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(Article begins on next page)

## **Analgesic Drug Taking: Beliefs and Behavior Among Headache Patients**

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**Objective.**—To explore beliefs and behavior with respect to analgesic drug taking in headache patients. To compare episodic headache to chronic headache sufferers.

**Methods.**—A consecutive series of 280 headache patients, newly admitted to the Headache Center of the University of Modena, all referred by their general practitioner, were asked to fill out a brief questionnaire, specially compiled for this survey. The questionnaire invited patients to indicate how they themselves thought they should best cope with their headache, and how they actually did so in practice.

**Results.**—The majority of our patients had a positive attitude towards over-the-counter analgesics, which they believed to be more adequate than prescription drugs for acute treatment of their headache. They handled analgesics very carefully, believing it correct to take the drug only when the pain became unbearable, if it was not possible for them to stop work. Chronic headache patients tended to consume more prescription drugs than episodic headache sufferers. Furthermore, the majority of chronic sufferers, as opposed to episodic sufferers, took the analgesic even when not at work.

**Conclusions.**—The use of over-the-counter drugs is considered the best way to treat acute headache even by subjects suffering from severe idiopathic headache and seeking professional care in specialized clinics. Prescribed analgesics are underused by patients with serious episodic headache, which is precisely the group for which they are principally intended.

**Key words:** drug taking, OTC analgesics, prescription analgesics, chronic headache, episodic headache

**Abbreviations:** OTC over-the-counter, GP general practitioner, IHS International Headache Society, EH episodic headache, CH chronic headache

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Although there is a high prevalence of headache disorders in the population at large, requests for medical consultation are relatively infrequent, and the majority of sufferers use self-medication, that is over-the-counter (OTC) analgesic drugs.<sup>1–4</sup> Indeed, self-medication is by now recognized as a fundamental element in safe-guarding health. More and more people responsibly choose between pharmaceuticals available without prescription. In general, these OTC drugs are not used as substitutes for prescribed medicines or healthcare assistance in cases of serious disease, but are principally used for treatment of illnesses which the patient regards as transitory and benign.<sup>5</sup> Those suffering from headache, however, take OTC analgesics not only for minor episodes of pain, but also for serious and debilitating headaches. In the United States, as many as 62.6% of women and 74.6% of men with severe headache use OTC drugs<sup>6</sup> while 45.3% of subjects suffering from disabling headaches use exclusively nonprescription medications.<sup>7</sup> Though the use of OTC drugs can be a valid, safe, and less expensive alternative to prescription drugs for treating the occasional headache of limited intensity, it does not seem to be the best therapy for more severe forms. In these cases, OTC drugs might be only partially successful and might even distance the patient from the search for a more adequate solution.<sup>8</sup> Many headache sufferers do not receive any preventive treatment, even though they might benefit from it.<sup>6</sup> In addition, in the case of very frequent headaches, excessive self-administration over a period of time might cause the discomfort to worsen and increase in frequency, causing a state of chronic headaches, dependence on the analgesic, and organic toxicity, all of which can jeopardize the effect of prophylactic therapy.<sup>9</sup> These potential risks of self-medication with OTC drugs are partially reduced if it is taken into consideration that the sufferers seem to be well aware of the serious-

ness of their headache, also in terms of human cost and social disadvantage.<sup>10,11</sup> They should, therefore, be able to evaluate when symptomatic self-administration of drugs is inadequate and other solutions are needed. Confirmation of this awareness is the data attesting that it is the patients themselves, those with severe and chronic headaches, who most frequently seek the specialist.<sup>2,6,12,13</sup> Consequently, persistence of self-medication, even where it is obviously unsatisfactory, might be due to problems of an economic nature, or to inadequacy in the national health system,<sup>7</sup> or more simply to negative experiences with prescribed drugs (lack of efficacy and/or adverse side effects). Indeed, results from a survey conducted in the United States show that 36% of women and as many as 51% of men use OTC drugs, even though they have received a medical diagnosis of migraine and have been prescribed appropriate drugs.<sup>6</sup>

In recent years, although the cause of primary headache is still not fully understood and no definitive cures are known, considerable therapeutic progress has been made. With regard to migraine, a serotonin agonist, sumatriptan, has become available specifically for the treatment of acute attacks. This drug has been shown to be effective, well tolerated,<sup>14</sup> and able to improve the quality of life of patients, even those suffering from severe migraine.<sup>15</sup> After the introduction of sumatriptan in Italy, we began receiving patients suffering from debilitating migraine who, although having been correctly prescribed sumatriptan by their general practitioner (GP), claimed not to have taken it or only to have taken it on very rare occasions when OTC drugs had not worked, or after hours of intense pain.

