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Research Submission

Defining Refractory Migraine: Results of the RHSIS Survey of American Headache Society Members

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Objectives.—To gauge consensus regarding a proposed definition for refractory migraine proposed by Refractory Headache Special Interest Section, and where its use would be most appropriate.

Background.—Headache experts have long recognized that a subgroup of headache sufferers remains refractory to treatment. Although different groups have proposed criteria to define refractory migraine, the definition remains controversial. The Refractory Headache Special Interest Section of the American Headache Society developed a definition through a consensus process, assisted by a literature review and initial membership survey.

Design.—A 12-item questionnaire was distributed at the American Headache Society meeting in 2007 during a platform session and at the Refractory Headache Special Interest Section symposium. The same questionnaire was subsequently sent to all American Headache Society members via e-mail. A total of 151 responses from AHS members form the basis of this report. The survey instrument was designed using Survey Monkey. Frequencies and percentages of the survey were used to describe survey responses.

Results.—American Headache Society members agreed that a definition for refractory migraine is needed (91%) that it should be added to the International Classification of Headache Disorders-2 (86%), and that refractory forms of non-migraine headache disorders should be defined (87%). Responders believed a refractory migraine definition would be of greatest value in selecting patients for clinical drug trials. The current refractory migraine definition requires a diagnosis of migraine, interference with function or quality of life despite modification of lifestyle factors, and adequate trials of acute and preventive medicines with established efficacy. The proposed criteria for the refractory migraine definition require failing 2 preventive medications to meet the threshold for failure. Although 42% of respondents agreed with the working definition of refractory migraine, 43% favored increasing the number to 3 (50%) or 4 (26%) preventive treatment failures. When respondents were asked if they felt that the proposed definition was appropriate to select patients for invasive procedures (patent foramen ovale repair or stimulators) only 44% agreed.

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Conflict of Interest: None

Conclusions.—There is a consensus for a need for a definition for refractory migraine and that it should be added to the International Classification of Headache Disorder-2. There was also general agreement by the responders that refractory forms of non-migraine headache disorders should be defined.

Key words: migraine, definition, refractory, survey

Abbreviations: AHS American Headache Society, Committee Definition Committee, ICHD-2 International Classification of Headache Disorders-2, PFO patent foramen ovale, RH refractory headache, RHSIS Refractory Headache Special Interest Section, RM refractory migraine

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Despite advances in headache therapies, some patients do not satisfactorily respond to or cannot tolerate current evidence-based treatments. This group of patients is often said to have refractory headache (RH). Although the concept of RH has a long history, there have been few attempts to formalize an operational definition.[1] The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) includes "intractable" as a modifier for migraine (including chronic migraine), but is not formally defined.[2] Goadsby et al were the first to propose specific operational criteria for intractable migraine and cluster headache based on an international consensus panel.[3]

To further develop a definition, the Refractory Headache Special Interest Section (RHSIS) of the American Headache Society (AHS) attempted to refine the definition of RH.[4] In March of 2006, a 16-item self-administered Internet questionnaire was sent to AHS members.[5] Respondents were asked for their opinion on various aspects of RH, including duration, associated disability, response to medications, and whether RH should be considered as an addition to the current International Classification of Headache Disorders-2 (ICHD-2) classification.

Of respondents, 64% believed RH should occur ≥15 days per month and 55% believed it should be associated with disability. A total of 79% of those answering the survey believed the definition of RH should include an inadequate response to multiple abortive and preventative medications and 57.5% believed it should be added to the ICHD-2 while 8.5% were opposed and 34% were unsure whether it should be added.

The Definition Committee of RHSIS (Committee) proposed criteria for RM utilizing the first survey results, a review of the literature, and collaborative discussions (Table 1). As part of the validation process, the Committee distributed a second survey assessing agreement among AHS members with the major components of the definition[6] (Appendix). The major components contained in the RM definition included (1) meeting the criteria of ICHD-2 Migraine or Chronic Migraine; (2) headaches that cause significant interference with function or quality of life despite modification of triggers, lifestyle factors; (3) adequate trials of acute medication; and (4) adequate trials of preventive medicines with established efficacy. The proposed criteria also added modifiers for RM with medication overuse and disability. We present herein the results of that survey and our proposal for revising the definition.

