Guidelines for the nonpharmacologic management of migraine in clinical practice

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Abstract

Objective: To provide physicians and allied health care professionals with guidelines for the nonpharmacologic management of migraine in clinical practice.

Options: The full range and quality of nonpharmacologic therapies available for the management of migraine.

Outcomes: Improvement in the nonpharmacologic management of migraine.

Evidence and values: The creation of the guidelines followed a needs assessment by members of the Canadian Headache Society and included a statement of objectives; development of guidelines by multidisciplinary working groups using information from literature reviews and other resources; comparison of alternative clinical pathways and description of how published data were analysed; definition of the level of evidence for data in each case; evaluation and revision of the guidelines at a consensus conference held in Ottawa on Oct. 27–29, 1995; redrafting and insertion of tables showing key variables and data from various studies and tables of data with recommendations; and reassessment by all conference participants.

Benefits, harms and costs: Augmentation of the use of nonpharmacologic therapies for the acute and prophylactic management of migraine is likely to lead to substantial benefits in both human and economic terms.

Recommendations: Both the avoidance of migraine trigger factors and the use of nonpharmacologic therapies have a part to play in overall migraine management.

Validation: The guidelines are based on consensus of Canadian experts in neurology, emergency medicine, psychiatry, psychology and family medicine, and consumers. Previous guidelines did not exist. Field testing of the guidelines is in progress.

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Résumé

Objectif : Donner aux médecins et aux membres des professions paramédicales des lignes directrices sur le traitement non pharmacologique de la migraine en pratique clinique.

Options : L'éventail complet et la qualité des traitements non pharmacologiques disponibles pour la prise en charge de la migraine.

Résultats : Amélioration de la prise en charge non pharmacologique de la migraine.

Preuves et valeurs : La création des lignes directrices a suivi une évaluation des besoins effectuée par des membres de la Canadian Headache Society et a comporté les mesures suivantes : énoncé d'objectifs, élaboration de lignes directrices par des groupes de travail multidisciplinaires qui ont utilisé des renseignements tirés de recensions d'écrits et d'autres sources, comparaison d'autres moyens



Education

Éducation

Information about the authors appears at the end of the article.

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cliniques et description de la façon dont on a analysé des données publiées, définition du niveau des données probantes dans chaque cas, évaluation et révision des lignes directrices au cours d'une conférence consensuelle qui a eu lieu à Ottawa du 27 au 29 octobre 1995, rédaction d'une nouvelle version à laquelle on a ajouté des tableaux indiquant des variables clés et des données tirées de diverses études, ainsi que des tableaux de données et des recommandations, et réévaluation par tous les participants à la conférence.

Avantages, préjudices et coûts : L'utilisation accrue de traitements non pharmacologiques pour la prise en charge active et prophylactique de la migraine devrait entraîner d'importants avantages sur les plans humain et financier.

Recommandations : L'évitement des facteurs déclenchants de la migraine et le recours à des traitements non pharmacologiques ont un rôle à jouer dans le traitement global de la migraine.

Validation: Les lignes directrices sont fondées sur le consensus d'experts canadiens en neurologie, en médecine d'urgence, en psychiatrie, en psychologie et en médecine familiale, ainsi que de consommateurs. Il n'y avait pas de lignes directrices auparavant. L'essai terrain des lignes directrices est en cours.

Commanditaires : La conférence consensuelle a bénéficié d'une subvention d'éducation sans restriction de Glaxo Wellcome Inc. La coordination rédactionnelle a été assurée par Medical Education Programs Canada Inc.

In a preceding companion paper we presented a series of recommendations for the diagnosis of migraine and for its management in the acute and interval stages. During the preparation of these guidelines we were aware of the potential role of nonpharmacologic methods of migraine management but wished to defer publishing our comments until further study of published data had been completed.

Although less common than tension-type headache,² migraine is the most common type of headache leading patients to consult a physician. Following accurate diagnosis, a careful explanation of the disorder and reassurance as to the absence of a serious underlying cause are important before embarking on a treatment plan. For most patients, a combination of nonpharmacologic and pharmacologic interventions should be used to control the headache disorder. Many of the nonpharmacologic therapies are based on the theoretic concept of migraine as resulting from neurochemical instability within the brain. These approaches, which are often "biobehaviouristic," may be complementary or adjunctive to pharmacologic treatment or may provide an alternative to it.