Furthermore, while in general these patients accepted a prophylactic therapy, they still resisted the use of sumatriptan or other prescribed drugs for treatment of acute headache. We felt that some of these subjects, even those with severe headaches, were inadequately treated, not due to a lack of availability of more effective treatment, but rather due to diffidence in the face of analgesic drugs, especially those requiring a prescription, which they viewed as stronger and thus more dangerous. We also noted a stoic attitude to pain in some of the patients.

The aim of this study was to examine the ideas and behaviors of patients with regard to use of analgesic medicines and their methods of tackling the pain. We also analyzed whether there were differences of opinion and behavior between patients with episodic and those with chronic headache.

The study was conducted with the use of a brief questionnaire, specially addressed to patients referred by their GPs for the first time to the outpatient clinic of the Modena University Headache Study Center.

## **PATIENTS AND METHODS**

**Patients and Procedures.**—As part of the study, a brief questionnaire was developed and comprised: (1) a sociodemographic part (age, sex, marital status, occupation); (2) a section dedicated to history and characteristics of the headache (age at onset, frequency [less than 1 per month, 1 to 2 per month, 3 to 5 per month, more than 5 per month, more than 15 days per month, daily], intensity [mild, moderate, severe], and duration (less than 4 hours, 4 to 72 hours, longer than 72 hours) during the previous 2 months; (3) another part in which the patients were asked whether they considered it better to consume an OTC or a prescribed drug to treat an attack, or not to consume analgesics at all, and in addition, they were asked what in fact they took when in the course of the headache they felt it right to take the drug and when in fact it was finally taken. Finally, they were asked what their behavior was if the headache came on during a working day or during a day off. A copy of this section of the questionnaire is appended.

Of 961 subjects sent by their GPs for the first time to the Modena University Headache Center Outpatient Clinic from the 1st of June 1994 to the 31st of May 1995, the questionnaire was administered to 637 consecutive patients aged 18 to 65 years. The questionnaire was given to the patients on their arrival at the center by two recent medical graduates, who explained the aim of the study and asked each person if he or she wished to participate. All subjects were told that the questionnaire was being used for research purposes only and was not part of the medical examination. The consenting patients were given the questionnaire, which they compiled in the waiting room before being seen by the physician. All subjects consented.

Subsequently, each patient, as is routine for new patients, was examined by a senior physician of the center, who compiled a full clinical history with special attention to the drugs used, whether OTC or prescribed, and formulated the diagnosis without being aware of the questionnaire responses. The same physician evaluated whether the questionnaire could be included in the study, according to the following criteria: primary headache for at least 1 year; diagnosis of migraine with or without aura, episodic tension-type headache, chronic tension-type headache according to the IHS classification<sup>16</sup> and migraine with interparoxysmal headache<sup>17</sup>; and having already received at least one previous prescription of a drug for acute treatment of headache.

According to these criteria, the questionnaires from 280 consecutive patients were selected. The remaining 357 were excluded because they did not fulfill the inclusion criteria: 156 patients had different diagnoses (ie, symptomatic headaches, posttraumatic headache, cluster headache, atypical facial pain, nonheadache disorders); 97 had recent onset headache (less than 1 year); 104 had never received analgesic drug prescriptions.

None of the 280 patients were taking prophylactic drugs for headache treatment at the time.

**Data Analysis.** — The data collected from the questionnaire, together with the diagnosis, were entered in a specially-prepared data base (DB3). A descriptive analysis of the whole population was made as well as a comparison

between two groups: (1) subjects with episodic headache (EH) (n=196) including patients with diagnosis of migraine with or without aura and those with episodic tension-type headache, and (2) subjects with chronic headache (CH) (n=84), including patients with a diagnosis of chronic tension-type headache and those with migraine with interparoxysmal headache. The type of drug used by the 41 subjects who had already received a prescription for sumatriptan before registering at the center, was also analyzed separately.

The statistical analysis employed the statistics program SPSS/PC for the chi-square test. When appropriate, Student's t-test for unpaired data was utilized. A level of  $P < 0.05$  was considered significant.

## RESULTS

**Demographic and Headache Characteristics.**—The 280 patients (233 women and 47 men) whose questionnaires were admitted to the study had a mean age of  $39.2 \pm 12.4$  years. The majority (57%) were between 26 and 45 years of age. Seventy-six percent were married, 18% were not married, and 6% were widowed or divorced. Subjects actively engaged at work were 63% (60 clerks, 51 blue-collar workers, 36 craftspeople and merchants, 26 teachers, and 4 company directors); 37% of the sample was composed of people not engaged in lucrative activity (50 housewives, 29 retirees, 13 students, and 11 unemployed).

