. the sampling method is block random and in the order of patients entering the department, they are in group A (GBP) and B (sodium VPA) and the sampling continued until the patients reached a sample size of n=70. In all patients, 6 and 12 weeks after taking the drugs, MHA was examined using HIT6 and MIDAS. the data were analyzed by SPSS 16.

Results: Results showed, HIT6 score reduced from 53.68 (8.98) to 42.02 (2.61) in GBP group, and reduced from 55.57 (9.24) to 41.91 (2.17) in VAP group. MIDAS score reduced from 14.28 (1.5) to 5.97 (1.12) in GBP group and reduced from 14.85 (3.39) to 6.4 (1.11) in VAP group. Also, in the group receiving GBP, HIT6 score reduced significantly (P=0.000, F=3960.727) and MIDAS score also reduced significantly (P=0.000, F=5509.340). Also, in VAP group, a significant reduction was found in HIT6 (P=0.000, F=4855.349) and MIDAS (P=0.000, F=1332.999)

Conclusions: Both GBP and VPA reduced MHA. For this reason, while suggesting the prescription of both of these drugs, it is suggested to conduct further studies in this field.

KEY WORDS: Gabapentin; Sodium valproate; Migraine; pain; Disability.

Cite as: Karimian M, Asadoola Y, Amin NG, Rahmatian A, Mohammadi HR, Shokri F, et al. Comparison of effectiveness of gabapentin and sodium valproate in patients with migraine. Gomal J Med Sci 2024 Jan-Mar;22(1):3-8. https://doi.org/1046903/gjms/22.01.1329

INTRODUCTION:

Migraine is a debilitating brain disorder as unilateral throbbing or pounding headache attacks for 4-72 hours. Migraine is a chronic neurological disorder defined by frequent headache attacks with symptoms such as nausea, sensitivity to light and sound.[1-4] Migraine is divided into two types with aura (MA) and without aura (MO). The average onset of MO is at the age of nineteen and MA is at the beginning of puberty, and the attack pattern in MO appears as several attacks repeated regularly in a month. On the other hand, MA attacks are much less and follow an irregular and unpredictable pattern.[5]

Migraine causes patients' disability so that these patients are either absent from work and study, or even if they attend, they do not have the necessary efficiency for learning or working.[6] In the U.K., annually, about $8.8 billion is spent on efficiency, 86 working

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Date Submitted: 24-04-2023
Date Revised: 15-11-2023
Date Accepted: 26-01-2024

days are passed and £1 billion is spent on healthcare services. Also, the economic loss in the US for 1000 employees are equal to US$84,000, $1.04 billion in Singapore, and US$2973-6176 in Malaysia.[7-16]

Pain is a morbidity relief of which is a priority.[17-23] MHA is a multifaceted pain that medical treatment alone does not lead to its reduction and several factors can affect it.[24] A variety of oral drugs are used to relieve pain[25,26], and gabapentin (GBP) and sodium valproate (VPA) are MHA reducing drugs.[27, 28] VPA is an anti-epileptic drug that is also used for migraine prevention.[29] VPA is used at doses of 500-1000 mg/day and reduces the postsynaptic effects of MHA by increasing GABA's postsynaptic effects.[30,31] GBP is another anti-epileptic drug that is used to relieve neuropathic pain, chronic pain, and pain after surgery and prevention of seizures. GBP exerts its analgesic activity through central and peripheral desensitization and relieves pain.[32,33] For this reason, a study was conducted to compare the effects of GBP and VPA on patients with migraine headaches.

MATERIALS AND METHODS

2.1 study design, settings and duration:

2.2 population, sample size, sampling technique, sample selection:

In this clinical trial, patients suffering from migraine in Ilam were included in the study and received preventive treatments of migraine in two groups: GBP (n=35) and VPA (n=35).

The study inclusion criteria included suffering from migraine according to the International Headache Society and the approval of a neurologist, age between 18-65 years, the absence of other ongoing treatments for migraine, and the patient's consent to participate in the study. The study exclusion criteria included the patient's sensitivity or contraindication to taking medicine, pregnancy, non-follow-up of the patient for any reason (such as travel, unwillingness, death, etc.).

In this study, headache impact test (HIT6) and Migraine Disability Assessment Scale (MIDAS) were used[34-37] (attached). HIT6 has 6 questions that measure the severity of migraine cases and the extent of its effect on a person's mood, spirit and physical activity. In HIT6, a score of 49 or less is considered as severity 1 (little or no), a score of 50-55 is severity 2, a score of 56-59 is severity 3, and a score of 60-78 is considered as severity 4 (severe effect). MIDAS has 5 questions that measure the number of days that the patient did not attend work or social activities due to migraine headaches in the last 3 months. In MIDAS, a score of less than 5 is considered as a severity 1 (minimal disability), a score of 6-10 is considered as a severity 2, a score of 11-20 is considered as a severity 3, and a score of 21 or more is considered as a severity 4 (severe disability).[34-37,38,39]

Before conducting the study, necessary explanations were provided on the objectives of the study and the research method, and if the patient participated in the study, written informed consent was obtained. The sampling method (Using a table of random numbers) is block random and in the order of patients entering the department, they are in group A (GBP) and B (sodium VPA) and the sampling continued until the patients reached a sample size of n=70. The statistician, the patient and the researcher who measured the dependent variables were not aware of the grouping of the study.

In all patients, 6 and 12 weeks after taking the drugs, MHA was examined using HIT6 and MIDAS.[40,53-56] Ethical considerations included obtaining written informed consent, assuring the patient that the information would remain confidential, not harming the patient during the study, and free withdrawal from the study. The data were analyzed by SPSS 16. Analyzed described demographic/grouping variables and research/outcome variable of each group by count, percentage, mean/median & SD. Analyzed described research variable for sample and also for population by 95% CI.

