ORIGINALARTICLE

Effectiveness of a Multidisciplinary Treatment Program for Chronic Daily Headache

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ABSTRACT: ***Background:*** Chronic daily headache (CDH: headache on fifteen days a month or more) is one of the most common forms of chronic pain. The relative efficacy of different treatment methods for these patients needs to be determined. ***Objective:*** To compare treatment outcomes for patients with CDH treated in a traditional office-based pharmacological treatment program with a second group treated in a multidisciplinary management program. ***Methods:*** Patient outcomes were measured using changes in the Headache Disability Inventory (HDI) and the Short-Form-36 (SF-36) over the treatment period. Outcomes from seventy patients treated in an office setting were compared to thirty-seven patients treated in a multidisciplinary headache treatment program. Both groups received similar pharmacological treatment. All patients treated in the office setting and the majority of patients in the multidisciplinary program had transformed migraine. ***Results:*** Even though a reduction in headache days per month occurred, mean headache related disability (measured by HDI) and mean Health Related Quality of Life (HRQoL measured by SF-36) did not improve for the patient group treated in the office setting but did improve significantly for the patient group treated in the multidisciplinary headache program. ***Conclusion:*** For patients with CDH, headache-related disability and HRQoL is more likely to improve with management in a multidisciplinary headache treatment program as compared to the traditional specialist consultation – family physician office-based setting.

RÉSUMÉ: Efficacité d'un programme de traitement multidisciplinaire pour la céphalée quotidienne chronique. ***Introduction:*** La céphalée quotidienne chronique (CQC), soit la présence de céphalée 15 jours ou plus par mois, est l'une des formes les plus fréquentes de douleur chronique. L'efficacité relative de différentes méthodes de traitement chez ces patients demeure indéterminée. Objectifs: Comparer les résultats du traitement de patients souffrant de CQC qui ont bénéficié d'un programme de traitement pharmacologique chez leur médecin et ceux de patients traités dans un programme multidisciplinaire. ***Méthodes:*** Les résultats chez les patients ont été mesurés par le changement du score du Headache Disability Inventory (HDI) et du Short-Form-36 (SF-36) pendant le traitement. Les résultats de soixante-dix patients traités en cabinet ont été comparés à ceux de trente-sept patients traités dans un programme multidisciplinaire de traitement de la céphalée. Les deux groupes ont reçu un traitement pharmacologique similaire. Tous les patients traités en cabinet et la majorité des patients dans le programme multidisciplinaire avaient des céphalées d'origine médicamenteuse. ***Résultats:*** Bien qu'il y ait eu une diminution du nombre de jours de céphalée par mois, l'invalidité moyenne reliée à la céphalée (mesurée par HDI) et le score du Health Related Quality of Life (HRQoLmesuré par le SF-36) ne s'est pas amélioré dans le groupe de patients traités en cabinet. Une amélioration significative a été observée dans le groupe traité dans le cadre d'un programme multidisciplinaire de traitement de la céphalée. ***Conclusion:*** Pour les patients souffrant de CQC et présentant une invalidité en relation avec la céphalée, la qualité de vie reliée à la santé est plus susceptible de s'améliorer avec la prise en charge dans un programme de traitement multidisciplinaire de la céphalée que dans le contexte de la consultation traditionnelle, que ce soit au cabinet du médecin spécialiste ou du médecin de famille.

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Headache is one of the most common forms of chronic pain. Approximately 15% of adult Canadians have migraine,[1] although their attack frequency varies widely. Between four and five percent of adults in Spain and the United States have daily or near daily headache.[2,3] In France, three percent of the population has headache every day.[4]

The majority of individuals with daily or near daily headache can be classified as suffering from either chronic tension type headache or transformed migraine (TM).[2,3] Patients with TM[5] are basically patients with migraine who have developed very frequent, often daily, headaches. Although overuse of symptomatic medications can lead to this syndrome,[6] in many patients the cause of this migraine progression is unknown. Patients with TM account for over 30% of patients referred to headache speciality clinics in North America.[7]

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Migraine and the chronic daily headache syndromes can lead to significant disability and reduction in health related quality of life (HRQoL).[8,9] Because of their frequency in the general population, these headache syndromes are a major health problem in Canada as in other countries, and a therapeutic challenge.

It has been our impression for some time that for many patients with TM the usual outpatient pharmacological regimens in common use in Canada are of limited benefit. On the other hand, multidisciplinary headache programs which combine both pharmacological and nonpharmacological treatments have the potential to be more effective.[10,11]

To investigate the outcomes of a primarily pharmacological outpatient treatment program, we followed with a variety of outcome measures, 70 patients with TM over a period of approximately one year (patient Group I in this study). To complement this study, when a new multidisciplinary chronic pain centre with a headache program was established in Calgary, we used the same outcome measures on an early patient cohort who completed this program (Group II in this study). We compare here the outcomes of these two treatment programs.