The EH group was comprised of 183 (93%) migraine sufferers and 14 (7%) episodic tension-type headache sufferers. The CH group was formed by 39 (46%) patients with chronic tension-type headache and 45 (54%) with diagnosis of migraine with interparoxysmal headache. Demographic characteristics of the two groups are presented in Table 1. The EH subjects were

**Table 1.—Patient Characteristics**

Variable	Episodic Headache Group* (n=196)	Chronic Headache Group* (n=84)
Ratio of women to men	83:17	83:17
Age, y**		
18–25	14	9
26–35	38	8
36–45	32	19
46–55	13	36
56–65	3	28
Marital status		
Married	75.5	77
Widowed/divorced	3.5	12
Unmarried	21	11
Occupation		
Employed	72.5	42
Unemployed	27.5	58

\*Values given in percentages.

\*\* $P < 0.001$  among groups, chi-square test.

Mean  $\pm$  SD age for the episodic headache group was  $35.5 \pm 9.7$  and  $47.8 \pm 13.8$  for the chronic headache group ( $P < 0.001$ , Student's t-test for unpaired data).

significantly younger (mean age  $35.5 \pm 9.7$  years) and had suffered from headache for a shorter time (mean duration of headache  $15 \pm 13.6$  years) than the CH subjects (average age  $47.8 \pm 13.8$  years, duration of headache  $24.8 \pm 17.1$  years) ( $P < 0.001$  for both). Only 41 subjects (female to male ratio 9.25:1, average age  $37.7 \pm 9.9$  years) had already been prescribed sumatriptan by their GP, either orally or both orally and by injection (5 of them) before reporting to the clinic. They represented 14.6% of the total sample. Twenty-seven (66%) were diagnosed as having migraine, while 14 (34%) migraine with interparoxysmal headache.

The majority of the sample group had suffered frequent prolonged headaches for many years. More than 95% of subjects, in both the EH and CH groups, stated in the questionnaire that the intensity of the pain was moderate or severe (Table 2).

**Type of Analgesic Used.**—The majority of those sampled, 54%, thought it better to treat the headache attack with an OTC drug, 40% used a prescription analgesic, and a minority of 6% preferred not to take drugs. Eight percent declared that they did not use analgesics, 49% used OTC agents, and 43% used prescription analgesics. The differences between what was thought to be best and what action was actually taken was not statistically significant (chi-square = 1.35,  $P = NS$ ).

The majority of OTC users were those suffering from episodic headache. The majority with chronic headache, though expressing the opinion that it was better to use OTC drugs, in reality used prescription analgesics (Table 3).

**Table 2.—Headache Characteristics**

Feature	Episodic Headache Group* (n=196)	Chronic Headache Group* (n=84)
Frequency/month		
<1	3	—
1–2	33.2	—
3–5	38.3	—
>5	25.5	—
>15 days	—	33.3
Daily	—	66.7
Length of attacks, h		
<4	11.2	21.4**
4–72	76	56
>72	12.8	22.6
Intensity		
Mild	3.6	2.4***
Moderate	50.5	46.4
Severe	45.9	51.2

\*Values given in percentages.

\*\* $P < 0.05$ .

\*\*\* $P = NS$ .

**Table 3.—Analgesic Drugs Patients Believed it Better to Take and Drugs They Actually Took for Their Headaches**

Type of Drug	Believed Better*		Actually Took**	
	Episodic Headache Group (n=196)	Chronic Headache Group (n=84)	Episodic Headache Group (n=196)	Chronic Headache Group (n=84)
OTC drugs	56.1	23.8	52	44
Prescription drugs	39.3	21.7	40.9	46.5
Not to assume any drug	4.6	9.5	7.1	9.5

Values given in percentages.

\*Chi-square = 3.02, *P*=NS.

\*\*Chi-square =1.61, *P*=NS.

There was no difference of opinions and conduct in the 41 patients prescribed sumatriptan by their GPs; 21 of them (51%) used the prescribed drug, 18 (44%) preferred and used OTCs, and 2 (5%) used no analgesic drug. No significant differences in age were detected between the 18 who declared the use of prescribed drugs (age 37.04 ± 9) and the 21 who used OTC drugs (age 39.5 ± 10.6) (*P*=0.4, Student's t-test). The remaining 2 patients were 34 and 44 years old.