METHODS

A 12-item questionnaire was distributed at the AHS meeting in 2007 during a platform session and at the RHSIS symposium. The same questionnaire was subsequently sent to all AHS members via e-mail. If members had already completed the questionnaire at the 2007 AHS meeting, they were asked not to complete the survey again. At the AHS meeting, we collected 90 completed surveys from AHS members. An additional 91 surveys were obtained by e-mail, but results were usable in only 61 subjects. A total of 151 responses from AHS members form the basis of this report. The survey instrument was designed using Survey Monkey.[7] AHS surveys collected during the AHS meeting were manually entered into the Survey

Table 1.—Proposed Criteria for Definition of Refractory Migraine and Refractory Chronic Migraine

Primary diagnosis	A. ICHD-II Migraine or Chronic Migraine B. Headaches cause significant interference with function or quality of life despite modification of triggers, lifestyle factors, and adequate trials of acute and preventive medicines with established efficacy. 1. Failed adequate trials of preventive medicines, alone or in combination, from at least two (2) of four (4) drug classes: a. Beta blockers b. Anticonvulsants c. Tricyclics d. Calcium channel blockers 2. Failed adequate trials of abortive medicines from the following classes, unless contraindicated: a. *Both* a triptan *and* DHE intranasal or injectable formulation b. *Either* non-steroidal anti-inflammatory drugs (NSAIDs) *or* combination analgesics
Adequate trial	Period of time during which an appropriate dose of medicine is administered, typically at least two (2) months at optimal or maximum-tolerated dose, unless terminated early due to adverse effects.
Modifiers	1. With or without medication overuse, as defined by ICHD-II 2. With significant disability, as defined by MIDAS score ≥11

Monkey database, while survey responses obtained via e-mail were entered via automated direct data entry. Frequencies and percentages of the survey were used to describe survey responses. Not every respondent answered all questions of the survey, and thus, percentages for each question were based on the total number of responses for that particular question. Comparisons in survey responses by demographic characteristics were accomplished using Fisher's exact statistics.

RESULTS

Respondents.—Of the 1472 members of AHS, 151 (11%) participated in the survey. The demographic characteristics of the 151 respondents are provided in Table 2 along with the collected characteristics of all AHS members; the sample had a mean age of 49 years and 66% were male. Of the respondents, 70% were neurologists, 73% had been in practice for at least 10 years, and 69% devoted at least half their professional time to headache. Participants were similar to the broader membership of AHS.[8]

Need for and Purposes in Defining Refractory Migraine.—There was overwhelming agreement with a need for the definition of RM. As seen in Table 3, 91% of respondents either strongly agreed or agreed there was a need for such a definition. This did not significantly vary by specialty, years in practice, or proportion of time devoted to the practice of headache.

Table 2.—Demographics of Respondents and AHS

	Survey respondents	AHS membership
Gender		
Male	94 (66%)	
Female	55 (33%)	
Age in years		
Mean	49	50-60 most common range
Median	50	
Specialty		
Neurology	68 (70%)	54%
Internal medicine/FP	7 (7%)	
Psychiatry/psychology	3 (3%)	66% MD/17% PhD
NP/PA	3 (3%)	
DDS	2 (2%)	
Other	14 (14%)	
Years in practice		
1-4	22 (15%)	80% are in clinical practice
5-9	18 (12%)	
10-14	14 (10%)	
15-19	35 (24%)	
>20	57 (39%)	>50%
Proportion of professional time devoted to headache		
<25%	12 (8%)	
25-49%	34 (23%)	
50-75%	29 (20%)	
>75%	71 (49%)	

Table 3.—Response to Survey Question: There is a Need for a Definition of Refractory Migraine†

Demographic characteristic	Strongly agree/agree	Neutral	Disagree strongly	*P* value‡
All responders (n = 147)	91% (134)	5% (8)	5% (5)	n/a
Specialty				
Neurology (n = 68)	93% (63)	3% (2)	4% (3)	.5305
Other (n = 29)	86% (25)	7% (2)	7% (2)	
Years in practice				
<10 years (n = 39)	95% (37)	0% (0)	5% (2)	.1145
≥10 years (n = 103)	90% (93)	8% (8)	2% (2)	
Proportion of time devoted to patient care				
<50% (n = 45)	93% (42)	7% (3)	0% (0)	.4150
≥50% (n = 97)	91% (88)	5% (5)	4% (4)	

†Responses expressed in percent based on total number of responders to survey question and to the demographic characteristic being reported.
‡*P* value based on Fisher's exact test.

Respondents were asked to select one or more listed applications for the definition as being important. As demonstrated in Table 4, those chosen included selecting patients for clinical drug trials (chosen by 85% of responders), for use in epidemiologic studies (77%), and in identifying those in need of treatment by headache specialists (72%). In comparison to those in practice for less than 10 years, those who were in practice for 10 years or more were more likely to favor using the RM definition in clinical trials of drug (89% vs 75%) and invasive devices (75% vs 58%). Assessment of the importance of the definition did not vary by specialty or percent of time devoted to the practice of headache medicine.

