

Instructions Leaflets On Antiepileptic Drugs Prescribed For Migraine Prophylaxis May Compromise Compliance

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Citation

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Abstract

Objective: Prophylactic treatment of migraine may be done with a variety of drugs, including antiepileptic drugs (AEDs). However, the leaflets inserted in the medication seemed to discourage patients to use these AEDs.

Methods: Individual interviews with forty individuals suffering from migraine who claimed to follow prescriptions given by doctors they trusted, independently of instructions inserted in medication packages.

Results: After reading these leaflets about AEDs used for migraine, two-thirds of these individuals said they would not take the drug, which was "too strong", "specific for epilepsy" or "had serious side effects".

Conclusion: The instruction leaflets accompanying AEDs apparently discourage patients to comply with prescriptions based on good results from clinical trials. This result seems to add to the high burden of migraine to the public and private health systems.

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INTRODUCTION

The use of antiepileptic drugs (AEDs) in migraine prophylaxis has provided doctors and patients with a powerful new tool for controlling migraine attacks ¹. A variety of clinical trials has consistently shown the benefits of such AEDs in improving this chronic medical condition ¹. Although not fatal in its outcome, migraine may have devastating effects both for personal and professional life of sufferers. Prophylactic treatment is often necessary, not only for better quality of life, but also to avoid the development of analgesic abuse.

However, in daily practice, migraine patients tend to use and even overuse analgesics without worries on side effects, but may be resistant to using prophylactic drugs. When

prescribed AEDs, they seem to worry over the instruction leaflets that accompany the drug and often question the need for such drugs. Frequently used drugs, such as beta-blockers, tricyclic antidepressives and AEDs have very little or no information of their use in migraine prophylaxis in the accompanying instructions.

We evaluated the possible influence of such leaflets on patient compliance by assessing the response of forty individuals from a general population to the prescription of AEDs for migraine.

PARTICIPANTS AND METHODS

Forty individuals (10 males, 30 females) over 16 years of age (mean age 36) were individually interviewed. None of them had sought medical consultations for their migraine. They were chosen from a variety of backgrounds, in different places of work or schools. They were volunteers to participate in this study, selected when all criteria for migraine were fulfilled. The social-cultural level as well as monthly income were variable, but relatively high. This intended to reflect the population seeking medical consultations in specialized headache clinics who could afford paying treatment with AEDs.

All individuals presented migraine for at least five years (average 16 years of disease) and fulfilled the criteria for prophylactic treatment due to frequency, severity and duration of migraine attacks. They all treated their attacks with analgesics, often to no avail, and they wished to have another option of treatment to be free of their migraine.

These individuals were selected also due to the affirmative answer to the initial question: “When a drug is prescribed by a doctor you trust, do you take it as recommended?”.

The interviewed then raised the question of reading and believing leaflets with instructions that accompany the drugs. Thirty-six individual claimed to read the leaflets, but they tend to trust the doctor and not the information given by the drug company. Three individuals claimed they do not read the information at all, trusting the doctor. Only one individual referred to read the instruction and not to take the drug without questioning the doctor on side effects.

The group was then divided into two subgroups, similar in all demographic aspects. To one group (n = 20, 5 males, 15 females), the leaflet accompanying divalproate (Depakote®) was given. To the other group (n = 20, 5 males, 15 females), the leaflet accompanying topiramate (Topamax®) was given. All individuals were informed that these were effective drugs for prophylactic treatment of migraine, as shown by well designed clinical trials. Any medical specialist on headache consulted was likely to prescribe one of these drugs.

RESULTS

Independently of age, gender, socio-cultural and economic level, only 35% of these individuals confirmed that they would take the AED after reading the instruction leaflet (7 out of each group of 20). Nine individuals referred they would not take the medication because they did not have epilepsy and six individuals considered this medication “too strong”. Most individuals (17) referred to be afraid of the adverse events reported on the instructions leaflet. Even with the inclusion of the word “migraine” in the Depakote® leaflet, patients considered that the medication was specific for epilepsy.

When informed of the price of this treatment, eleven individuals said they felt discouraged to use them (5 Depakote®, 6 Topamax®). This finding was also unrelated to any of the demographic data, including monthly income. From this group of eleven individuals, eight had already

claimed they would not use the drug due to possible side effects.

DISCUSSION

Information on leaflets accompanying AEDs known to be useful for migraine prophylaxis had a very negative effect on compliance in our study. Even if prescribed by a medical doctor with special training for treating headaches, about 2/3 of these individuals would not take the medication. This population was selected carefully to provide individuals who had suffered from migraine for many years and who claimed to fully comply with prescriptions made by doctors they trusted. In our daily practice, most patients come to the consultation due to a list of doctors working in public or private health services. The impersonal relation of these doctors with migraine patients to whom AEDs are prescribed may provide an even worse compliance². From the results of this pilot study, we concluded that 65% would not take the medication as prescribed due to the information accompanying the AED. We also noted that 27.5% of migraine patients would feel discouraged to buy the medication due to costs of treatment, some of whom had already considered the drug inappropriate. In total, 72.5% of the initial population of forty individuals in the present study were unlikely to adhere to the treatment. This result may also be analyzed on the basis of costs on consultations which will not result into compliance, thus increasing further the socioeconomic burden of migraine^{3, 4}.

A recent report showed similar results for the treatment of migraine attacks in the USA⁵. The authors observed that two-thirds of migraine sufferers delayed or avoided using prescribed drugs for an attack because they were concerned with potential side effects of these drugs.

Well designed clinical trials do not consider such facts. Inclusion of patients is only done after they are fully aware of possible side effects of the AEDs and accept entering the clinical study. In these trials, medication is provided by the sponsor and price of treatment is not an issue. The use of AEDs for prophylactic treatment of migraine provides good results both in clinical trials and in daily practice. However, it remains to be seen if this population who responds to such treatment in clinical trials really reflects the population we see daily.

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