**When Patients Took the Analgesic.** —Of the 258 patients using analgesics, 49% thought it was correct to take them only when the pain became intolerable, 43% at the onset of pain, and a minority, 8%, before the pain actually started. In fact, an even larger majority, 56%, said they actually took the analgesic only when the pain became unbearable, 41% at the onset, and only 3% before onset. The difference between what they thought it was better to do and what they actually did is statistically relevant (chi-square = 7.14, *P*<0.05).

The majority of the subjects, both those with chronic and those with episodic headache, resorted to the analgesic only when the pain became intolerable. However, all 57% of subjects with chronic headache felt that they should have taken the drug before or at the onset of pain (Table 4).

**Behavior When Onset of Headache was on a Working Day or on a Day Off.** —On working days, only 13% of the sample group reported they had to break off work; instead 52% continued after taking an analgesic and 35% did not take anything. If the headache came on during their day off, 44% of patients stopped whatever they were doing; 38% took an analgesic and continued their activity; while 18% carried on regardless, without taking anything. The behavior of the patients was, thus, significantly different according to where onset occurred (chi-square = 65.99, *P*<0.0001 ).

During a working day, the percentage of subjects who said they stopped work due to the

**Table 4. —Time Patients Believed it Better to Take the Drug and When They Really Took Analgesic Drugs in the Course of Their Headache**

Time	Believed Better*		Really Took**	
	Episodic Headache Group (n=182)	Chronic Headache Group (n=76)	Episodic Headache Group (n=182)	Chronic Headache Group (n=76)
Before onset	6.6	19	3.3	4
At onset	42.9	4.7	39	44.7
When the pain became unbearable	50.5	46.4	57.7	51.3

Values given in percentages.

\*Chi-square = 1.91, *P*=NS.

\*\*Chi-square = 0.88, *P*=NS.

headache was small and identical in the two groups. The majority of subjects with chronic headache, as opposed to those with episodic headache, did not stop their activity when the headache came on a day off, but took an analgesic and carried on with what they were doing (Table 5).

## COMMENTS

The great reliance on the practice of self-medicating with OTC analgesics among people suffering from headache cannot be exclusively attributed to the lack of therapeutic alternatives. Instead, our survey showed that self-medication was the preferred choice for acutely treating the disorder in 54% of subjects who had been suffering severe and debilitating headache over a period of many years. Though all had already been prescribed at least one analgesic drug, only 43% of the sample said they actually used it. It is interesting to note that our data, although obtained from a limited sample of subjects and bearing in mind that Italians do not often resort to self-medication, are similar to results obtained from larger samples taken from the general population and in the United States.<sup>6,7</sup>

In our sample, the preference for self-medication was not a substitute for or an alternative to medical assistance, nor did it seem to affect the search for other solutions. In fact, these people did turn both to their GPs and to our center. Rather, headache patients seem to consult specialists for a different reason (ie, explanations about their headache) than for pain relief.<sup>18,19</sup> Indeed, our patients showed a marked reluctance to use analgesics: 8% did not take them at all and 56% admitted using them only when the pain became unbearable. They also admitted that maybe they waited too long before taking the analgesic. In all, 51% thought it correct to take the analgesic before or at onset of the headache, but only 44% of patients actually followed this course. This ambivalence was even more evident among the CH group: the majority thought it would be better to take the drug before or at onset of the headache, but they did just the opposite, delaying as long as possible the consumption of the drug. To be stoic in the face of pain on the part of headache sufferers is common to hospitalized and cancer patients, many of whom use analgesics with extreme caution, only taking them when the pain is extremely intense and stating they are satisfied with the antalgic treatment even when the physician is not so sure of its efficacy. In such patients, the resistance to analgesic use could be due to fear of becoming dependent and resignation to what is seen as the inevitability of pain.<sup>20</sup> From our survey, it seems that the decision to use analgesics or not depends more on the circumstances than the pain in itself. On working days, the majority (52%) took the drug and continued working; while during a day off, only 38% took the analgesic in order to go on with their leisure activity in spite of the headache. This tendency to sacrifice preferentially social and family activities rather than work, also found by other authors,<sup>7,21</sup> might represent an attempt to limit intake of drugs even if the subject's quality of life might be compromised. On the basis of the foregoing, it is not at all obvious that the availability of better drugs will lead directly to a greater benefit for the patients. For example, in different contexts, the improvement in the quality of life obtained with use of sumatriptan in clinical trials might be less than

**Table 5.—Patients' Behavior When Headaches Started on a Working Day and on a Day Off**

Behavior	Working Day*		Day Off**	
	Episodic Headache Group (n=196)	Chronic Headache Group (n=84)	Episodic Headache Group (n=196)	Chronic Headache Group (n=84)
Went on working/activities without taking any drug	38.8	26.2	16.3	22.6
Took an analgesic and went on working/activities	47.9	60.7	35.2	4.52
Interrupted work/activities	13.3	13.1	48.5	32.1

Values given in percentages.