Table 4.—Response to Survey Question: Which of the Applications of a Definition of Refractory Migraine Are Important?†

Demographic characteristic	Identifying those in need of treatment by headache specialists	Identifying those in need of specific treatment modalities	Selecting patients for clinical drug trials	Selecting patients for invasive treatment trials	For use in epidemiologic studies
All responders (n = 151)	72% (108)	72% (109)	85% (128)	70% (106)	77% (116)
Specialty					
Neurology (n = 68)	71% (48)	81% (55)	90% (61)	78% (53)	81% (55)
Other (n = 29)	79% (23)	79% (23)	86% (25)	66% (19)	76% (22)
P value‡	.4580	.9999	.7285	.2144	.5916
Years in practice					
<10 years (n = 40)	68% (27)	70% (28)	75% (30)	58% (23)	73% (29)
≥10 years (n = 106)	74% (78)	74% (78)	89% (94)	75% (79)	78% (83)
P value‡	.5366	.6810	.0663	.0677	.5121
Proportion of time devoted to patient care					
<50% (n = 46)	61% (28)	63% (29)	78% (36)	70% (32)	74% (34)
≥50% (n = 100)	76% (76)	76% (76)	87% (87)	70% (70)	77% (77)
P value‡	.0768	.1165	.2219	.9999	.6817

†Responses expressed in percent based on total number of responders to survey question 2 and to the demographic characteristic being reported.
‡*P* value based on Fisher's exact test.

Table 5.—Response to Survey Question: Rank the Applications in the Order of Importance†‡

Application	Most important	Second in importance	Third in importance	Fourth in importance	Fifth in importance
Identifying those in need of treatment by headache specialists	40% (47)	16% (19)	13% (15)	9% (11)	9% (10)
Identifying those in need of specific treatment modalities	22% (26)	33% (39)	13% (15)	9% (10)	3% (4)
Selecting patients for clinical drug trials	18% (21)	23% (27)	32% (38)	9% (10)	9% (10)
Selecting patients for invasive treatment trials	9% (11)	10% (12)	14% (16)	32% (37)	15% (17)
For use in epidemiologic studies	9% (10)	8% (9)	20% (24)	20% (23)	23% (27)

†Responses expressed in percent based on total number of responders to survey question 3.1 (n = 117).
‡No significant differences by specialty, years in practice, or time devoted to patient care.

Participants were then asked to choose and rank the most important and second most important application of the RM definition. Table 5 presents the distribution of applications ranked by responders by order of importance for the definition of RH. When asked which application of a RM definition was the *most* important, respondents selected identifying patients in need of treatment by headache specialists (40%), identifying patients in need of inpatient treatment (22%), use in clinical trials of drugs (18%) or invasive devices (9%). When asked which application was second most important, respondent selected identifying those in need of specific treatment modalities (33%) and selecting patients for clinical drug trials (23%).

A total of 76% of responders indicated identifying patients in need of treatment by a headache specialist or inpatient treatment as the first or second most important applications for the definition. There was no statistically significant difference in either the first or second ranked applications by either specialty, years in practice, or percent of practice devoted to headache.

Revising the RM Definition.—In total, 42% of respondents would not want to change the working definition of RM for the application they ranked as most important, while 43% wanted to make changes for that application. The most frequently desired change, reported by 41% of respondents, was to increase the required number of failed preventative medication classes. The criteria required failure in 2 classes. Of those who desired a change, 50% would require 3 failed classes and 26% would require 4 failed classes. There was no statistically significant difference by either specialty, years in practice, or percent of practice devoted to headache.

Twenty-four percent of responders would modify the RM definition by increasing the number of failed acute treatments. Of these, 45% wanted to increase the number of failed acute treatments from 2 to 3, and 14% preferred to increase the number of failed acute treatments to 4. Of the responders in favor of changing the definition, 45% suggested changes either by increasing the number of failed preventives or abortive medications. Only 19% thought that modifying the definition required increasing both the number of abortive and preventives agents.

For the application which responders ranked as second most important, 61% would not change the definition. Twenty-four percent of the responders would increase the number of preventives necessary, of which 75% suggested increasing the failed preventives necessary from 2 to 3. Only 19% felt failing all 4 classes of preventives were necessary. Sixteen percent would increase the number of abortives one needed to fail, with 33% of these suggesting 3 abortive agents be failed, and 25% favoring 4.