METHODS

Two groups of patients with headache were studied. Group I consisted of 75 consecutive patients who were referred for the first time to the Headache Clinic at the Foothills Medical Centre (FMC) between December 1997 and January 1999.

Group II consisted of 52 consecutive patients who were referred to, assessed and accepted by the headache program at a multidisciplinary pain program at the Calgary Chronic Pain Centre (CCPC). Patient intake for this group began when the CCPC opened in July 2000. All patients discharged from the program by December 1, 2002 were included.

Ethics approval for data collection for both programs was obtained from the Conjoint Health Research Ethics Board of the University of Calgary.

The physician component for treatment of both groups was provided by the same neurological physician team, although some changes in physician personnel occurred between the times of treatment of Group I and Group II.

As was the case for Group I, all nondrug costs for Group II were covered by Alberta Health. There were no additional direct costs to the patients for attending the CCPC. The CCPC was a special joint project of Alberta Health, the Alberta Medical Association and the Calgary Health Region.

Group I (Pharmacological Group)

Subjects

For this prospective study, patients were drawn from new consecutive referrals to a subspecialty Headache Clinic at FMC in Calgary. Eligibility criteria included a diagnosis of TM (without or without medication use)[5] made at the time of their first clinic visit and patient willingness to sign informed consent.

Patients who met entry criteria and signed informed consent were administered a study questionnaire by one of us (CMR), either in person at their first clinic visit or over the phone within a few days. The study questionnaire included the Headache Disability Inventory (HDI)[12] and the Short Form-36 (SF-36).[13] Patient headache diaries were also available for analysis, as these were routinely sent to patients for completion several months prior to their first clinic visit.

Treatment program

Patients were treated in the clinic's usual treatment program, which was primarily a physician-based pharmacological program in which the patients were followed both by the neurologist consultant in the clinic and by their family physician. After their initial clinic visit, patients were routinely brought back for follow-up every three to five months. During the approximately one year duration of their participation in this study, patients received from the clinic an average of 2.5 clinic visits (range 1-6), 2.4 new symptomatic medication prescriptions (range 0-8), and 2.0 prophylactic medication prescriptions (range 0-5). During clinic visits, patients also received a variety of written information appropriate to their situation with regard to headache and its treatment, and received counselling and education from a nurse experienced in headache management. Patients were able to telephone the clinic nurse for advice, and made an average of two calls (0-12). Patient visits to their family physician during the study, and the use of alternative medicine therapies was not monitored.

Outcome evaluation

The study was designed for CMR, a master student, to administer the outcomes questionnaire at approximately one year after clinic entry, or at the time of patient discharge from the clinic, whichever occurred sooner. Patients might be discharged earlier from the clinic for a variety of reasons, including substantial improvement. Where possible, study exit was arranged to coincide with a clinic follow-up visit and, as a result, some patients remained in the study for longer than a year. Patients were also asked to complete our standard headache diaries for several months prior to exit from the study. The outcomes questionnaire, which included the HDI and the SF-36 was administered an average of 11.6 months (range 5-17 months) after study entry. Results from these disability and HRQoL measures were compared to the same measures completed by the patient at baseline.

On the headache diaries, patients provided their headache intensity rated on a scale of 0-10 for each of three daily time segments (morning, afternoon and evening/night). For patients who provided both baseline and study exit headache diaries, the number of headache days per month was calculated for a 28-day month, by counting the number of time segments as defined above with headache, and dividing by three. Headache "days" were, therefore, not calendar days with headache but included only time periods with headache. Mean monthly headache intensity likewise reflected only time with headache, in that intensity scores for all time segments with headache during the month were summed and divided by the number of segments with headache. Time segments with zero pain were therefore not included in the mean monthly headache intensity calculation.

Group II (Multi-Disciplinary Group)

Subjects

All patients discharged from the CCPC Headache Program during the time specified above were included. Inclusion criteria for Group II therefore were the admission criteria for the CCPC Headache Program. These included headache on fifteen days a

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month or more, absence of any ongoing headache-related litigation or a headache-related Worker's Compensation Board claim, and absence of any disabling medical or psychiatric condition which would make it difficult for the patient to take part in a multidisciplinary program. Patients must have had chronic daily headache for at least six months, in order to ensure that other community resources had been insufficient to meet the patient's needs.

