

Long-term effects of a sensitisation campaign on migraine: the Casilino study

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Abstract In 2003, we conducted a sensitisation campaign on migraine in the Casilino district of Rome, by sending a letter with the ID Migraine test to all the households and placing posters in the GPs' waiting room. Out of 195 headache patients recruited, 92% had migraine while 73% had never consulted a physician for headache. The aim of this study was to evaluate the long-term impact of this campaign. The follow-up was performed by a telephone interview. The questionnaire considered the characteristics of headache, quality of life, preventive and acute treatments, drug efficacy, comorbidity and subjective usefulness of the campaign. Of the 179 migraineurs, 90.5% (mean age 40.7 ± 16.5 , 139 females) were included in the follow-up. An improvement was observed in mean pain intensity (-13.9% ; $p < 0.0001$) and mean HIT-6 score (-6.1% ; $p = 0.0003$). The campaign was considered to be useful by 63.6% of cases, while 66.1% reported an improvement in their clinical status. Improved patients showed a decreased mean number of days with headache per month (-51.7% ; $p < 0.0001$), pain intensity (-21.8% ; $p < 0.0001$), headache duration (-18.1% ; $p = 0.0008$) and HIT-6 score (-11.7% ; $p < 0.0001$). Our data suggest that the effects of a "single shot" campaign are beneficial not only in a short-term perspective, but even in the long term. Moreover, the lack of benefit in more severe cases suggests that such patients should not be treated by GPs alone: patients in whom the HIT-6 score, frequency,

severity or duration of headache worsen should be promptly referred to the headache clinic.

Keywords Sensitisation campaign · Migraine · Follow-up · Disability

Introduction

In general practice, few patients consult a physician for headache [1] and about half of those who do are correctly diagnosed and receive proper treatment [2]. This is an important point if we consider that migraine is a disabling disease with high social and economic costs e.g. it is one of the main causes of lost working days [3, 4]. Lipton and colleagues [10] demonstrated that approximately 30–40% of migraine patients are not aware that they suffer from migraine, the result being that they are frequently self-medicated or treated inappropriately.

Education is the key to increasing the number of correct diagnoses and to providing the best therapies for migraineurs.

Several studies have demonstrated that sensitisation and education campaigns improve patients' compliance with therapy and clinical management and reduce the social costs of migraine. As suggested by T.J. Steiner [5], sensitisation of the population might be achieved by making people aware that a problem exists and informing them on how to recognise common headache disorders, avoid mismanagement and use cost-effective pharmaceutical treatments.

In 2003, a sensitisation campaign on migraine was conducted in the Casilino district of Rome [6]. A primary care group of GPs in the Casilino district of Rome was involved in the study. The Casilino district is a well-defined area,

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located in the suburbs of Rome, with a relatively homogeneous socio-cultural background. In January 2003, we started an awareness campaign by sending a letter with a copy of the ID Migraine screening test to all the households and placing posters in the GPs' waiting room. In a previous study, the Identification of Migraine (ID Migraine) questionnaire was found to be a valid and reliable screening test for migraine [7].

If the subjects suffered from headaches that interfered with their daily lives and wished to seek advice, they were invited to contact their GPs for a visit and free consultation with a headache expert.

This "postal" campaign led to 195 headache patients consulting their GPs. Ninety-two per cent of these patients ($n = 179$) were migraineurs, while 73% had never consulted a physician for headache. The aim of the present study was to evaluate the long-term impact of this campaign, particularly the effects on the clinical characteristics of migraine and disability.

Methods

Three years after the postal campaign, we performed a follow-up telephone interview.

In 2003, our previous study involved ten GPs and a population of about 12,000 people, contacted by mail and posters located in GPs' waiting rooms. Both the letter and poster stressed the impact of headache on quality of life and included the Italian version of the three-item Identification of Migraine (ID Migraine) screening test, consisting of questions on disability, nausea and photophobia. All the subjects that suffered from headaches were invited to contact their GPs for a visit and a free consultation with a headache expert. More than 8,000 letters were delivered to households. Patient consultations started after 30 days and lasted for the following 4 months. A preliminary diagnosis was made by the GP while an independent confirmatory diagnosis was made by the headache specialist. Headache diagnosis was made according to ICHD-I criteria (1988) [8].

