A Migraine Disease Management Program in the Primary Care Setting: Impact on Patient Quality of Life and Productivity Loss

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Abstract

• **Objective:** To assess the impact of a migraine care program on patient health-related quality of life and productivity loss associated with migraine.

• **Design:** Prospective observational study.

• **Patients and setting:** 1126 consecutive consulting patients who screened positive for migraine in 27 primary care clinics.

• **Measurements:** Patients completed questionnaires, including the Headache Impact Test (HIT-6), the Migraine-Specific Quality of Life Questionnaire (MSQ), and items related to migraine-associated time lost from work/school and nonwork activities at the beginning and end of the study.

• **Results:** 258 migraine patients completed the study. Mean age of participants was 41 years; 85% were white and 77% were women. The percentage of patients whose HIT-6 total score reflected substantial or very severe headache impact was 75.3% at study entry compared with 68.8% at study end ($P < 0.05$). Mean changes from baseline also reflected improvement ($P < 0.05$) for the MSQ Role Function-Restrictive domain. Mean lost time equivalents from work/school and nonwork activities were lower in the 3 months after the migraine care program ($5.7 ± 11.9$ days) than during the 3 months before study entry ($8.7 ± 15.8$ days; $P < 0.05$).

• **Conclusion:** The migraine care program in primary care was associated with reductions in headache impact and lost work/school productivity and activity time in patients with migraine and improvements in certain aspects of health-related quality of life.

Migraine is a highly prevalent and debilitating condition that exerts a substantial impact on individuals and society [1–11]. Migraine sufferers experience considerable disability and impairment of quality of life, and lost productivity due to migraine is estimated to be $5.6$ to $17.2$ billion per year in the United States. Despite the humanistic and economic burden of migraine, the condition is underrecognized and undertreated [12–15].

To help improve awareness and recognition of migraine and to enhance the quality of headache care, the Migraine Care Program was developed. The Migraine Care Program is a disease management program developed by GlaxoSmithKline that contains educational materials and tools for patients and health care providers. Educational modules for health care providers cover migraine epidemiology, triggers, impact, pathophysiology, diagnosis, and treatment. The program also introduces 2 brief patient surveys to assist health care providers in managing migraine in clinical practice. Patient tools include a headache diary and an action plan to be completed with a health care provider.

In a prospective observational study in which patients with migraine received 12 weeks of care from primary care providers who had been introduced to the Migraine Care Program, the percentage of patients rating themselves as satisfied or very satisfied with the quality of migraine care increased from 32% at baseline to 48% at the end of the 12 weeks [16–18]. In addition, the proportion of providers who considered understanding of headache impact to be important or very important in treatment decisions and the proportion who considered themselves satisfied or very satisfied with patients’ descriptions of headache severity/symptoms and impact increased. The current investigation was conducted to extend this assessment of the Migraine Care Program by evaluating its effects on patients’ headache-related disability, health-related quality of life, and migraine-associated time lost from work and nonwork activities.

**Methods**

This prospective, 2-phase, observational study was conducted...
at 27 primary care practices in the United States. None of the practices routinely used a questionnaire to screen headache patients prior to the study. Phase 1 involved introducing the Migraine Care Program to 49 primary care providers in the practices and providing them with education, including use of a screener to identify patients with migraine. Phase 2 involved following 470 patients who had received a confirmed clinical diagnosis of migraine from these primary care providers in phase 1. This report focuses on data on headache disability, health-related quality of life, and time lost from activities for patients participating in phase 2. Data from phase 1 and patient and provider satisfaction data from phase 2 are reported elsewhere [16–18].

During phase 1, primary care providers (physicians, nurse practitioners, and physician assistants typically responsible for performing headache assessments) were introduced to the Migraine Care Program. They completed an educational program that was delivered via a 38-minute DVD and accredited by the Accreditation Council for Continuing Medical Education. After they completed the program, each primary care provider screened patients for migraine by administering the 10-question Headache Assessment Quiz (HAQ) (Figure 1) to 100 consecutive consulting adult patients between 18 and 65 years of age visiting the practice, regardless of the reason for consultation.