Patients were referred to the program by their family physician or by specialists. A nurse coordinator screened all referrals to ensure that they met program entry criteria. Prior to assessment for the Headache Program, all patients completed the HDI and the SF-36 as part of the program's pre-assessment questionnaires. Patients also evaluated various aspects of their headache on a 0-10 scale, including average headache pain and maximum intensity and minimum intensity of headache pain in the past week. Prior to admission to the CCPC Headache Program, patients were assessed by a neurologist, psychologist, occupational therapist and physiotherapist. A management meeting was then held, the treatment plan discussed with the patient, and the patient admitted to the program if it was felt the program would benefit the patient and the patient committed to taking part.

Treatment program

Patients were assessed and followed by a neurologist, who was responsible for making a diagnosis, optimisation of pharmacological therapy, and for medical follow-up of patients during their treatment. As in Group I, all patients in Group II received symptomatic medications for headache, and the great majority in both groups received prophylactic medications as well. The nursing coordinator was available for advice in person during clinic visits and by telephone at other times, and provided patients with written information as required. Some one-on-one psychological therapy was available to patients, but this was minimal, with the great majority of the nonpharmacological therapy provided in group sessions. Patients also received physiotherapy as considered appropriate by the program physiotherapist and physician, and instruction in posture and exercise by a kinesiologist. Dietary counselling was also available. Several lectures on pain-related topics were available to the patients and their families.

The nonpharmacological backbone of the CCPC Headache Program was participation in the patient groups. These are summarised below. While virtually all patients took part in the Self Management group, participation in the other groups was more varied. For example, many patients enhanced some of the skills they learned in the Self Management group further by taking part in the Relaxation group, but only a few patients took part in the Rebuilding Self and Relationships group. After completion of the Self Management group, patients attended other groups as recommended by CCPC staff based upon patient clinical features, and as allowed by patient interest and the time patients had available. The groups generally consisted of 6-14 individuals, and were led by an appropriately qualified psychologist, occupational therapist or nurse. Many of the groups had two leaders. All group leaders had experience working with patient groups, either before the centre opened, or obtained this experience at the CCPC working as a team with more experienced group leaders. All group leaders had prior experience in the treatment of chronic pain, although not necessarily with headache. The patient groups all contained a mixture of patients from our three pain programs: headache, musculoskeletal pain and pelvic pain. The Exercise group was led by a kinesiologist, with input from our physiotherapists.

The following is a brief summary of the groups available to patients:

1. *Self Management Group.* This group promoted the development of adaptive pain-coping strategies so that patients could achieve their goals, improve daily functioning, and increase self-reliance in the management of their pain. Topics included self-monitoring, relaxation, distraction, pacing, cognitive restructuring, and communication. This group was a requirement for all patients admitted to the CCPC Headache Program.
2. *OT Tips.* This group consisted of an individual session with an occupational therapist to develop practical coping strategies to help the patient deal with the impact of pain on their every day activities. Sessions covered topics such as how modifying one's approach to activity can prevent pain from increasing, and included activity analysis, pacing, energy conservation, and work simplification discussions.
3. *Sleep Group.* This group promoted the development of sound sleep habits so patients could improve the depth and continuity of their sleep. This was achieved through review of attitudes and beliefs about sleep, stimulus control, relaxation, worry control, and development of a sleep hygiene plan. Topics covered included sleep monitoring, sleep habits, sleep hygiene, stimulus control procedures, medication and cognitive strategies.
4. *Relaxation Group.* In this group, clients were introduced to various forms of relaxation including deep breathing, body scan, progressive muscle relaxation, visualisation, pain transformation, autogenics and meditation.
5. *Exercise Group.* The goals of the exercise program were to improve aerobic endurance, improve core stabilisation, increase flexibility and increase muscular strength and endurance.
6. *Rebuilding Self and Relationships.* This group was designed for people who wanted to explore in depth how chronic pain had affected their lives and their relationships. The purpose of this group was to help the patients develop to their fullest potential despite chronic pain. Possible themes that could be explored in the group included loneliness, isolation, shame, anger, loss, self-worth, sexuality, body image, intimacy, communication, family of origin and healthy relationships.
7. *Family Workshop.* The family workshop was designed for the individual with chronic pain and an important person in his or her life. This workshop allowed patients to discuss the effects of pain in relationships, coping with pain in relationships, and the influence of cultural ideas on pain.
8. *Nutrition Group Assessment and Counselling.* Patients referred to the nutrition program were screened by the dietician and provided either with one-on-one counselling or put into a nutrition group. Self-assessment, goal setting and healthy eating skills pertaining to the group's specific nutrition concerns were discussed.
9. *Maintenance Group.* The maintenance group was for patients

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who wanted to continue to develop and problem solve the application of Self Management strategies within a supportive group environment.