In the present study, we focused our attention on the 179 migraineurs previously diagnosed. We compared data about migraine patients collected in 2003 (baseline), with

those obtained at follow-up, by means of a telephone interview carried out from January to April 2006.

The questionnaire used [9] considered the main characteristics of headache, such as the location, type, intensity (on a scale 0–10), frequency (days with headache/month) and duration of attacks. Furthermore, how headache affected the patients' quality of life was investigated by means of the HIT-6 and MIDAS (Migraine Disability Assessment Scale). Patients were also asked what acute and prophylaxis treatments they took. The efficacy of acute therapy was assessed by means of the MIGRAINE-ACT. Any comorbidity was recorded. Lastly, patients were asked to provide a subjective evaluation of the usefulness of the sensitization campaign.

Results

The sensitisation campaign resulted in the enrolment in the study of 195 patients, 91.8% of whom ($n = 179$) were found to be affected by migraine, with or without aura, according to the ICHD-I criteria (1988) [6].

Three years later, 90.5% ($n = 162$) of the 179 migraineurs originally recruited were interviewed by phone.

The remaining 9.5% ($n = 17$) were not interviewed because they could no longer be contacted by telephone ($n = 12$), had emigrated to another country ($n = 2$) or had died ($n = 3$). In 2003, the patients' mean age was 40.7 ± 16.5 years; 85.8% ($n = 139$) of the patients were female, with an average school attendance index of 8.5 ± 3.2 years. Forty-one patients (25.3%) presented migraine with aura. The demographic and clinical characteristics of the population who completed the follow-up ($n = 162$) did not differ from those observed in the sensitisation campaign ($n = 179$).

The baseline and follow-up migraine characteristics of the 162 migraine patients are summarized in Table 1.

At follow-up, 61.1% ($n = 99$) of the cases were found to have a severe disability (HIT-6 >55). Moreover, 56.1% ($n = 91$) of the study population presented a MIDAS grade III-IV score.

Comorbidity was observed in 33.9% ($n = 55$) of the cases: hypertension in 11.7% ($n = 19$), rheumatic disorders

Table 1 The baseline and follow-up migraine characteristics of the 162 patients

	Baseline	Follow-up	Δ %	
Frequency (days/month)	8.1 ± 8.9	7.4 ± 10.1	-8.6%	NS ($p = 0.5249$)
Intensity (0–10)	8.6 ± 1.5	7.4 ± 2.1	-13.9%	$p < 0.0001$
Duration (h)	37.1 ± 24.9	33.7 ± 24.6	-9.1%	NS ($p = 0.2154$)
HIT-6	61.3 ± 7.6	57.5 ± 11.0	-6.1%	$p = 0.0003$
MIDAS (grade III-IV)	60.5%	56.1%	-7.2%	NS ($p = 0.4302$)

Table 2 Characteristics of improved and not improved patients

	Improved/not improved	Parameters			Patients	
		Frequency	Duration	Intensity	No. of cases	Percent
Improved	Better	Better	Better	Better	11	6.8
Improved	Better	Better	Better	Worse	1	0.6
Improved	Better	Better	Better	Stable	3	1.9
Improved	Better	Better	Stable	Better	40	24.7
Improved	Better	Better	Stable	Stable	38	23.5
Improved	Worse	Better	Better	Better	2	1.2
Improved	Stable	Better	Better	Better	2	1.2
Improved	Stable	Better	Better	Stable	1	0.6
Improved	Stable	Stable	Stable	Better	9	5.6
Total improved					107	66.1
Not improved	Stable	Stable	Stable	Stable	13	8.0
Not improved	Worse	Worse	Worse	Worse	2	1.2
Not improved	Worse	Worse	Stable	Stable	1	0.6
Not improved	Worse	Stable	Worse	Worse	3	1.9
Not improved	Worse	Stable	Stable	Stable	12	7.4
Not improved	Stable	Worse	Stable	Stable	3	1.9
Not improved	Better	Worse	Stable	Stable	2	1.2
Not improved	Better	Stable	Worse	Worse	7	4.3
Not improved	Worse	Better	Stable	Stable	1	0.6
Not improved	Worse	Stable	Better	Better	10	6.2
Not improved	Worse	Better	Worse	Worse	1	0.6
Total not improved					55	33.9