Formulation of the guidelines

MEDLINE was searched for articles published from 1975 to 1996 using the following medical subject headings: "migraine" and "alternative medicine" or "acupuncture" or "biofeedback" or "chiropractic" or "hypnosis" or "herbal medicine." We restricted our search to Englishlanguage papers dealing with the disorder as it affects

adults. In addition, previous reviews (e.g., meta-analyses³ and standard texts) were consulted. Of the approximately 330 publications retrieved, we excluded those that, by examination of title, abstract or text, were nonrandomized, uncontrolled or unblinded trials, case reports, commentaries or reviews without further assessment. We refer to the remaining publications in this paper. We solicited the opinions of participants in the Canadian Headache Society's 2-day workshop on migraine clinical practice guidelines held in Ottawa in October 1995, both on that occasion and in subsequent discussions. Other publications that appeared outside the search period 1975–1996 and that were highly relevant to the subject matter were included. Our method of rating the validity of published work⁴ in these guidelines is the same as in our previous paper except for the addition of meta-analysis to level III evidence. The following recommendations represent our consensus opinion.

Patient education

Patient education refers to "the information provided by health professionals to headache patients." Patient education is a necessary component of any treatment plan, and it is recommended that it include the following items (level III evidence, class B recommendation):

 The diagnosis of migraine should be given clearly and confidently after the appropriate history-taking and clinical examination and, when necessary, after investigations have been completed. Patients should be reassured that they do not have a serious underlying cause for the headaches, such as a brain tumour.



- Patients should be provided with a basic interpretation of migraine as a physiologic disorder: a genetically based, neurochemical instability of the nervous system triggered by various intrinsic or extrinsic factors, or both. A brief description of what is known of the central and peripheral vascular and humoral mechanisms may aid motivation and an understanding of the treatment plan.
- Wherever possible, printed materials should be used to reinforce the practitioner's orally presented educational advice. Ideally, patients will be interviewed on at least a second occasion so that their learning can be reviewed.
- Practitioners should establish realistic goals and expectations of treatment, explaining the possible treatment options available (including their benefits and limitations) and describing the concept of control as opposed to cure. Patients should be encouraged to regard themselves as active partners in the treatment plan, sharing a responsibility for managing the disorder with their physician.
- Patients may be referred to the Migraine Association of Canada for information and support and may benefit from referral to local self-help groups.

Trigger factors

Migraine attacks or other headaches are often triggered (rather than caused) by one or more of the factors listed in Table 1⁵⁻¹² (level II-2 evidence). (Some of these triggers have also been recorded as relevant in patients with tension-type headaches.⁵) The information about most agents, although repeatedly encountered, is anecdotal; even the effect of dietary factors is uncertain in the absence of published randomized controlled trials. Clinical experience indicates that ingestion of foods containing nitrites, aspartame or monosodium glutamate, and the cumulative effect of eating foods with a high content of neurotransmitter precursors, such as tyramine, tyrosine and phenylalanine, are associated with the precipitation of migraine headaches and that their avoidance leads to a reduction in headache frequency or severity^{7,11,13,14} (level III evidence, class B recommendation). However, this observation has not been subjected to a randomized clinical trial.

Although many of these trigger factors are common to most patients who experience migraine, each person is likely to have a unique inventory of triggers acting singly or together to precipitate a migraine attack. Universal clinical experience suggests that a first step in management should be the identification and avoidance, where relevant, of the factors listed in Table 19 (level III evidence, class B recommendation).

- Discuss the role of trigger factors such as stress as aggravators of an underlying migraine proneness rather than as having a causal role. The use of a headache diary is helpful for most patients.
- Provide information about the factors known to trigger migraine.
- Review patient diaries and help provide strategies for avoiding trigger factors.

Acute nonpharmacologic treatment

Most of the nonpharmacologic measures found to be effective in alleviating an acute migraine headache have been reported anecdotally. The application of cold or pressure to the head has been assessed as valuable^{15–17} (level II-2 evidence, class B recommendation). Reduction of activity and of sensory input in a quiet or dark environment and attempts to sleep are used almost universally by people with migraine, even without medical advice (level III evidence, class B recommendation), and are supplemented by the use of pharmacologic therapies when not adequate in isolation. The addition of "self-management training" to ergotamine therapy in the acute stage may be of value¹⁸ (level II-2 evidence, class B recommendation). No other studies of the additive effects of pharmacologic and nonpharmacologic remedies were found.