For the 37 patients in our data analysis, group attendance was as follows: Self Management group 34, Relaxation group 22, Sleep group 14, Maintenance group 10, Family Workshop 4, and Rebuilding Self group 3. Data were not readily available for OT Tips, Exercise group and Nutrition group as those groups evolved in form over the data collection period.

Outcome evaluation

The HDI, the SF-36 and the pain intensity measures described above were completed by the patients again at exit from the CCPC Headache Program. Exit from the program occurred an average of eleven months after initiation of treatment (range 2-22 months). Results from these assessments were compared to the patient's baseline data.

Data Analysis

The main outcome measures used for both Group I and Group II were the HDI and the SF-36.

HDI. The HDI[12] is a 40-item self-assessment questionnaire, which is designed to measure the functional and emotional impact of headache on the patient. It measures self-perceived disability related to headache by asking patients to respond to questions such as "my headache makes me feel frustrated" or "I do not enjoy social gatherings because of my headaches" on a three-point scale: yes, sometimes, and no.

SF-36. The SF-36 Health Survey[13] uses eight scales to measure three aspects of physical and mental health: functional status, well-being, and perception of health. The questionnaire asks patients to self-rate 36 items, which measure eight health concepts. These concepts include: physical functioning, role functioning (physical), role functioning (emotional), social functioning, mental health, general health perceptions, vitality, and bodily pain.

Statistical Methods

The t-test was used for all statistical comparisons, with the paired sample t-test used where appropriate.

RESULTS

Group I

Seventy-five patients from the FMC-based Headache Clinic (pharmacological group) were entered into the study, but five patients did not complete exit questionnaires. For the 70 patients completing the study, mean age was 41, 84% were female, and 34% were college/university graduates. All patients had a diagnosis of TM and 43 of the 70 patients were medication over-users at study entry. Seventeen of the 43 patients (40%) were able to stop their medication overuse during the study.

Only 48 patients provided both baseline and exit headache diaries. For this group, headache days per month were reduced from a mean of 23.4 at baseline to 19.2 at study exit ($p<0.0001$). It should be noted that headache days were not calendar days (see Methods). Seventeen of the 48 patients had an improvement in headache days per month of 25% or more, and only two patients worsened by 25% or more.

For the patient group with diaries, mean headache intensity did not change. Mean headache intensity for this group was 4.6/10 at baseline and 4.5/10 at study exit. Mean monthly headache intensity did decrease by 25% or more in eleven patients, but increased by the same amount in nine patients.

The mean total HDI score for the group of 70 patients who completed this measure at both study entry and exit was 53.4 at study entry (Figure 1A). This figure remained essentially unchanged at study exit at 51.5 ($p=0.46$). Sixteen out of the 70 patients did show 25% or greater reduction in their HDI score but twenty patients showed a worsening of their HDI scores by a similar amount.