Responders were largely in agreement that 2 months on a preventive at optimal or maximum-tolerated dose was an adequate trial. Sixty-eight percent either strongly agreed or agreed with this statement. Twenty-eight percent disagreed with this period of treatment, and 4% were neutral. Of those who thought 2 months was inadequate, most were in favor of a 3-month trial (85%).

When asked whether the definition was adequate for selecting patients for invasive trials such as PFO repair or stimulators, only 44% agreed or strongly agreed, while 34% were neutral, and 20% disagreed or strongly disagreed. There was no significant difference by specialty, years in practice, or percent of practice devoted to headache.

There was consensus on whether the definition of RM should be added to the ICHD-2. Eighty-six percent agreed or strongly agreed with this statement. There was agreement among responders that primary headache types such as tension type (56%), cluster (71%), and TACs (69%) were all candidates for the designation "refractory." There was also broad agreement with headache disorders other than migraine being designated as "refractory," with 87% of respondents agreeing or strongly agreeing with this statement. Those spending greater than 50% of their time on headache treatment or research were significantly more in favor of this designation (92%) than those spending less than 50% of their clinical time (74%). There was no significant difference by specialty or years in practice.

Finally, survey respondents were asked to comment on the proposed RM definition. There were a total of 111 comments from 68 respondents. Some suggested that the RM definition could be utilized for increased reimbursement in treatment of RM patients, justifying the use of botulinum toxin injections, or for insurance coding. In terms of the RM criteria, respondents commented that a failure of a minimum of 2 triptans might be added in the acute treatment criteria, while others suggested adding failure of SNRI's in the antidepressant class. Lastly, other comments included a better definition of what constitutes "failure" of a preventive.

DISCUSSION

The intent of the survey was to assess the views of AHS members on the proposed definition of refractory migraine. Despite obtaining responses from 11% of AHS members, our sample was broadly representative of AHS in terms of age and gender, specialty, and duration in practice. There was widespread agreement on the need for a definition of RM. Most respondents felt there was a need for the definition for RM, that it should be added, to the ICHD-2, and that criteria for refractory forms of other primary headache disorders should be developed.

In the present survey, 84% favored adding a formal definition for RM to the ICHD-2. This represents a 27% increase from the initial survey of AHS members. This may reflect the visibility given to RH via a proposed formal definition, recent literature, and a RHSIS symposium at the AHS annual meeting.

The Committee's primary impetus for generating the definition was to facilitate the appropriate level of care for refractory patients. Survey responders ranked as optimizing patient treatment as the most important need for a RM definition. There was agreement between the Committee and those responding to the survey that patient care was of paramount importance.

We selected only AHS members because of their interest in headache treatment and research. This group may be biased in favor of the need for defining and further study of RM. However, it is the authors' belief that this group is most able to contribute to the initiative at this stage because of their expertise and experience.

Though the vast majority of respondents supported the development of a RM definition, most favored one or more changes in the definition we proposed. In our current survey, 41% reported were in favor of modifying the criteria by increasing the required number of failed preventative medication classes to more than 2 out of 4 classes. There was extensive discussion by the Committee in selecting the appropriate number of preventives necessary to meet the criteria of "failure." While requiring failure of 3 classes may create a higher threshold to obtain higher intensity of treatment, it also would ensure greater specificity and uniformity. Acknowledging the criticism of the survey responders, the Committee agreed to increase the number of preventives required from 2 to 3.

Respondents to the survey indicated an interest in a variety of applications for the RM definition. It may be that the appropriate RM definition will vary with the context and the objectives of the user. The most suitable definition may be determined by the risks and benefits of the application. To identify

patients in need of referral to a specialist, a less restrictive definition is desirable. If a patient fails 3 preventives and meets the other criteria, the patient may be considered refractory to treatment at the primary care level. A majority of the respondents felt this definition was not stringent enough to identify those who would qualify for trials using invasive approaches. While the use of one definition that is inclusive is less cumbersome, invasive trials carry a higher risk of morbidity, and perhaps should be more stringent. If the goal is to apply the definition in epidemiologic research, then it is crucial to have an operational straightforward definition that can be reliably applied on a broad scale.

CONCLUSION

There was broad agreement on a need for a RM definition and its addition to the ICHD-2. Field testing will be necessary to clarify whether our current proposal distinguishes the group we intend to define, bearing in mind the competing issues of specificity and sensitivity. Further modifications to the definition may be necessary. In the interim, discussion has focused attention on the concept of RM. The increased visibility of the applications of the definition will ultimately benefit RM patients.