Table 3 Comparison of headache parameters (baseline versus follow-up)

	Baseline			Follow-up				
	Improved (n = 107)	Not improved (n = 55)	<i>p</i>	Improved (n = 107)	$\Delta\%$	Not improved (n = 55)	$\Delta\%$	<i>p</i>
Frequency (days/month)	8.5 ± 9.0	7.3 ± 8.8	NS (<i>p</i> = 0.42)	4.1 ± 7.2	-51.7%	13.8 ± 11.7	+89.0%	<i>p</i> < 0.0001
Intensity (0–10)	8.7 ± 1.5	8.1 ± 1.6	NS (<i>p</i> = 0.34)	6.8 ± 2.2	-21.8%	8.7 ± 1.5	+7.4%	<i>p</i> < 0.0001
Duration (h)	35.2 ± 24.2	40.7 ± 26.2	NS (<i>p</i> = 0.20)	28.8 ± 22.8	-18.1%	43.1 ± 25.3	+5.8%	<i>p</i> = 0.0008
HIT-6	61.2 ± 7.7	61.4 ± 7.5	NS (<i>p</i> = 0.86)	54.0 ± 11.0	-11.7%	64.1 ± 7.3	+4.3%	<i>p</i> < 0.0001

in 10.4% (*n* = 17) and endocrine dysfunction in 17.2% (*n* = 28).

Lastly, the sensitization campaign was judged positively by 63.6% (*n* = 103) of patients.

A change in at least one of the following parameters was reported by 149 patients (92.0%): intensity of pain, headache duration and days with headache per month. On the basis of these three parameters, an improvement in the patients' condition was defined as follows: at least one parameter was better at follow-up and there were no worsening in either of the other parameters, or a worsening in one parameter was present but both the other parameters were better. In the other cases not improvement was stated. According to this classification, 66.1% (*n* = 107) of

patients experienced an improvement, while the remaining 55 patients did not improve (33.9%) (Table 2).

By dividing migraineurs into two groups [(a) improved and (b) not improved] we observed statistically significant differences in the headache frequency, pain intensity, duration of attack and HIT-6 (Table 3).

Among the 107 patients who improved, the frequency dropped in 93 (86.9%) patients, the duration was reduced in 17 (15.9%) and the intensity decreased in 64 (59.8%). More than half of these 107 patients showed an amelioration in at least two parameters.

A frequency higher than 15 days/month of headache was observed in 18.5% (*n* = 30) of all cases, approximately half of whom (46.6%) had presented chronic daily

Table 4 Differences in the quality of life in migraineurs who use triptans and those using other drugs and/or no drugs

	Follow-up		
	Triptans (<i>n</i> = 27)	No triptans (<i>n</i> = 135)	
HIT-6	57.9 ± 11.9	57.4 ± 10.8	NS (<i>p</i> = 0.8377)
MIDAS III-IV	51.9%	57.0%	NS (<i>p</i> = 0.0617)

headache since the start of the study. All those with chronic daily headache since the beginning did not improve at follow-up.

Drugs were used to treat the acute attack by 85.2% (*n* = 138) of the patients. Triptans were used by 16.7% (*n* = 27) of patients, while the remaining 68.5% (*n* = 111) used NSAIDs or paracetamol.

A total of 4.3% (*n* = 7) of the population started taking triptans after specialist prescription during the sensitisation campaign.

Among the 138 patients who took drugs to treat the acute attack, the therapy was effective, according to the MIGRAINE-ACT criteria, in 49.3% (*n* = 68) of the cases. A pain-free condition was observed within 1 h in 48.5% (*n* = 67) of the patients, within 2 h in 24.6% (*n* = 34) and within 24 h in 26.8% (*n* = 37). Overall, pain relief was reported to be rapid, with pain being relieved within 2 h in 73.2% (*n* = 101) of cases. Nevertheless, headache hardly affects daily life planning in 51.4% (*n* = 71) of cases treated by attack therapy.

In the patients who use triptans (16.7%, *n* = 27), a free-pain condition was achieved in 40.7% (*n* = 11) within 1 h, in 55.6% (*n* = 15) within 2 h and in the remaining 3.7% (*n* = 1) within 24 h. Although triptans induced pain relief within 2 h in 96.3% (*n* = 26) of the cases, headache related discomfort did not allow the planning of daily life in 63.0% (*n* = 17) of the cases.

In 51.8% (*n* = 14) of the population, the use of triptans was associated with a MIDAS grade III-IV score.

As regards the quality of life of migraineurs, assessed by means of the HIT-6 and MIDAS, no significant differences were observed between those who used triptans and those taking other drugs (such as NSAIDs or paracetamol) or no drugs (Table 4). In this regard, the majority of patients could not have a normal daily planning although the use of symptomatic treatment showed efficacy in pain relief.

Only 13% (*n* = 21) of the population took drugs as migraine prophylaxis. An improvement in the headache characteristics (days per month, intensity and duration of pain) was observed in a large group of patients (71.4%, *n* = 15) who use prophylactic therapy.

Patients who suffered from psychiatric morbidity, such as anxiety and depression disorders, at the time of enrolment improved more than those who did not (37.4% vs 25.5%).

At the follow-up, among the improved patients, the female/male ratio dropped (4.9:1.0 vs. 10.0:1.0), the mean age was younger (43.6 ± 16.3 vs. 44.0 ± 15.1 year), onset occurred at an earlier age (19.9 ± 11.3 vs. 20.7 ± 11.1 years) disease duration was longer (23.4 ± 15.1 vs. 22.5 ± 12.6 years), menstruation affected migraine less (37.1 vs. 44.0%). Migraine patients that improved at follow-up showed also a higher number of first diagnoses made by headache specialists at baseline (74.8 vs. 69.1% of cases). Furthermore prophylactic therapy was more adopted (14 vs. 10.9%) while specific attack therapy with triptans was not (12.2 vs. 25.5%) (Table 5).

Thirty-one (28.9%) of the patients who improved presented other associated diseases including hypertension (*n* = 10), hormonal dysfunctions (*n* = 12) and skeletal disease (*n* = 9), whereas we observed comorbidity in 24 patients (43.6%) of the not improved, hypertension in 10 patients, hormonal dysfunctions in 12 and skeletal disease in 10.

Discussion

Migraine is a disease that is frequently not diagnosed and is consequently untreated. A study in the United States

Table 5 Characteristics of the two groups examined

	Improved (<i>n</i> = 107)	Not improved (<i>n</i> = 55)	
Sex (f; m)	4.9:1.0	10.0:1.0	NS (<i>p</i> = 0.1818)
Current age (years)	43.6 ± 16.3	44.0 ± 15.1	NS (<i>p</i> = 0.8850)
Starting age (years)	19.9 ± 11.3	20.7 ± 11.1	NS (<i>p</i> = 0.6841)
Duration of disease (years)	23.4 ± 15.1	22.5 ± 12.6	NS (<i>p</i> = 0.6647)
Influence of menstruation (female <i>n</i> = 139)	37.1% (<i>n</i> = 33/89)	44.0% (<i>n</i> = 22/50)	NS (<i>p</i> = 0.4232)
First diagnosis	74.8% (<i>n</i> = 80)	69.1% (<i>n</i> = 38)	NS (<i>p</i> = 0.4419)
Use of triptans	12.2% (<i>n</i> = 13)	25.5% (<i>n</i> = 14)	<i>p</i> = 0.0314
Prophylactic therapy	14.0% (<i>n</i> = 15)	10.9% (<i>n</i> = 6)	NS (<i>p</i> = 0.5769)

demonstrated that more than half of all migraineurs were never correctly diagnosed according to the ICHD-I criteria [10].

Indeed, the study reported that only a third of patients suffering from headache go to a physician for a consultation and that only half of those who do receive appropriate treatment [11–13]. Several findings reported by epidemiological studies point to a lack of communication between physicians and patients, which in part explains the considerable number of patients who do not seek medical care [2, 10, 14].

In a recent multicentre, Italian study, Cevoli et al. [29] confirmed that although migraine results in a significant degree of disability, deteriorates the quality of life and has substantial economic costs, most people with migraine do not receive a correct diagnosis and are likely to be inadequately treated. It should be pointed out that inappropriate treatment leads to poor patient satisfaction, which may in turn result in patients dropping out of care, thereby increasing the risk of self-medication and, eventually, headache chronification and medication overuse.

This is the consequence a general unawareness in the general population of migraine as a disability that seriously affects the quality of life and has a high socio-economic impact.

The campaign's central tenet is that the health-care solution for headache in most areas of the world is education. By educating, we can raise awareness that a problem exists and inform people on how to recognise common headache disorders and avoid mismanagement, as well as provide advice on appropriate lifestyle modifications and cost-effective pharmaceutical treatments [5].

The aims of the sensitisation campaign were to up-date physicians and inform patients on migraine and on how to diagnose and treat it. This campaign offered patients suffering from migraine the opportunity to seek medical care for specialist management. Patients thus learnt how to recognise symptoms and how to manage headache, especially with regard to what drugs are available and when to take them, with emphasis being placed on the importance of an early intervention. Offering patients a correct diagnosis and establishing contact with medical care thus strongly improved the prognosis of migraine [15, 16].

The importance of this approach is confirmed by other authors [17] who have conducted similar studies designed to demonstrate how an educational campaign might improve the clinical status and reduce the misuse of drugs among migraineurs. After 6 months, the group of patients enrolled in the study by Rothrock et al. displayed a lower frequency of attacks (average 14 vs. 8 days/month), reduced disability according to the MIDAS (24 vs. 14), reduced drug use during the acute attack and improved compliance with prophylactic therapy.

In another study conducted on patients who were diagnosed in primary care and who then attended an education programme organised by specialists, Blumenfeld et al. [18] noticed a significant improvement in migraineurs and in their quality of life after 6 months' follow-up when compared with the baseline values.

Donnet et al. [27] organised a "Tour de France of migraine" consisting of free-access conferences held in six large towns in France following a wide public information campaign. The aim of that sensitization campaign was to provide participants with educational information on migraine and on current therapies. Headache sufferers were then invited to respond to two consecutive questionnaires delivered at the end of the conferences and 3 months later to assess the influence of the information delivered on the management of migraine. Three months after the conferences, there was a marked improvement in migraine-related disability, as reflected by a significant decrease in the mean Headache Impact Test 6-item score.

Harpol et al. [19] also reported a marked reduction in the MIDAS (mean 21.2 points) after a campaign that focused on the type of headache, triggering factors and the use of a diary.

The 3-year follow-up after our sensitisation campaign led to an improvement in migraine in 66.1% of cases. It is noteworthy that 74.8% of the patients we enrolled had never previously been diagnosed as migraineurs.

The aim of our study, which was to improve general disease management among migraineurs, was largely achieved.

Although not statistically significant, we noticed that the majority of patients who benefited most from the campaign were those with the highest severity scores at baseline, as assessed on the basis of the intensity, duration, HIT-6 and comorbidities.

We may speculate that one of the reasons for such a marked improvement following a "single shot" campaign is ascribable to an increased awareness of the disease and information on the drugs available and when to take them.

Moreover, the headache training of GPs enhanced the accuracy of diagnosis in migraineurs and the administration of appropriate treatment. Karli et al. [20], in a prospective study, investigated the effects of a 2-day headache education programme for GPs designed to improve the diagnostic accuracy. It is noteworthy that after this programme the correct diagnosis of migraine rose from 56.3 to 81.0% and significantly improved the choice of proper treatment. In this light, it might be worth to recommend specific training for the use of simple tools as HIT-6 scale or ID-migraine by medical school or national health services. These instruments might help to improve early detection of migraineurs and the impact of headache on daily living by GPs.

When we analysed the clinical characteristics of the migraineurs who improved and those who did not improve, we found a higher percentage of patients with organic comorbidities (such as rheumatic or endocrine disorders) or more resistant headaches (such as chronic migraine) in the not improved group. The lack of benefit in more severe cases after 3 years confirms that such patients should not be treated by GPs alone, but should immediately be referred to the headache clinic to avoid delaying effective treatment any further.

Surprisingly, patients with anxiety or depressive symptoms in our study benefited more from the sensitization campaign than patients without psychiatric comorbidities, even though the difference was not significant. This may be due to increased levels of attention and care by GPs towards headache patients after the campaign, two aspects that are likely to play a pivotal role in the clinical improvement of these patients.

Approximately half of the patients who took either specific or aspecific drugs to treat the acute attack also presented a therapeutic efficacy with a 2-h pain free index in 73.2% of cases. This may be due to the early identification of the headache features, which enables a better management of symptoms and the early intake of drugs so as to increase their efficacy [21–23].

Despite being relieved of pain within 2 h, a normal daily plan was not possible in 51.4% of patients. This finding indicates that disability is not only related to pain control but also to pain relief symptoms. Therapeutic adjustments should perhaps also be taken into consideration in patients who become pain-free within 2 h.

Despite the strong evidence of the efficacy of triptans reported in previous studies [24, 25], few patients in our group used this family of drugs (16.7%), confirming the results yielded by other studies conducted on general migraine populations (7.5%) [26]. Among patients that used triptans, seven received these specific treatments from headache specialists during the campaign, while 20 were taking triptans before the campaign. As we stated above, the aims of our campaign was to improve general disease management among migraineurs. The campaign encouraged patients not only to seek treatments, but also to perform a better management of therapy by teaching how and when to take drugs and to avoid possible stressing factors. The sensitization/education of patients strongly impact on patients' quality of life and produce additional clinical benefits [27].

Panconesi et al. [28], in a review of the Italian population, confirmed that a very low percentage (about 10%) of migraine patients used triptans, and showed that a large percentage of patients (40–60%) who do use them only take them once a year. One possible explanation for this finding may be the low diagnosis rate of migraine [29]. The

possible causes of the underdiagnosis of migraine and scarce administration of triptans by GPs are: little time to spend with the patient, complexity of the IHS diagnostic criteria, high variability of the clinical signs in migraine patients and high cost of triptans. The high percentage of single prescriptions of triptans may indicate that many migraineurs have relatively few attacks or that triptan therapy does not effectively control their migraine because it is not fully effective and/or has side effects.

Our findings regarding the use of prophylactic therapy are similar to those on triptans: it was seldom adopted in either our study (13.0%) or those of other authors (11.2%) [1].

The “single shot” campaign aimed at enhancing the therapeutic management of migraine by GPs thus proved to be ineffective.

Last but not least, the campaign was judged to be useful by 63.6% of the population examined, which thus confirms the generally positive feedback from patients for such studies.

Conclusion

In conclusion, our study demonstrates that the clinical status of a large proportion of the patients enrolled in the campaign improved.

Indeed, our data indicate that the benefits of the sensitisation campaign we conducted were not only immediate but even long term, as demonstrated by the fact that after 3 years symptom relief was either maintained or improved further in the majority of patients.

This type of campaign might provide a means of identifying two populations of migraineurs: one that benefits considerably from exposure even only once to migraine information, another with a more resistant headache status (such as chronic daily headache or prevalence of comorbidities). Different groups may require different approaches, consisting of referral of the former to a general practitioner and of the latter to a highly specialised headache centre. In this regard, referral to the headache clinic should be considered for those patients in whom the HIT-6 score, frequency, duration or severity of headache worsen.

Since the majority of the patients enrolled were diagnosed during the campaign, we may conclude that the improvement is due to specialist consultations, to an awareness of both the disease and triggering factors as well as to the advice given on migraine drugs and their use. Only a minority of cases remained stable or worsened. The general characteristics of headache at baseline do not allow patients to be selected according to the expected clinical outcome. The need for a close and constant interaction between general practitioners and specialists to monitor the

clinical evolution of the disease and to refer patients who do not respond to standard treatment to specific care units cannot be emphasised enough.

This study therefore confirms that sensitisation campaigns are an effective means of educating physicians and the general population to recognize diseases that are underdiagnosed, such as migraine, so as to improve the diagnosis and provide specific therapy, thereby reducing the social and economic impact of these diseases. A more effective management of the therapy and general care of these patients might significantly cut the social costs of migraine and enhance the quality of life of subjects with this debilitating disease.

Conflict of interest None.

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