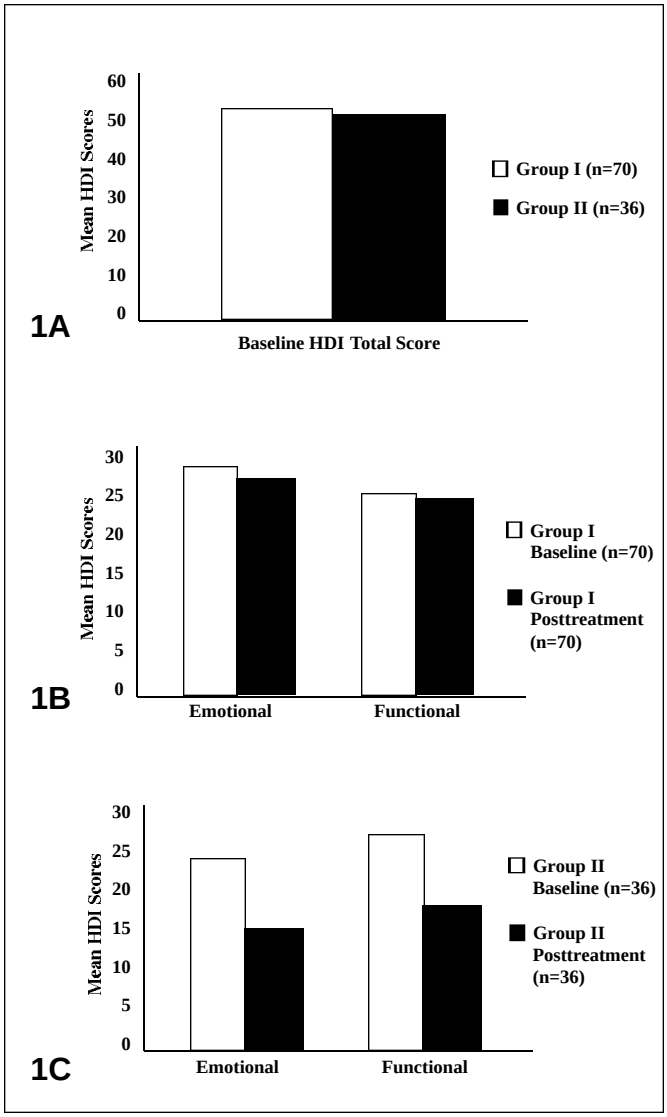

Figure 1: Mean HDI scores (total scores) are shown for Group I (pharmacological office-based program) and for Group II (multidisciplinary program) at baseline (before treatment) (1A). Baseline HDI scores were very similar in the two patient groups. In 1B, baseline and post-treatment HDI scores are shown for Group I. Scores for both the emotional and functional subscale of the HDI are shown. Neither changed significantly with treatment. Figure 1C shows the same measurements for Group II. For Group II, post-treatment scores were both improved from baseline ($p < 0.001$).

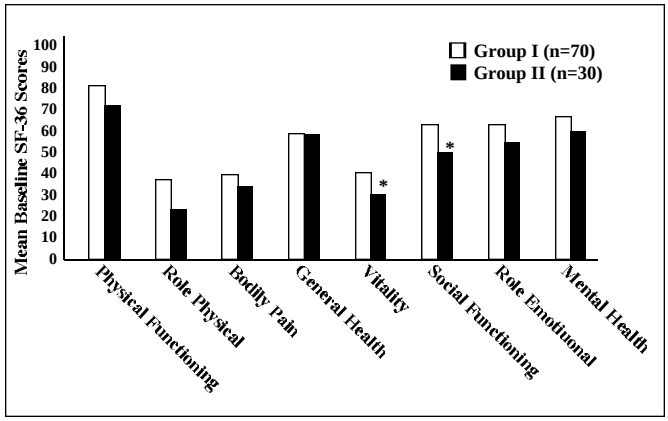

Figure 2: *Mean baseline scores for the eight SF-36 subscales for both patient groups.Scores for the Group II (multidisciplinary program) were generally lower than scores for Group I (pharmacological office-based program), indicating poorer health-related quality of life. Differences were statistically significant for only two subscales: vitality and social functioning.*
** $p < 0.05$*

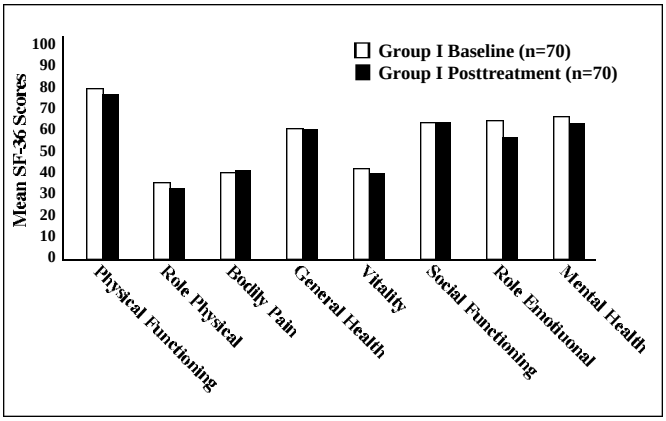

Figure 3: *Mean baseline and post-treatment scores are shown for all subscales of the SF-36 for Group I.None of the changes were significant at the $p < 0.05$ level.*

Our patients showed marked impairment of HRQoL with mean scores for this patient group, well below Canadian norms for all subscales of the SF-36. Baseline SF-36 scores are shown in Figure 2. At exit, mean scores for our patient group on the various subscales of the SF-36 had not improved and, in fact, showed a small trend for worsening on most subscales (Figure 3).

Group II

Fifty-two patients were discharged from the CCPC Headache Program during the study period. Four patients withdrew from the program immediately after assessment, and therefore did not participate in any patient groups. One patient participated in a few group sessions, but then moved away, and provided no follow-up or outcome data. These five patients were therefore not entered into our analyses. Ten patients either completed the program or took part in a significant number of groups but an admission or discharge HDI or SF-36 was not available for analysis. The clinical outcomes of these patients were assessed by chart review to ensure that this group would not bias our data sample. Based upon the patients' self-assessment at discharge and the assessment of CCPC staff, seven of the ten patients were felt to have at least a 50% reduction in their overall headache problem at discharge (five were felt to have excellent results: >80% improvement). We feel, therefore, that the outcomes in this patient group were at least as good as in the patients who completed our outcome measures (HDI, SF-36). Our data analysis, therefore, is unlikely to have been biased by poor responders tending not to complete our outcome measures. These patients were not analysed further.