Relaxation therapy, hypnosis, transcutaneous electrical stimulation, acupuncture, and occipital or supraorbital nerve blockade have also been used in the acute situation and are considered in the following section.

Table 1: Potential triggers of migraine headache (level III evidence, class A recommendation)

Emotional stress Changes in behaviour

Missing a meal; hypoglycemia Sleeping more or less than usual

Environmental factors

Bright or flickering light Loud noise

Weather changes Strong odours Allergens

Foods and beverages

Chocolate

Cured meats (e.g., hot dogs, bacon) Caffeine-containing beverages Alcoholic beverages, especially

red wine Other, individually recognized

dietary factors Chemicals

Aspartame

Monosodium glutamate (MSG, natural flavour, hydrolysed vegetable protein)

Benzene Insecticides

Nitrites (as in preserved meats)

Drugs Atenolol

Caffeine (and caffeine withdrawal)

Cimetidine Danazol Diclofenac H, receptor blockers

Hydralazine Indomethacin Nifedipine Nitrofurantoin

Nitroglycerin Oral contraceptives (ethinyl

estradiol +) Reserpine

Note: This is not an exhaustive list. The headaches caused are not always characteristic of migraine, and their occurrence varies from person to person and from occasion to occasion



Specific treatments

Biobehavioural measures

Biofeedback

Biofeedback refers to the use of monitoring instruments to detect, amplify and display internal physiologic processes on-line, so that the patient may learn to alter these processes at will. Various types of biofeedback have been used successfully as prophylaxis for migraine.¹⁹ The preferred technique is thermal control, in which the patient learns to elevate finger temperature during therapy sessions using a digital temperature-reading device.²⁰ Blood volume pulse biofeedback is also considered to be effective, whether the subject learns to increase or decrease the pulse amplitude.²¹⁻²³ Analysis of the literature is complicated by the frequency of reports describing combined therapies and the paucity of appropriate placebocontrolled studies. A meta-analysis²⁴ of 25 controlled studies of biofeedback indicated that its efficacy is comparable to that of prophylactic pharmacotherapy^{19,21,25-42} (level II-1 evidence, class A recommendation), and sustained improvement has been demonstrated. 43,44 Although relaxation therapy and biofeedback probably confer equal therapeutic benefit,³⁷ there appears to be no advantage to combining them^{3,45,46} (level II-1 evidence, class B recommendation).

A report denying the value of biofeedback has also been published,³⁶ and it is not possible to predict which patients are most likely to benefit. The effect of combining biofeedback with pharmacologic therapy has seldom been studied. Biofeedback requires a substantial time commitment on the part of the patient, which may limit its use.

The following are recommendations for the use of biofeedback in the management of migraine (level III evidence, class B recommendations).

- Determine the availability and feasibility of biofeedback administered by a trained health care professional as a treatment resource in the community.
- Select patients for biofeedback therapy according to their perceived motivation and financial resources.
- Consider biofeedback as an adjunct to pharmacologic therapy or as an alternative for patients intolerant of medications.
- Encourage the maintenance of biofeedback skills in responsive patients.

Relaxation therapy

A biobehavioural approach to migraine comprising relaxation techniques (including progressive muscular relaxation, breathing exercises or directed imagery) may^{24,25,27,43,47-51} (level III evidence) or may not^{33,52} reduce the frequency of episodes. Meta-analysis suggests that relaxation is as effective as biofeedback^{53,54} (level III evidence, class B recommendation). Where a treatment effect has been reported, it may be enhanced by the addition of prophylactic agents such as β-blocking drugs⁵⁵ (level II-1 evidence, class B recommendation). The usual goal of relaxation therapy is the development of long-term prophylaxis rather than the reduction of pain during an acute attack. However, a few patients can abort a slowly evolving migraine using these techniques. Relaxation may be taught one-on-one or in a group setting by an appropriately trained physician, psychologist or other therapist. As with biofeedback, availability, patient acceptance and the time commitment involved may limit its use. Selfinstruction, with the use of audiotapes, may be possible in strongly motivated patients.

The following are recommendations for the use of relaxation therapy (level III evidence, class B recommendations).

- Determine the availability of relaxation therapy locally.
- Select only motivated patients for such training.
- Instruct the patient that relaxation therapy is intended to provide long-term prevention of headaches rather than short-term pain relief.
- Consider the use of individual, group and self-directed sessions for relaxation training.
- Consider combining relaxation training with other types of therapy.