RESULTS

The results of Table 1 show the comparison of HIT6 and MIDAS scores in the study groups (GBP and VAP). Results showed, HIT6 score reduced from 53.68 (8.98) to 42.02 (2.61) in GBP group, and reduced from 55.57 (9.24) to 41.91 (2.17) in VAP group. MIDAS score reduced from 14.28 (1.5) to 5.97 (1.12) in GBP group and reduced from 14.85 (3.39) to 6.4 (1.11) in VAP group.

Results showed, in the group receiving GBP, HIT6 score reduced significantly (P=0.000, F=3960.727) and MIDAS score also reduced significantly (P=0.000, F=5509.340). Also, in VAP group, a significant reduction was found in HIT6 (P=0.000, F=4855.349) and MIDAS (P=0.000, F=1332.999) (Tables 2 and 3).

Table 1: Comparison of the M (SD) score of the questionnaires used in the two study groups

Variable		pre	Post 1	Post 1	P
GBP Group	HIT6	53.68(8.98)	48.45(5.25)	42.02(2.61)	0.000
	MIDAS	14.28(1.5)	10.22(2.46)	5.97(1.12)	0.000
VAP Group	HIT6	55.57(9.24)	46.65(5.13)	41.91(2.17)	0.000
	MIDAS	14.85(3.39)	9.17(3.08)	6.4(1.11)	0.000

Table 2: Tests of Between-Subjects Effects for HIT6 and MIDAS score all groups

Source			Type III Sum of Squares	Mean Square	F	Sig.
GBP	HIT6	Intercept	242496.343	242496.343	3960.727	.000
		Error	2081.657	61.225		
	MIDAS	Intercept	10842.752	10842.752	5509.340	.000
		Error	66.914	1.968		
VPA	HIT6	Intercept	242400.238	242400.238	4855.349	.000
		Error	1697.429	49.924		
	MIDAS	Intercept	10802.143	10802.143	1332.999	.000
		Error	275.524	8.104		

Table 3: Mauchly's Test of Sphericity for HIT6 and MIDAS score all groups

Source		Mauchly's W	Approx. Chi-Square	Sig.	Epsilon	
					Greenhouse-Geisser	Huynh-Feldt
GBP	HIT6	.602	16.740	.001	.715	.738
	MIDAS	.635	14.974	.001	.733	.758
VPA	HIT6	.646	14.399	.001	.739	.764
	MIDAS	.748	9.584	.008	.799	.832

DISCUSSION

Conducting studies in the field of known diseases can greatly contribute to the scientific progress of medicine. So that the evidences of past studies have shown the progress and development of medical sciences in order to advance health goals.[57-59] It is important to pay attention to ways to reduce pain in patients.[60-62]

MHA has a high prevalence and its prevalence has been examined in various meta-analyses in Iran. So that in s study by Farhadi et al. (2016), it was equal to 14%[40], 7.14%-18.11% in a study by Sadeghi et al. in adults and 1.7%-12.3% in children.[41] In s study by Mirmosayyeb et al., the prevalence was 31% in patients with MS.[41] When a disease has a high prevalence, therapeutic interventions should be done to reduce its symptoms and complications.[42,43]

According to the results, both GBP and VPA drugs had reduced MHA. For the effect of GBP, in a study, Zain et al. used GBP and topiramate, and both groups experienced a reduction in attacks and pain intensity. But in the topiramate group, pain reduction was higher.[44] Also, in a study, Gholami et al. compared GBP and theophylline on pain after cesarean section, and pain reduction in the theophylline group was higher than the GBP group.[45]

For the effect of VPA in both groups of children and adults, various studies have been conducted. In the group of children in a study by Amanat et al., 158 children were prescribed cinnarizine, VPA and placebo. After 4 weeks of administration of VPA, VPA had reduced children's MHA.[46] Also, in a study by Serdaroglu et al. in the age group of 9-17 years with a minimum study duration of 12 months[47], in a study by Bidabadi and Mashouf in the age group of 5-15 years and the intervention duration of 4-6 months[48] and in a study by Unalp et al. with an intervention duration of about 4-6 months[49] VPA had reduced MHA. Also, in a study by Pavitt et al., the severity of MHA was reduced from 6.9 to 5.4.[50]

For the effect of VPA on MHA in adults, a study by Shahien et al. found that the administration of 900-1200 mg of VPA for patients with an average age of 35.7 years reduced MHA in 75% of cases.[51] In a study by Rahimdel et al., 500 mg/day of VPA was administered to the patients and MHA of the patients was examined. The results showed a reduction in headache frequency from 6.5 to 2.1.[52] In a study by Hesami et al., 147 patients were prescribed pregabalin (50 mg) and VPA (200 mg) and both drugs reduced MHA.[53]

CONCLUSION

Both GBP and VPA reduced MHA. For this reason, while suggesting the prescription of both of these drugs, it is suggested to conduct further studies in this field. One of the strengths of the study was the innovation in conducting the study. So that this study has been done for the first time in Ilam (Iran). failure to complete other questionnaires has been one of the weak points of this study. For this reason, it is suggested to carry out other studies that complete other questionnaires and also evaluate clinical variables.

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CONFLICT OF INTEREST
Authors declare no conflict of interest.
GRANT SUPPORT AND FINANCIAL DISCLOSURE
None declared.

AUTHORS' CONTRIBUTION

The following authors have made substantial contributions to the manuscript as under:

Conception or Design:	MK, YA
Acquisition, Analysis or Interpretation of Data:	MK, YA, NGA, AR, HRM, FS, EB
Manuscript Writing & Approval:	MK, YA, NGA, AR, HRM, FS, EB

All the authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.