The remaining 37 patients form the basis of our data analysis. Of these, 36 patients provided a complete baseline and discharge HDI, and 30 provided a complete baseline and discharge SF-36.

For these 37 patients, the mean age was 42 (range 18-60). Seventy-six percent (76%) were female, and 32% were college/university graduates.

Fifty-four percent (54%) had a diagnosis of TM,[5] with nine out of twenty patients showing overuse of symptomatic medications. Eight of the nine patients with TM and medication overuse (89%) were documented as no longer showing overuse at discharge. Other diagnoses (only the main headache diagnosis for each patient is considered here) were chronic tension-type headache[14] (14%), headache associated with cervical spine disorders[14] (14%), new daily persistent headache[5] (8%), and chronic post-traumatic headache[14] (8%). One additional patient had migraine without aura with 12 headache days a month at the time of assessment, although headache had been present at greater frequencies in the past.

The mean baseline total HDI score for Group II was 51.5 (Figure 1A). At study exit, the mean total HDI score had improved to 34.0, a highly significant change ($p<0.001$). Eighteen out of 36 patients showed a 25% or greater reduction in HDI scores. A much smaller number, two out of 36 patients showed a worsening of their HDI scores by a similar amount.

For Group II, HRQoLas measured by mean scores on the SF-36 subscales showed a marked improvement between study entry and study exit for the 30 patients who provided both baseline and exit data (Figure 4). All eight subscales of the SF-36 showed statistically significant improvement ($p\leq0.05$). The greatest improvements were seen in the role physical, bodily pain, vitality, and social functioning subscales ($p<0.01$).

Patients in the CCPC Headache Program also completed a pain rating scale on a 0-10 point scale for current pain level and lowest, highest, and average pain levels over the past week at study entry and exit. As can be seen from Figure 5, mean pain ratings for the patient group showed a downward trend for all four measures.

Comparisons for Group I and II

As can be seen from Figure 1A, mean total baseline HDI scores were virtually identical for Groups I and II. Figure 1B shows that for Group I, virtually no change occurred in HDI scores, both for the emotional and functional subscales, over the time period of the study. For Group II, the multidisciplinary

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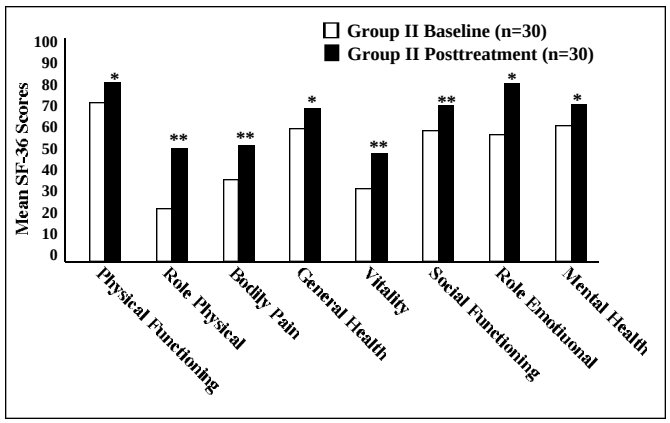

Figure 4: *Mean baseline and post-treatment scores are shown for all subscales of the SF-36 for Group II.Higher scores on the SF-36 indicate improved HRQoL. Scores on all subscales showed significant improvement ($p < 0.05$).*
* $p < 0.05$
** $p < 0.01$

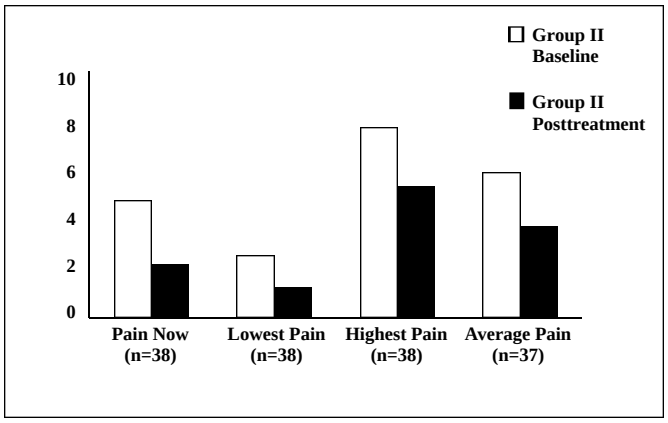

Figure 5: *Mean pain scores are shown for Group II as rated by patients for the past week. Baseline scores and post-treatment scores are compared. Maximum possible score indicating the most severe pain possible was ten (scale 0-10).*

patient group, substantial improvement occurred, with major reductions in HDI scores on both subscales (Figure 1C). Mean HRQoL as measured by the SF-36 was similar in the two patient groups at study entry, although there was a trend on most subscales for somewhat lower scores (worse HRQoL) for the multidisciplinary patient group (Group II) (Figure 2). These differences reached statistical significance at the $p<0.05$ level for only two subscales (vitality and social functioning). For all other subscale comparisons, the differences at baseline between the two groups were not statistically significant with $p>0.1$.