Cognitive-behavioural therapy

Cognitive-behavioural therapy (CBT) is designed to help patients identify and modify maladaptive responses that may trigger or aggravate a migraine headache. The role of emotional reactivity as a trigger for migraine is considered to be pertinent in many patients, who may indulge in self-blame, hopelessness and catastrophic thinking. 10 CBT is based on the principle that anxiety and distress are aggravators of an evolving migraine headache; it attempts to introduce a more adaptive approach as well as to help develop a specific action plan. Stress-management training is often part of this approach. CBT is usually combined with other behavioural therapies but has been shown to be effective on its own^{56,57} (level II-2 evidence, class B recommendation). Individual therapist, group and self-help programs have been used, with variable effects^{30,50,56-61} (level III evidence, class C recommendation). However, as with other behavioural therapies, such factors as availability, cost, patient acceptance and the time commitment required may restrict their use. These techniques are usually combined with biofeedback, although



uncontrolled studies have shown their efficacy in reducing the intensity, duration and frequency of headaches when used alone^{46,51} (level III evidence), sometimes despite minimal contact with a therapist⁵⁷ (level II-2 evidence).

The following recommendations (class B) apply to the use of CBT for migraine.

- Identify maladaptive thinking that may negatively affect the patient's migraine state.
- Help the patient develop an action plan for migraine attacks.
- Use individual, group and self-help methods to encourage more adaptive thinking.
- Encourage the maintenance of CBT techniques.
- Combine CBT with other migraine treatments.
- Identify patients suitable for more specialized CBT.

Psychotherapy

Psychotherapy has been claimed in a single trial to enhance the value of biofeedback.⁶² It is suggested that psychiatric referral of patients with migraine is indicated solely for the presence of a coexistent psychiatric disorder (level III evidence, class C recommendation). However, referral to a psychologist to improve stress management may be appropriate in selected cases. The use of psychosocial interventions⁶³ appears to be of modest value (level III evidence, class B recommendation).

 Psychiatric referral of patients with migraine is not indicated except in the presence of a coexistent psychiatric disorder (class D recommendation).

Hypnosis

Hypnosis may reduce distressing sensory input as it does in other pain disorders and may have a placebo effect. It was more effective than prochlorperazine in one randomized controlled trial,⁶⁴ and a meta-analysis of largely uncontrolled studies also suggested benefit when hypnosis was combined with CBT⁶⁵ (level II-2 evidence, class B recommendation).

 Hypnosis may have a limited role in the management of migraine in a small subgroup of patients who are both willing and suitable subjects (class B recommendation).

Physical measures

Complementary or alternative therapies may be described as interventions that lack either a valid scientific basis or adequate documentation of their effectiveness in the treatment of specific conditions. Chiropractic, osteopathy and acupuncture have been used in the management of migraine.

Physiotherapy, osteopathy and chiropractic

Physiotherapy, osteopathy, chiropractic and other physical therapies have rarely been subjected to trial, and evidence for the superiority of any one form of cervical manipulation is lacking. 66,67 The rationale for such therapies is found in the presumption that cervical dysfunction is relevant in the genesis of migraine, although we identified no level I or II evidence to support this contention. In 2 randomized studies, one with added follow-up, chiropractic manipulations reduced migraine frequency and severity 68,69 (level I evidence, class B recommendation). Aerobic training may reduce the number but not the severity of migraine headaches 70,71 (level III evidence, class C recommendation).

• The value and cost-effectiveness of physiotherapy, osteopathy and chiropractic in the management of migraine have not yet been determined. It is therefore inappropriate for a physician to refer patients for such treatments, but patients who are strongly motivated to seek such help need not be dissuaded as long as they are made aware of the uncertain benefits so far recorded (class C recommendation).

Transcutaneous electrical stimulation and acupuncture

Transcutaneous electrical stimulation⁷² (level II-2 evidence) and acupuncture^{73–76} (level I evidence, class B recommendation) have been claimed in small series to provide some relief from migraine.

 Patients who enquire about transcutaneous electrical stimulation and acupuncture should be made aware of the lack of firm evidence as to the benefits and costeffectiveness of these treatments in the management of migraine (class C recommendation).