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APPENDIX

The RHSIS Survey

(*The Refractory Headache Special Interest Section Survey*)

Name: (Optional)_____E-mail or Phone #: (Optional)_____

Questions About You

Gender: ❑ Male ❑ Female **Age**:_____years old

Your specialty: ❑ Neurology ❑ Internal Medicine/Family Practice ❑ Psychiatry/Psychology ❑ Nurse Practitioner/ Physician Assistant ❑ Dentist ❑ Other_____

Years in Practice (Please do NOT count years in residency or training):

❑ 1-4 years ❑ 5-9 years ❑ 10-14 years ❑ 15-19 years ❑ ≥20 years

What proportion of your professional time is devoted to patient care, teaching and research related to headache?
❑ <25% ❑ 25-49% ❑ 50-75% ❑ >75%

Are you an AHS member? ❑ Yes ❑ No

Refractory Migraine Questions

1. **There is a need for a definition of Refractory Migraine?**
❑ Strongly agree ❑ Agree ❑ Neutral/Don't know ❑ Disagree Strongly
2. **Which of the following applications of a definition for Refractory Migraine are important or very important?**
Check all that apply

a. ❑ For use in clinical practice to identify patients in need of treatment by headache specialists.
b. ❑ For use in clinical practice to identify patients in need of specific treatment modalities such as inpatient treatment.
c. ❑ For use in clinical trials to identify patients potentially eligible for research using single or combination drug treatments.
d. ❑ For use in clinical trials to identify patients potentially eligible for research of invasive treatments such as PFO closure or occipital nerve stimulation.
e. ❑ For use in epidemiological studies to measure the prevalence and burden of specific groups of headache sufferers.
f. ❑ Other, specify_____

Appendix. (Cont.) The RHSIS Survey

(*The Refractory Headache Special Interest Section Survey*)

3. Of the applications of the definition listed above list them by letter (ie, 1 a) here in their order of importance to you. 1. _____ 2 _____ 3._____ 4._____ 5._____ **6**_____

4. How would you change the Refractory Migraine proposed definition for the purpose you ranked as most important in question 3? *Please check all that are applicable.*

a. ❑ No changes
b. ❑ A higher number of preventatives needs to have been failed. (How many?_____)
c. ❑ A fewer number of preventatives needs to have been failed. (How many?_____)
d. ❑ A higher number of abortives needs to have been failed. (How many?_____)
e. ❑ A fewer number of abortives needs to have been failed. (How many?_____)
f. ❑ Eliminate the disability modifier.
g. ❑ Other, specify_____

5. How would you change the Refractory Migraine proposed definition for the purpose you ranked as second most important above in question 3 (That is the one you ranked number 2?)

Please check all that are applicable.

a. ❑ No changes
b. ❑ A higher number of preventatives needs to have been failed. (How many?_____)
c. ❑ A fewer number of preventatives needs to have been failed. (How many?_____)
d. ❑ A higher number of abortives needs to have been failed. (How many?_____)
e. ❑ A fewer number of abortives needs to have been failed. (How many?_____)
f. ❑ Eliminate the disability modifier.
g. ❑ Other, specify_____

6. Two months, as stated in the current refractory migraine criteria, is sufficient to make a judgment as to whether a medication is an effective migraine preventive or not.

❑ Strongly agree ❑ Agree ❑ Neutral/Don't know ❑ Disagree ❑ Strongly disagree

Appendix. (Cont.) The RHSIS Survey

(*The Refractory Headache Special Interest Section Survey*)

7. How many months do you believe each individual headache preventative should be tried before reporting it as a failed preventative medication, when it is at the appropriate dose for headache prevention and it is tolerated by the patient?

❑ 2 months ❑ 3 months ❑ 4 months ❑ other (How many? _____months)

8. Do you believe the criteria in the current definition are appropriate to select patients who may be candidates for invasive procedures, such as PFO repair or stimulators?

❑ Strongly agree ❑ Agree ❑ Neutral/Don't know ❑ Disagree ❑ Strongly disagree

If no please explain:

9. A formal definition of Refractory Migraine should be added to the ICHD?

❑ Strongly agree ❑ Agree ❑ Neutral/Don't know ❑ Disagree ❑ Strongly disagree

10. Should headache disorders other than migraine be designated as refractory headache disorders?

❑ Strongly agree ❑ Agree ❑ Neutral/Don't know ❑ Disagree ❑ Disagree Strongly

11. If you agreed to question 10, which of the other headache disorders would you consider being modified by the term "refractory"?

❑ Tension-type headache ❑ Cluster headache
❑ All trigeminal autonomic cephalgias ❑ Secondary headaches
❑ Other, specify_____ ❑ I would not consider other headache disorders

12. Other comments or suggestions: