

Prevalence of Migraine in Patients With a History of Self-reported or Physician-Diagnosed “Sinus” Headache

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Background: Symptoms referable to the sinus area are frequently reported during migraine attacks, but are not recognized in diagnostic criteria. Underrecognition of migraine may be partly attributed to a variable clinical presentation, and migraines with “sinus” symptoms contribute to this problem. This study was conducted to determine the prevalence of migraine-type headache (International Headache Society [IHS]-defined migraine without aura [IHS 1.1], migraine with aura [IHS 1.2], or migrainous disorder [IHS 1.7]) in patients with a history of self-described or physician-diagnosed “sinus” headache.

Methods: During a clinic visit, patients with a history of “sinus” headache, no previous diagnosis of migraine, and no evidence of infection were assigned an IHS headache diagnosis on the basis of headache histories and reported symptoms.

Results: A total of 2991 patients were screened. The majority (88%) of these patients with a history of self-described or physician-diagnosed “sinus” headache were diagnosed at the screening visit as fulfilling IHS migraine criteria (80% of patients) or migrainous criteria (8% of patients). The most common symptoms referable to the sinus area reported by patients at screening were sinus pressure (84%), sinus pain (82%), and nasal congestion (63%).

Conclusions: In this study, 88% of patients with a history of “sinus” headache were determined to have migraine-type headache. In patients with recurrent headaches without fever or purulent discharge, the presence of sinus-area symptoms may be part of the migraine process. Migraine should be included in the differential diagnosis of these patients.

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OVER THE PAST DECADE, the ability of clinicians to help migraine sufferers to achieve meaningful control of acute episodes of migraine has increased substantially because of significant advances in knowledge about the pathophysiology of migraine; new, more effective treatment options; and a better understanding of how to manage migraine in clinical practice. Despite these advances, the percentage of the migraine population who report having been diagnosed with migraine increased only modestly over the 10-year period between 1989 and 1999, and an estimated half of the 28 million individuals with migraine in the United States remain undiagnosed.^{1,2} Recent research suggests that, among the factors contributing to underrecognition of migraine, the variability in its clinical presentation may be one of the most important. Specifically, migraine can be accompanied by symptoms commonly associated with other headache types, a factor that may confuse attempts at diagnosis.^{3,4} “Sinus” headache may con-

stitute one of the most commonly confused clinical presentations of migraine.

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Headache associated with acute sinusitis can occur but is regarded as being relatively rare.^{3,5-8} Patients with this presentation most commonly have other clinical manifestations of sinusitis such as purulent nasal discharge and pathologic radiographic findings. The International Headache Society (IHS) recognizes acute sinus headache (IHS 11.5.1) but states that it occurs in conjunction with acute sinusitis and includes fever and purulent discharge as part of the diagnostic criteria.⁸ The IHS further states that chronic sinusitis (IHS 11.5.2) is not validated as a cause of headache or facial pain unless it relapses into an acute phase.

Sinus-associated symptoms such as runny nose, congestion, and ocular symptoms can frequently occur in migraine.^{3,5,9} In one study (n=177), approximately half of patients (46%) with IHS-defined mi-

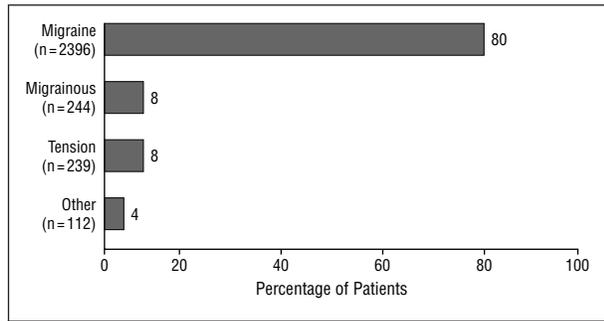


Figure 1. Physician diagnoses of 2991 patients with “sinus” headache according to self-description or previous physician diagnosis.

graine with or without aura experienced unilateral nasal and/or ocular symptoms such as watery eyes, nasal congestion, and runny nose with their headaches.⁹ The lack of awareness that sinus and nasal symptoms can be common in migraine may account for the finding that patients with IHS-defined migraine are often diagnosed with “sinus” headache but not with migraine. In the 1999 US population-based American Migraine Study II, 40% of respondents meeting IHS criteria for migraine, or an estimated 11.1 million Americans, reported a physician diagnosis of “sinus” headache with or without additional headache types.^{3,4} Of those meeting IHS criteria for migraine who were not diagnosed with migraine, 42% were diagnosed with “sinus” headache. Data from a small (n=47), clinic-based pilot study extend these findings by suggesting that patients with self-described “sinus” headache often meet IHS criteria for migraine but are not diagnosed with migraine.³ Nearly all patients (98%) with self-described “sinus” headache met IHS criteria for migraine-type headache (ie, migraine with or without aura or migrainous disorder).

Results of the latter study suggest that overdiagnosis of “sinus” headache contributes to the underrecognition of migraine; however, the small sample size of the study precludes definitive conclusions about the data. The study described herein was conducted to extend earlier observations by using a large, clinic-based sample to determine the prevalence of IHS-defined migraine without aura (IHS 1.1), migraine with aura (IHS 1.2), and migrainous disorder (IHS 1.7) in patients with a history of self-described or physician-diagnosed “sinus” headache.

METHODS

PATIENTS

Male and female patients aged 18 to 65 years were eligible if they had experienced at least 6 self-described or physician-diagnosed “sinus” headaches during the 6 months before screening. Exclusion criteria included prior diagnosis of migraine or use of triptans; radiographic evidence of sinus infection within the past 6 months; and the occurrence of fever or purulent/discolored nasal discharge indicative of infection or postnasal drainage with their self-described “sinus” headaches. All patients provided written, informed consent to participate in the study.

PROCEDURES

This protocol for this prospective, open-label, observational study (GlaxoSmithKline protocol SUM40294) was approved by in-

stitutional review boards for each of the 452 North American primary care study sites. During a clinic visit, patients completed the 6-question Headache Impact Test (HIT-6), a headache disability assessment tool¹⁰; rated their satisfaction with current headache medication (*very dissatisfied, dissatisfied, somewhat dissatisfied, neither satisfied nor dissatisfied, somewhat satisfied, or very satisfied*); and recorded characteristics of their headaches. On the basis of patients’ headache histories and reported symptoms, clinicians recorded an IHS headache diagnosis (IHS 1.1 [migraine without aura], 1.2 [migraine with aura], 1.7 [migrainous], 2.1 [episodic tension-type], or other). Patients diagnosed at the screening visit with migraine by IHS 1.1 or 1.2 were entered into a treatment phase and the remainder were discontinued from the study. The treatment results, which are open-label, were not primary end points of the study and are reported elsewhere.¹¹

END POINTS AND DATA ANALYSES

The primary end point was the percentage of patients with a history of self-reported or physician-diagnosed “sinus” headache who were assigned IHS 1.1 or 1.2 diagnoses during the clinic visit. Baseline data including characteristics of typical prestudy headaches, mean HIT-6 score, and percentage of patients satisfied with prestudy headache medication were also summarized. The HIT-6, previously shown to be reliable and valid, comprises 6 questions measuring the impact of headaches on functional ability.¹⁰ Total score ranges from 36 to 78. The higher the score, the greater the headache impact. Scores of 60 and above, the highest HIT-6 headache impact category, reflect very severe headache-related impact on functional ability.

All data were summarized by using descriptive statistics. No formal statistical tests were performed.

RESULTS

PREVALENCE OF MIGRAINE IN PATIENTS WITH A HISTORY OF “SINUS” HEADACHE

The number of patients screened for the study was 2991. Most (80%; n=2396) of these patients with a history of self-described or physician-diagnosed “sinus” headache were diagnosed at the clinic visit as fulfilling IHS criteria for migraine without aura (IHS 1.1) or migraine with aura (IHS 1.2) (**Figure 1**). Most of the 2396 patients with IHS 1.1 or 1.2 diagnoses were white women (**Table**). Patients’ mean age was 39.3 years.

BASELINE HEADACHE CHARACTERISTICS OF PATIENTS WITH A MIGRAINE DIAGNOSIS

At screening, patients with IHS 1.1 or 1.2 diagnoses reported a prestudy history of a mean of 3 “sinus” headaches per month. Typical “sinus” headache pain was reported to be moderate or severe by 97% of patients; and mean HIT-6 score was 62.8, a value reflecting very severe headache impact. Most patients with IHS 1.1 or 1.2 diagnoses reported typical migraine characteristics such as worsening of pain with physical activity, nausea, pulsating/throbbing pain, photophobia, and phonophobia (**Figure 2**). Most patients with IHS 1.1 or 1.2 diagnoses also reported characteristics that are typically associated with “sinus” headache, such as sinus pressure, sinus pain, and nasal congestion.

More than two thirds (67%) of patients with IHS 1.1 or 1.2 diagnoses expressed some degree of dissatisfac-

Demographics, Patient Disposition, and Headache Characteristics of 2396 Patients Diagnosed at Screening With International Headache Society–Defined Migraine (1.1 or 1.2)

Variable	Value
Female, No. (%)	1837 (77)
Ethnicity/race, No. (%)	
White	2041 (85)
Black	148 (6)
Asian	58 (2)
American Hispanic	130 (5)
Other	19 (<1)
Age, mean (SD), y	39.3 (10.9)
No. of “sinus” headaches per month, mean (SD)	3.3 (2.9)
Typical “sinus” headache pain, No. (%)	
No pain	0
Mild	61 (3)
Moderate	1218 (51)
Severe	1117 (47)
HIT-6 score,* mean (SD)	62.8 (6.6)
Satisfaction with “sinus” medication use before the study,† No. (%)	
Very dissatisfied	402 (17)
Dissatisfied	639 (27)
Somewhat dissatisfied	572 (24)
Neither satisfied nor dissatisfied	247 (10)
Somewhat satisfied	413 (17)
Satisfied	94 (4)
Very satisfied	28 (1)
Usual prestudy headache therapy,‡ No. (%)	
Nonnarcotic analgesics	1770 (74)
Nonsteroidal anti-inflammatory drugs	1733 (72)
Decongestants	1349 (56)
Antihistamines	1144 (48)
Combination drugs	762 (32)
Narcotic analgesics	339 (14)

*n = 2350; HIT, Headache Impact Test.

†n = 2395.

‡Patients could name more than 1 prestudy headache therapy.

tion with the medication that they used to treat their “sinus” headaches. Most common prestudy headache medications included nonnarcotic analgesics, nonsteroidal anti-inflammatory drugs, decongestants, and antihistamines (Table).

COMMENT

The results of this primary care clinic-based study involving approximately 3000 patients show that patients with a history of self-described or physician-diagnosed “sinus” headache and no previous diagnosis of migraine commonly met IHS criteria for migraine or migrainous headache. Physicians determined that 80% of patients met IHS criteria for migraine without or with aura, and 8% met IHS criteria for migrainous headache. These findings corroborate the results of an earlier pilot study (n = 47) in which 98% of patients with at least a 1-year history of self-described “sinus” headache met IHS criteria for migraine or migrainous headache.³ Considered together, the data demonstrate that patients and physicians commonly label migraine attacks that have “sinus” features as sinus headache.

Patients’ and health care providers’ failure to recognize migraine may have arisen from the pattern of symp-

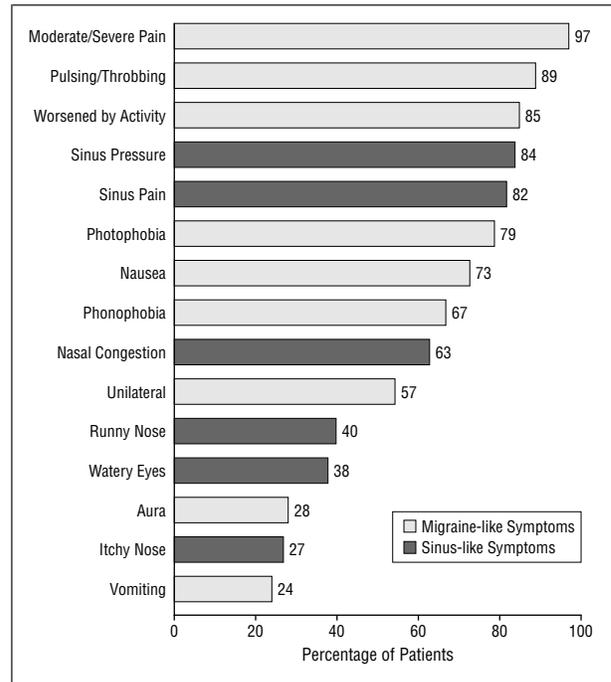


Figure 2. Percentage of 2396 patients with International Headache Society–defined migraine reporting sinus- and migraine-associated symptoms at the clinic visit.

oms these patients experienced. Although most patients reported typical migraine symptoms such as photophobia and phonophobia, the majority also reported nasal and ocular symptoms. These symptoms are traditionally associated with sinus headache but not migraine. The study did not delineate patients who were self-identified as having “sinus” headache vs those who were physician diagnosed. The failure to recognize typical migraine symptoms in the presence of sinus area symptoms can be patient or physician driven. Lipton et al¹² reported that “sinus” headache is one of the most commonly reported terms used by undiagnosed migraineurs to identify their headaches. Diamond¹³ reported that many migraineurs may receive a “sinus” headache diagnosis instead of or in combination with a migraine diagnosis. Dowson et al¹⁴ have also reported in large study evaluating diagnoses by diaries that physicians are more likely to diagnoses migraine when patients self-report a migraine diagnosis and consistently experience the better known features of migraine. Thus, epidemiological studies suggest that confusion of “sinus” headache and migraine may be driven by both patients and physicians.

The tendency to conceptualize nasal and ocular symptoms as being uncharacteristic of migraine may be attributed in part to IHS criteria, which do not list these symptoms as criteria for assigning a migraine diagnosis. The IHS criteria notwithstanding, headache experts describing their clinical experience note the frequent occurrence of nasal and ocular symptoms in migraine,^{5,15} and their observations have been borne out in clinical studies. For example, in the 47-patient pilot study reported above, 74% of patients with IHS-defined migraine reported stuffiness, and 60% of patients reported runny nose with their headaches.³ Likewise, in a study

of 177 consecutively consulting patients meeting IHS criteria for migraine, 46% reported unilateral nasal or ocular symptoms, including lacrimation, conjunctival injection, and nasal congestion, with their migraine headaches.⁹ Also, patients may conceptualize these symptoms as “sinus,” as advertising of over-the-counter sinus medications has repeatedly conveyed that pounding pain associated with these symptoms are “sinus” headache.

In clinical practice, recognizing that patients with episodic headaches predominated by nasal and sinus symptoms actually suffer from migraine is critically important because accurate diagnosis determines the appropriate course of treatment. Particularly for patients whose HIT-6 scores at the screening visit reflected very severe headache impact, migraine-specific therapy is most likely to relieve pain and to restore functional ability. Symptom-targeted therapies such as antihistamines and decongestants may treat the nasal and ocular symptoms but generally are not considered to be therapies that would relieve migraine pain and associated symptoms.

The occurrence of nasal or ocular symptoms in migraine is not surprising given the neurophysiology of the sinuses. The neural innervation of the sinuses comprises trigeminal fibers, which are known to be involved in migraine pathogenesis, as well as parasympathetic and sympathetic fibers, which can be activated by trigeminal stimulation.³ Migraine-associated alterations in trigeminal and/or autonomic activity may explain nasal and ocular symptoms in migraine. For example, “sinus” symptoms in migraine have been hypothesized to arise from activation of the trigeminal-autonomic reflex, which is mediated by a circuit of trigeminal afferents and parasympathetic efferents that innervate the lacrimal glands and the nasal mucosa.⁹

The results of the present study, while representative of a clinic population sufficiently affected by their headaches to consult doctors for them, may not generalize to the general population composed of consulters and non-consulters with headache. Furthermore, the results may not be wholly representative of headache consulters in that patients with headaches meeting criteria for IHS 11.5.1, or acute sinus headache, were not enrolled in the study. The IHS diagnostic criteria for acute sinus headache, or diagnosis code 11.5.1, include (1) purulent nasal discharge; (2) pathological sinus findings in tests including radiography, computed tomography, or magnetic resonance imaging, and/or transillumination; (3) simultaneous onset of headache and sinusitis; and (4) headache localized to specific facial and cranial areas near the sinuses.⁸ All 4 criteria must be present to diagnose sinus headache. Also, in this study, no comparisons can be made between these patients with self-described vs physician-diagnosed “sinus” headache nor to patients with documented “sinus” headache. As allergists and neurologists contend that “sinus” headache is rare even among patients with sinus infection, one must question what is documented “sinus” headache, especially in the absence of infection? These areas require further investigation.

In conclusion, in this study, 88% of patients with a history of self-described or physician-diagnosed “sinus” headache were determined to have migraine-type headache (ie, IHS-defined 1.1, 1.2, or 1.7 [migrainous]

headache). Patients experienced sinus pain, sinus pressure, nasal symptoms, and ocular symptoms as features of migraine. Patients were significantly impacted by their “sinus” headaches, and they were dissatisfied with their pre-study headache medications, none of which was a migraine-specific therapy. The results indicate that the presence of nasal or ocular symptoms often considered to be features of “sinus” headache should not automatically trigger a sinus diagnosis or exclude a diagnosis of migraine but should prompt assessment of the patient for migraine as well as sinus headache. Accurate diagnosis of headache is essential for patients to receive appropriate therapy and to achieve an optimal treatment outcome.

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