While for Group I there was no change in mean scores on any subscale of the SF-36 during the time of the study, ($p>0.05$ for all) (Figure 3), there was substantial improvement in the HRQoL for Group II. Mean scores for Group II patients improved during the time of the study on all subscales of the SF-36 ($p\leq0.05$) (Figure 4).

Because Group I consisted entirely of patients with TM, whereas Group II patients had chronic daily headache resulting from a variety of diagnoses, a subanalysis was done for the twenty patients in Group II with a diagnosis of TM. This analysis showed that the patients with TM in Group II had very similar outcomes as Group II as a whole, and that the patients with TM in Group II had better outcomes than those in Group I.

Despite the smaller numbers (n=20), the TM patients in Group II showed statistically significant improvement ($p < 0.05$) on both the emotional and functional subscale of the HDI, and on four subscales of the SF-36 (role physical, bodily pain, vitality and social functioning). The remaining four subscales of the SF-36 all showed improved scores from baseline to discharge, but these were not statistically significant.

Discussion

In our two headache patient groups, only the group which participated in the multidisciplinary pain program (Group II) experienced improvement in terms of headache-related disability as measured by mean patient scores on the HDI and in HRQoL as measured by the SF-36. Our finding that these two measures did not change for Group I, which received primarily pharmacological therapy in an office setting, suggests that for patients with TM and headache on 15 days a month or more, who are severe enough to be referred to a specialty headache clinic in Canada, drug therapy alone is not enough to make a major difference for many patients. Although this patient group did experience a small but significant reduction in headache days per month, it is important to note, however, that mean headache intensity during times of headache did not change. This is in keeping with data that for patients with migraine who have relatively frequent headaches, headache intensity may be the major determinant of disability.[15] It is of interest to note that, although assessed by a different measure, we found evidence that mean headache intensity decreased for Group II, the multidisciplinary group. On comparison of patient pain ratings for the previous week at study entry and exit, mean scores for all four ratings provided by the patients decreased by 30% or more (Figure 5), indicating a clinically significant change.[16,17] Therefore, a multidisciplinary pain program, which included pharmacological therapy, seemed able to reduce perceived headache intensity. Whether this occurred because headache pain actually reduced in severity or because it was perceived as less severe because of better patient pain coping skills is impossible to determine from our data.

It seems clear that for many patients with difficult headache problems, it is important that headache management programs be available that go beyond simple physician office visits, pharmacological therapy, and the provision of information about headache and its management. If we are to have a chance to improve the HRQoL of these patients, and to reduce the degree of headache-related disability present, more treatment options are needed. Our data indicates that patient groups led by nonphysician health professionals, which are focused on providing patients with the skills to cope with and manage their headaches can make a difference when added to pharmacological management.

While providing interesting data regarding the benefit of a

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multidimensional approach to treating headaches, our study does have limitations. Firstly, it is not a randomised trial, but is rather best described as an unblinded outcome cohort study for a multidisciplinary pain program with historical controls. Headache diagnoses differed somewhat between the two patient groups, although the majority of patients in both groups met diagnostic criteria for TM.[5] It is unlikely that the prognosis in general for those patients with nonmigraine diagnoses in Group II was any better overall than for patients with TM, and in fact it likely was worse for some (i.e. chronic post-traumatic headache). In support of this, an analysis of the TM patients in Group II showed very similar improvement in this subgroup as compared to Group II as a whole (see Results section). Patient "drop-outs" in Group II are also a concern, as not all patients provided baseline or outcome data. Our study, therefore, is not an "intent-to-treat" analysis. Review of the charts of the patients without outcome HDI and SF-36 data indicated that clinical outcomes seemed at least as good in this group of ten patients as it was for the 37 patients in the study. This may have been the case because some of the missing data resulted from imperfect data collection procedures in the early phases of the Pain Centre, rather than patient noncompliance.

Finally, although headache-related disability as measured by the HDI was very similar in both patient groups at baseline, there was a trend for patients in Group II to have more impairment of HRQoL as measured by the SF-36. The difference between the two groups at baseline was small, and not statistically significant for the majority of the SF-36 subscales. It is unlikely then that this small difference had a major influence upon our results. It does indicate, however, that the patients in Group II were at least as severely affected by their headache disorders as the patients in Group I making comparisons of these groups appropriate. It remains possible that other significant baseline characteristics, e.g. motivation to participate in therapy, were different between the two groups at baseline. It must also be pointed out that we do not have long term follow-up data for either group to ensure that the therapeutic gains or lack thereof were maintained over the long term.