Other measures

Occipital or supraorbital nerve blockade with local anesthetics, sometimes augmented by steroids, has been reported in uncontrolled studies to be effective in the relief of migraine.^{77,78} Patients with posttraumatic headache may respond better than other patients^{79,80} (level III evidence, class C recommendation).

A single trial of orally administered magnesium (as magnesium dicitrate, 600 mg/d) indicated that it provided useful prophylaxis⁸¹ (level I evidence, class B recommendation). In an open pilot study followed by a small randomized placebo-controlled trial, riboflavin (400 mg/d) was found to be effective for migraine prophylaxis^{82,83} (level I evidence, class B recommendation). Riboflavin has an excellent tolerability profile (with no risk of drug interactions) and, although the evidence is preliminary, is a



promising option for migraine prophylaxis. Comparative trials with established prophylactic agents are warranted. We found no adequate evidence that nutritional therapy confers benefit.

Two small randomized controlled trials have shown the efficacy of the herb feverfew in migraine prophylaxis. Since feverfew appears to have a relatively benign side effect profile (occasional mouth ulceration and contact dermatitis), it may be considered as an option for migraine prophylaxis. However, there are no studies documenting its long-term safety or efficacy. Comparative trials with other established prophylactic agents are warranted (class B recommendation).

Other treatments, including naturopathy and homeopathy, have not been subjected to sufficient critical study to allow appropriate evaluation. Nevertheless, it seems reasonable to accept the use of such approaches by patients who are enthusiastic about them or as adjunctive treatment for those in whom conventional therapy has proven inadequate (class C recommendation).

No high-level evidence was found to support claims of the utility of alternative therapies. Many are considered to be based on dubious or quasiscientific theories of migraine causation. Such "natural" therapies are, however, widely accepted by the Canadian population, although their efficacy and safety have seldom been subjected to critical study. In the absence of controlled trials, most are assumed to be safe, but it would be reasonable for their promoters to provide warnings about their potential hazards, as is the case with "ethical" pharmaceuticals (class C recommendation).

- Occipital or supraorbital nerve blockade may be tried in the acute stage in subjects with initial pain localization to the occipital or frontal region respectively, but it is not a convenient form of therapy if required repeatedly (class B recommendation).
- There may be value in oral magnesium therapy for prophylaxis, but this has not been studied adequately. Evidence for the use of riboflavin is more convincing. There is no evidence that these agents are unsafe in reported dosages (class C recommendation).
- A trial of feverfew may be appropriate in prophylaxis (class B recommendation), but there is a lack of evidence regarding the usefulness of other herbal therapies.
- Patients who enquire about naturopathy and homeopathy should be made aware of the lack of firm evidence as to the benefits and cost-effectiveness of these therapies in the management of migraine (class C recommendation).

Summary

The assessment of nonpharmacologic therapies in the

management of migraine must be somewhat subjective because most studies have not used the strict methods that are required today in clinical trials of pharmacologic agents. As a result, the number of recommendations based on level I evidence that can be made is small. It is notable that "the impact of non-pharmacological treatment of headaches . . . has been almost invariably assessed via patients' self-monitoring of headache activity" and that many of the measures (e.g., the "Headache Index" and Clinician Improvement Ratings⁶¹) are considered unreliable by virtue of their tendency to overestimate improvement (level III evidence). We found no adequate studies of the cost-effectiveness of the treatments examined.

Most of the therapies examined have at least the capacity to induce a placebo response and appear harmless, with the exception of allergic reactions to injected local anesthetics (rare), infection from acupuncture needles and harm done by chiropractic manipulations (also rare). We therefore consider it unjustifiable to assign class D or E recommendations to more than a few of them.

In many of the studies, various therapeutic strategies were combined in the treatment of patients, some of whom had different kinds of headache, and few reflected any theoretic premise as to the pathophysiology of migraine. In some studies, benefits of the therapy in question were not demonstrable, presumably because the "control" group was treated in a manner that was therapeutic or because the therapy is actually not beneficial. A reduction in headache frequency or severity of about 30% to 45% seems to have been achieved with most of the treatments, with minimal, if any, additional benefit from the combination of any 2 or more of them. The size and nature of the placebo effect thus remains an important question that must be resolved before confident recommendations can be made on the use of most nonpharmacologic therapies in the management of migraine.

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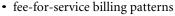
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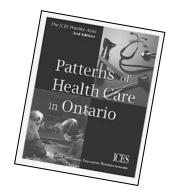
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