During phase 2, each primary care provider recruited up to 10 patients who screened positive for migraine on the HAQ in phase 1 and who fulfilled diagnostic criteria for migraine (International Headache Society criteria 1.1 or 1.2) [19] to continue in the study for the ensuing 12 weeks. To ensure that the study sample represented both newly diagnosed and previously diagnosed patients, at least half of the patients from each provider had to be newly diagnosed through phase 1 screening. Study providers also recorded in case report forms any headache medications that patients were taking at the time of screening. Study providers also recorded in case report forms any medication changes that were made at the study visit before the beginning of phase 2.

All patients provided written informed consent to participate in phase 2. At the beginning of phase 2, eligible patients received Migraine Care Program educational materials including a migraine diary and a pamphlet about the causes, triggers, and symptoms of migraine and migraine types from their health care provider. They received migraine care for the ensuing 12 weeks from their regular health care provider, who could prescribe any pharmacologic or nonpharmacologic migraine treatment to patients at their discretion.

Measures
The impact of migraine was measured using the Headache Impact Test (HIT-6), a 6-item instrument that has shown evidence of reliability and validity for assessing the impact of headache on patients’ lives [20]. HIT-6 scores, derived by summing the patient’s responses to all items, can range from 36 (lowest possible score) to 78 (highest possible score). Scores of 49 or less reflect little or no impact; scores between 50 and 55 reflect some headache impact; scores between 56 and 59 reflect substantial impact; and scores of 60 or more reflect severe headache impact on patient’s ability to function in everyday life.

The Migraine-Specific Quality of Life Questionnaire (MSQ, version 2.1), a 14-item disease-specific instrument that has shown evidence of reliability and validity, assesses 3 aspects of health particularly affected by migraine: Role Function-Restrictive (degree to which performance of normal activities is restricted by migraine), Role Function-Preventive (degree to which performance of normal activities is prevented by migraine), and Emotional Function (emotional effects of migraine) [21]. Each of the 3 MSQ dimensions is scored independently. For each dimension, scores range from 0 to 100, with higher scores indicating better health status. Both the HIT-6 and MSQ have been widely used in migraine clinical studies [14,22–29].

Patients were also asked to respond to items relative to migraine-associated time lost from work/school and nonwork activities. Patients were instructed to respond to HIT-6 and MSQ items based on their experience during the previous 4 weeks and to items on time lost due to migraine based on their experience during the previous 3 months. Patients completed the questionnaires before and after phase 2.

Analysis
Responses to the HIT-6 and MSQ were summarized with descriptive statistics. The Wilcoxon signed rank test was used to compare differences in the distribution of HIT-6 total scores and patient characteristics. Random effects generalized least squares regression was used to compare differences in mean MSQ scores from baseline to the end of the study for each of the 3 dimensions while controlling for age, gender, race, and study site effect. These statistical analyses included data from patients with evaluable responses at both baseline and the end of the study.

Patients’ responses to the items on time lost from work/school and nonwork activities were used to assess overall productivity loss, measured as lost time equivalents. Lost time equivalents are measured as the sum of migraine-attributed absenteeism and presenteeism. Absenteeism is defined as days missed from work/school and/or activities outside of paid work/school because of migraine. Presenteeism was calculated as the number of days performing work/school and/or activities outside of paid work/school with migraine symptoms × ([100% – % effectiveness while continuing activities with symptoms] ÷ 100). This method of calculating lost time equivalents has been previously employed in migraine studies [30–33]. Lost time equivalents because of
migraine were compared between baseline and the end of the study using random effects generalized least squares regression controlling for age, gender, race, and study site effect.

Results

Sample

The 49 participating primary care providers recruited 4443 patients to complete the HAQ during phase 1. Of these 4443 patients, 1527 screened positive for migraine, and 1126 had the diagnosis confirmed during further evaluation by their primary care provider.

The number of patients who participated in phase 2 was 470 (Table 1). Most of these patients were white (85%), most were women (77%), and 51% had not received a diagnosis of migraine from a health care professional prior to this study. Demographic and migraine characteristics of patients in the sample reflected those reported in a population-based survey in which migraine prevalence was higher in women and whites, and only about half of migraine patients reported a physician diagnosis of migraine [1,12]. On average, patients had 4.25 migraines per month, and approximately 46% of patients rated their migraine pain as severe prior to the study. Mean age of patients in the phase 2 sample was 41 ± 11.9 years.