Strengths of our study include the uniform use of two validated outcome measures, the HDI and the SF-36, for both patient groups. It was also a strength that essentially the same neurologist team provided treatment supervision and pharmacological therapy for both groups. Despite some staff turnover, the same philosophy of pharmacological management was used. Additionally, both patient groups were followed for a very similar length of time, a mean of 11.6 months for Group I, and 11 months for Group II.

As a result of some of the shortcomings listed above, our study cannot be regarded as definitive. It does, however, provide evidence that there is a serious need for Canadian Healthcare to rethink how patients with chronic daily headache are managed in most Canadian centres.

The poor treatment outcome in Group I, which received only pharmacological therapy, was disappointing but perhaps not surprising. The patients referred to the FMC Headache Clinic had generally exhausted the treatment options provided by their family physicians and often those of other specialists. Although many well-done clinical trials have shown a number of prophylactic drugs to be helpful to many migraine patients, such trials[18] typically exclude patients who have failed more than two previous prophylactic drug trials, or who have headache on more than 15 days a month. As a result, findings from such treatment trials cannot be extrapolated to the patients reported here.

It is likewise perhaps not surprising that a more complex and intensive headache treatment program such as our multidisciplinary treatment program would produce better patient outcomes than a simpler program. There is a significant body of evidence that indicates use of many of the non-pharmacological interventions used in our multidisciplinary pain program are beneficial for patients with migraine and chronic tension-type headache. The focus of our Self Management group, for example, was to empower patients to take control of their headache problem. It has been shown that individuals who perceive an internal locus of control pertaining to their headaches use less medication and report less affective distress than individuals who perceive their headaches as relating to an external locus of control and who have comparable levels of headache activity.[19,20] Similarly, patients who feel they are capable of taking action to influence their headaches have lower levels of affective distress.[21]

Training in relaxation methods was part of our Self Management group and the Relaxation group. Relaxation training has clearly been shown to be helpful in patients with recurrent headache disorders. In a recent meta-analysis, relaxation therapy produced a 37% average improvement in headache, as compared to 12% for a medication-placebo.[22] Relaxation training alone does not produce significant improvement in over half of chronic headache patients,[23] so it is important that it be part of a more comprehensive program.

Stress is a common migraine trigger,[24,25] and may also influence headache and headache-related disability in other ways. Stress management training (cognitive therapy) has been shown to provide benefit in migraine similar to that of relaxation therapy,[26] although this therapy has been studied more in patients with tension-type headaches where it has proven quite effective.[27] An important aspect of cognitive therapy is that patients learn self-monitoring skills, and be able to analyse their times of headache onset. Along with cognitive restructuring, our Self Management group emphasized these skills.

The patients in our multidisciplinary program had the benefit of both pharmacological and nonpharmacological therapies and this may have contributed to their better outcomes. There is some evidence that combining the two approaches results in a better treatment outcome in migraine[28,29] but the available evidence is equivocal and limited, and more research is needed.

It is also important to note that patients in the multi-disciplinary program were more successful in stopping their symptomatic medication overuse (89% of patients with TM in Group II versus 40% of patients with TM in Group I). This may have been because patients in Group II had much more ongoing support as part of the multidisciplinary program, and were taught other ways of dealing with some of their headaches. This better success in stopping medication overuse may have contributed to the better outcomes in Group II.[30]

An important aspect of our multidisciplinary treatment program was that virtually all the nonpharmacological management was delivered through patient groups. There has been little formal study of the effectiveness of headache

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treatment delivered in this way, but others have reported positive experiences.[31] Using groups instead of individual therapy sessions has the potential to greatly reduce the costs of non-pharmacological treatment programs, an important consideration for any health care system.

Our results indicate that further careful study of the relative merits of various types of multidisciplinary treatment programs versus primarily physician-based pharmacological treatment is warranted for patients with refractory headache disorders. In fact, this issue needs to be examined in the total context of headache management. Consideration should be given as to whether learning effective Self Management skills early could significantly influence the course of a patient's headache syndrome over time. There is growing concern that frequent migraine attacks over long periods of time may result in greater refractoriness to therapy.[32,33]

Multidisciplinary headache programs are uncommon in the Canadian health care setting. It is appropriate that more data be obtained so that a national strategy can be developed to treat headache as effectively as possible as it is one of the most common chronic pain disorders.

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