\*Chi-square = 4.51, *P*=NS.

\*\*Chi-square = 6.42, *P*<0.05.

expected. In our survey, 49% of subjects prescribed this drug did not in fact take it.

These patients had appropriately received a prescription for sumatriptan, considering their general clinical conditions, diagnoses, and severity of migraine. We have no information about the behavior of the prescribing physician, in particular on the instructions given to patients. It is possible that sumatriptan had been perceived simply as an additional symptomatic drug, with the disadvantage of being more expensive. (In Italy, the patient has to pay 50% of the cost of this drug for both oral and parenteral formulations.)

However, it must be underscored that prescription analgesics for relief of acute attacks were underused by those to whom they were given: only 40.9% of subjects with episodic headaches took them. Conversely, 46.5% of patients with chronic headache consumed them. In this group, where the problem is often that of limiting the use of analgesics, a greater propensity to use the drugs was observed, even when work matters were not involved. When the headache came on during a day off, 45.2% of chronic sufferers took the drug; whereas only 35.2% of episodic headache sufferers did. This data reflects the danger of analgesic abuse in patients with chronic headache. Since in our case studies EH and CH groups did not differ in pain intensity, it is probably the chronicity of the headache rather than severity which leads to more ready consumption of the analgesic.

Nevertheless, our patients' behavior suggested a tendency opposite to drug abuse: most subjects suffering from frequent and severe attacks were extremely cautious about drug use, with the possible risk of enduring pain that, at least in part, could have been avoided.

We did not investigate the motivations and factors that might have induced our patients to state their opinions and behaviors. We can not fully rely on the validity of self reported analgesic drug use. For instance, patients might have underestimated the actual drug use for fear of being stigmatized as drug abusers, or otherwise might have overestimated it, in the attempt to underscore the importance of their headache. Furthermore, since the questionnaire was completed before the medical examination, the patients/subjects might have tried to give answers they believed the doctor wanted. By including two specific questions, however, one regarding how the patient thinks they should behave and the other concerning their actual behavior, our intention was to encourage them to state how their actions and thoughts might be at odds.

Our findings cannot be generalized, since they were obtained in a selected sample of patients; possibly other populations and settings may yield different results.

Despite these limitations, from our survey it emerges that the majority of patients suffering from a high frequency, intensity, and duration of headaches and who attended a specialty center were wary of taking analgesics drugs, which they took only when the pain became unbearable in order to carry on working. Overall, they felt it better to use OTCs. This behavior might be the expression of a conflict between the true severity of the pain they suffer and the way society perceives headaches as being banal, benign, and subjective.<sup>22</sup> Since it is patients who ultimately decide whether to take a drug or not, we think that it is crucial to estimate patients' beliefs and attitudes in order to optimize acute headache treatment and improve their quality of life.

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#### **Appendix.—Questions on Drug Taking and Patient Behavior**

Here we ask you to give one response to the following questions:

- (A) When you are suffering from headache, which of the following do you think it best to take?
- (1) an OTC analgesic
  - (2) an analgesic prescribed by a doctor
  - (3) nothing
- (B) When you are suffering from headache, do you think it better to take the analgesic drug:
- (1) before onset of pain
  - (2) when the pain starts
  - (3) when the pain has become unbearable
  - (4) you do not take analgesic drugs
- (C) If your headache comes on during a working day, how do you normally react?
- (1) Do you continue to work without taking analgesics?

- (2) Do you take an analgesic drug and continue to work?
  - (3) Do you stop work and go home?
- (D) If your headache comes on during your day off, how do you normally react?
- (1) Do you carry on regardless without taking drugs?
  - (2) Do you carry on doing whatever you were doing after taking an analgesic drug?
  - (3) Do you stop whatever you are doing and go to bed?
- (E) When you are suffering from headache, do you normally take:
- (1) an OTC analgesic
  - (2) an analgesic prescribed by a doctor
  - (3) you do not take analgesic drugs
- (F) When you are suffering from headache, do you normally take an analgesic drug:
- (1) before onset of pain
  - (2) when the pain comes on
  - (3) when the pain becomes unbearable
  - (4) you do not take analgesic drugs

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