The numbers of patients completing the baseline and end-of-study questionnaires were 470 and 258, respectively. The 212 patients who participated in phase 2 but did not complete the end-of-study questionnaires showed modest...
differences from those who completed the study. Compared with patients completing the study, dropouts were more likely to be male (31.4% vs. 16.7%; $P < 0.01$), nonwhite patients (20.8% vs. 9.9%; $P < 0.01$), with slightly more frequent migraines (mean, 4.8 vs. 3.8 migraines per month; $P = 0.04$), and who did not use any treatment to manage migraine prior to the study (25.1% vs. 16.7%; $P = 0.03$).

Adjustments to Prestudy Medication Regimens

Over-the-counter medications were the most common class of pharmacotherapy used to treat headaches during the 3 months prior to the study in the phase 2 sample as recorded by care providers in case report forms (Table 1). At the beginning of phase 2, primary care providers changed the headache medication regimen of 197 of these patients (42%). Of the 205 total changes to medication regimens, 83% (170/205) involved adding a medication, 11% (21/205) involved discontinuation of a medication, and 7% (14/205) involved dose adjustment. Among the medications that were added, 87% (148/170) were triptans, 3.5% (6/170) were antidepressants, 3% (5/170) were nonsteroidal anti-inflammatory drugs (NSAIDs), and less than 2% (3/170) were narcotic medications. The majority of dose adjustments were made on triptans (8/14 [57%]), and 48% (10/21) of discontinued medications were NSAIDs.

HIT-6

The percentage of patients whose HIT-6 total score reflected substantial or very severe headache impact (total score ≥ 56) was 75.3% (347/461) at study entry compared with 68.8% (174/253) at the end of the study ($P < 0.05$).

MSQ

Mean MSQ domain scores at baseline and at the end of study are shown in Figure 2. All 3 MSQ domain scores were significantly affected by age and gender. Male or older patients had higher MSQ scores than female or younger patients ($P < 0.05$). After controlling for demographic factors and study site, MSQ score for the Role Restrictive domain significantly increased (mean $\pm$ SD, 61.1 $\pm$ 26.4 at baseline vs. 67.3 $\pm$ 23.5 at the end of study; $P < 0.001$). Improvement in Emotional Function scores also approach statistical significance (mean $\pm$ SD, 71.7 $\pm$ 27.3 at baseline vs. 76.3 $\pm$ 25.2 at the end of study; $P = 0.057$). However, mean score difference from baseline to the end of the study was not significant for the Role Preventive domain.

Lost Time Equivalents

Summary statistics for individual data components used to compute lost time equivalents for paid work/school activities and nonpaid activities at baseline and at the end of the study are shown in Table 2. Overall productivity loss as measured in lost time equivalents decreased significantly during the 3 months after patients received headache care from providers who had participated in the Migraine Care Program (mean $\pm$ SD, 8.7 $\pm$ 15.8 days at baseline vs. 5.7 $\pm$ 11.9 days at the end of the study; $P < 0.01$). When productivity loss was analyzed separately for paid work/school activities (mean $\pm$ SD, 4.3 $\pm$ 7.9 days at baseline vs. 2.8 $\pm$ 7.4 days at the end of the study; $P < 0.01$) and nonpaid activities (mean $\pm$ SD, 5.4 $\pm$ 10.9 days at baseline vs. 2.9 $\pm$ 5.4 days at the end of the study; $P < 0.01$), lost time equivalents were

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**Table 1. Patient Characteristics: Phase 2 ($n = 470$)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age ± SD, yr</td>
<td>41 ± 11.9</td>
</tr>
<tr>
<td>Female, %</td>
<td>77</td>
</tr>
<tr>
<td>Race, %</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>85</td>
</tr>
<tr>
<td>Black</td>
<td>6</td>
</tr>
<tr>
<td>Hispanic</td>
<td>6</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
</tr>
<tr>
<td>Medications used for headache during the 3 months before the study, %*</td>
<td></td>
</tr>
<tr>
<td>Over-the-counter medications</td>
<td>70</td>
</tr>
<tr>
<td>Triptans</td>
<td>19</td>
</tr>
<tr>
<td>Prescription NSAIDs</td>
<td>14</td>
</tr>
<tr>
<td>Combination analgesics</td>
<td>9</td>
</tr>
<tr>
<td>Narcotics</td>
<td>5</td>
</tr>
</tbody>
</table>

NSAIDs = nonsteroidal anti-inflammatory drugs.

*Does not sum to 100% because patients could have taken multiple medications.

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**Figure 2. Migraine-Specific Quality of Life Questionnaire (MSQ) domain scores at baseline and week 12. *Difference significant at $P < 0.05$. †Difference significant at $P < 0.01$.**
Migraine program

also significantly decreased over the 3-month follow-up for both types of activities (Figure 3).

Discussion

The results of this study corroborate previous findings documenting the deleterious impact of migraine on patients’ lives [1–11]. Patients with a confirmed diagnosis of migraine were substantially impacted by their migraines at study entry, as demonstrated by responses at baseline on the HIT-6 and the MSQ. In view of the substantial negative impact of migraine on quality of life and functional ability, improvement in these parameters is integral to successful headache management. The results of this study suggest that the Migraine Care Program was associated with improvements in functional ability and certain aspects of quality of life. At the end of the study, the percentage of patients reported substantial or very severe headache impact was significantly decreased, time lost from paid work/school and other activities were significantly reduced, and patient quality of life in terms of how migraines had restricted normal activities was significantly improved. These improvements coincided with an adjustment in headache medication regimen for many patients. Primary care providers in our study adjusted the headache medication regimen relative to that used before the study for 42% of patients—most often by adding migraine-specific therapy with a triptan. These results are consistent with the findings in another study, which showed that increasing triptan use with initiation of a disease-management program for headache coincided

Table 2. Contributors to Lost Time Equivalents for Paid Work/School and Nonpaid Activities

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Week 12</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contributors to lost time equivalents for paid work/school (n = 122)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hours missed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>1.1 ± 2.1</td>
<td>0.6 ± 1.6</td>
</tr>
<tr>
<td>Median (range)</td>
<td>0.0 (0–12)</td>
<td>0.0 (0–11)</td>
</tr>
<tr>
<td>Hours worked with symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>14.1 ± 27.8</td>
<td>9.8 ± 19.7</td>
</tr>
<tr>
<td>Median (range)</td>
<td>4.0 (0–180)</td>
<td>3.0 (0–90)</td>
</tr>
<tr>
<td>% Effectiveness while continuing work/school with symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>62.8 ± 23.4</td>
<td>68.8 ± 23.2</td>
</tr>
<tr>
<td>Median (range)</td>
<td>70.0 (0–100)</td>
<td>75.0 (0–100)</td>
</tr>
<tr>
<td><strong>Contributors to lost time equivalents for nonpaid activities (n = 177)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hours missed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>2.5 ± 7.9</td>
<td>1.4 ± 3.8</td>
</tr>
<tr>
<td>Median (range)</td>
<td>0.0 (0–80)</td>
<td>0.0 (0–80)</td>
</tr>
<tr>
<td>Hours continued activity with symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>11.4 ± 23.8</td>
<td>8.9 ± 21.7</td>
</tr>
<tr>
<td>Median (range)</td>
<td>3.0 (0–90)</td>
<td>2.0 (0–90)</td>
</tr>
<tr>
<td>% Effectiveness while continuing activity with symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>60.7 ± 23.3</td>
<td>60.7 ± 23.3</td>
</tr>
<tr>
<td>Median (range)</td>
<td>70.0 (0–99)</td>
<td>70.0 (0–99)</td>
</tr>
</tbody>
</table>

Figure 3. Lost time equivalents and components at baseline and week 12. Lost time equivalents were calculated as hours missed from work/school and/or activities outside of paid work/school because of migraine + ([1 – % effectiveness while continuing activities with symptoms/100] × hours performing work/school and/or activities outside of paid work with migraine symptoms. Top figure shows lost time equivalents when paid work/school activities and activities outside of paid work/school were combined. Bottom figure shows results when the 2 types of activities were analyzed separately. *P < 0.01 based on generalized least squares controlling for age, gender, race, and study site.
with reductions in overall health care costs and emergency department visits [34].

Although initiation of the Migraine Care Program was consistently associated with significant improvement across various outcome measures, the magnitude of improvement might seem small as compared with those typically observed in clinical trials of acute migraine treatments. The relatively small improvements might be attributed in part to the heterogeneous nature of the sample, which makes it difficult to detect group effects on standard measurements. Unlike most clinical trials, the study sample was not selected with respect to headache severity or frequency—parameters that can significantly influence outcomes. In addition, patients with very severe headaches may require additional care and follow-up before marked improvement can occur. The relatively small improvements observed in this study might also point to the intractable nature of migraine. Even with proper diagnosis and treatment, migraine might require more ongoing management than that was provided in this study. The Migraine Care Program was limited in that it did not require any follow-up physician encounters. Follow-up physician encounters to reinforce prior assessments and fine-tune therapy might have led to larger improvements in patient outcomes in this study. Future migraine disease management programs should consider integrating education with follow-up care.

The results of this study should be viewed in light of its limitations. First, the observations design of this study does not allow the improvements in patient outcomes to be attributed unequivocally to the Migraine Care Program. For example, measurement artifact or maturation, rather than the effects of the Migraine Care Program per se, could have influenced patient outcomes. Second, due to resource constraints, not all patients confirmed to have migraines by a primary care provider participated in this study. Of the 1126 patients that were confirmed to have migraines in phase 1, only 470 (42%) were recruited to participate in phase 2 to provide data for this analysis. It is possible that patients who agreed to participate were those that perceived a benefit from the Migraine Care Program and were already on the path to improvement. Third, the high patient attrition rate in this naturalistic study could have limited the generalizability of study results. While the attrition rate is not surprising given that patients were not provided any financial or treatment incentives to remain in the study for the 12-week period, it is likely that patients with poor outcomes were more likely to withdraw prematurely than were patients with better outcomes. Patients who did not remain in the study for the 12-week period might not have perceived benefit from the program.

As gatekeepers of the health care system, primary care providers are often responsible for providing headache care. Using the screening questionnaire provided by the Migraine Care Program followed by clinical evaluation, 25% of primary care patients were found to have migraine. This prevalence estimate is consistent with a previous epidemiologic study that found 23% of households contained at least 1 member suffering from migraine [1] and a general practitioner study conducted in France that found about 25% of patients presenting to the general practitioner offices were migraine sufferers according to International Headache Society criteria [14]. Another U.S. waiting room study, which utilized a 3-item ID Migraine screener to identify migraine patients in primary care and headache specialist offices, found that 79% patients visiting doctor offices suffered from migraine [35]. The inclusion of headache specialist offices in the latter study probably biased the chance of finding migraine patients upwards.

Despite the encouraging results of this study, it is important to note that the success of a disease management program is contingent upon primary providers’ willingness to participate. Over 70% providers participating in this study were satisfied/very satisfied with using the HAQ at the end of this study [17]. Although these data were from a selected group of providers who agreed to participate in this study, their positive perception of the disease management tool suggests that its implementation in clinical practice is likely to be feasible and acceptable to most clinicians.

In summary, the results of our study suggest that initiation of the Migraine Care Program in primary care might improve certain aspects of health-related quality of life and reduce disability and migraine-attributed lost time in some patients with migraine. Future research evaluating long-term outcomes of disease management programs integrating both provider and patient education is needed.

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Author contributions: conception and design, WJK, SHL; analysis and interpretation of data, WJK, SHL, SPB; drafting of the article, SHL, SH, SPB; critical revision of the article, WJK, SHL, JBP, JHR, SH, SPB; provision of study materials or patients, WJK, JBP, JHR, SH; statistical experience, WJK, SPB; obtaining of funding, SPB; administrative or technical support, SPB; collection and assembly of data, JHR, SH.
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