Prevalence of Migraine Sufferers Who Are Candidates for Prevention Therapy

Results from the American Migraine Prevalence and Prevention (AMPP) Study

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Disclosure

- The American Migraine Prevalence and Prevention (AMPP) study is an ongoing project funded by the National Headache Foundation via an unrestricted grant from Ortho-McNeil Neurologics, Inc.
- The data presented here are from the initial population screening phase of the project. Follow-up research is planned to assess headache-related impairment and the impact of prevention treatment.
- Dr. Silberstein is a consultant for Ortho-McNeil Neurologics, Inc.

Migraine Prevention Background

- Migraine prevalence in the US has been well established:
 - 5-6% Males
 - 17-18% Females
 - 12% Overall
- However, little research has been attempted to estimate the prevalence and patterns of migraine disability where prevention may be warranted.
- This study provides national level estimates of the need for migraine prevention.

AMPP Study Objectives

- To estimate prevalence of migraine sufferers in the general population.
- To define the prevalence of sufferers who might benefit from preventive treatment.
- To characterize the demographics of this group.
- To assess the disease burden among this group.

Methods

- In 2004, a validated migraine symptom screening survey was mailed to a representative sample of 120,000 US households from the NFO/TNS panel.
- Panel households are matched to US census based on:
 - Age and gender of household head
 - Household income and size
 - Urban Vs. rural residence
 - Census region
- Each household member with severe headache was asked to complete the screening survey.

Methods (continued)

- The self-administered survey included questions on:
 - Headache symptoms/features (to classify cases)
 - Headache-related impairment (none, some, severe or bed rest required)
 - Migraine Disability Assessment (MIDAS)
 - Headache frequency
- Headache frequency data were collected two ways:
 - A. About how often do your severe headaches occur?

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# in a week ___ OR # in a month ___ OR # in a year ___
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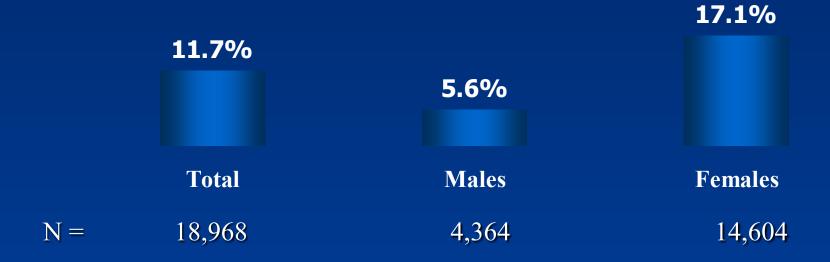
 B. On how many days in the last three months did you have a headache? (From MIDAS)
 # of days

Prevention need was estimated using both approaches, data for the more conservative approach "B" are presented here.

Results

- Of 120,000 households
 - 77,879 responded (65% household response)
- Of 257,339 individuals age 12+
 - 162,576 responded (63% individual response)
- Of 162,576 respondents age 12+
 - 30,721 had severe headache (18.9%)
 - 18,968 had migraine (11.7%)

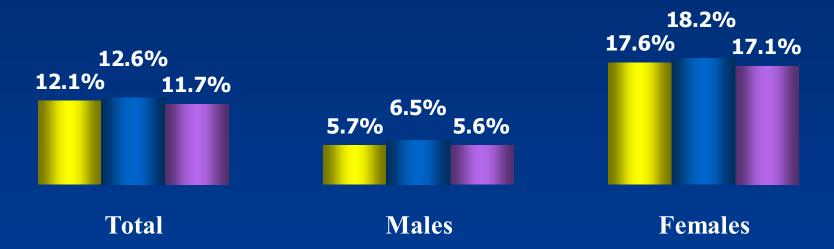
Estimated Migraine Prevalence From AMPP 2004 (ICDH-2 Symptom Criteria)



One Year Period Prevalence for Those Age 12+

2004 AMPP Prevalence Vs. Historical Data With Similar Methodology





One Year Period Prevalence for Those Age 12+

W.F. Stewart, et al. JAMA. 1992; 267:64-69 R.B. Lipton, et. al. Headache 2001; 41:646-657

Prevention Need

- The decision to use preventive treatment should be based on doctor-patient collaboration as well as:
 - Headache frequency
 - Headache-related impairment
- In this study self-reported past 3-month headache frequency data were obtained (via MIDAS) and standardized to an average month.
- Expert consensus opinion was used to classify individuals into those where:
 - Prevention should be "offered"
 - Prevention should be "considered"
 - Prevention is "not indicated"

Preventive Rx Need Among Migraine Cases (Past 3-month frequency)

How are you usually affected by severe headaches?	Monthly Migraine Days (# of Days in Last 3 Months - MIDAS)						
	≤1	2	3	4-5	6-10	11+	Total
Able to Work/ Function Normally	4.4%	0.6%	0.7%	0.6%	0.5%	0.4%	7.2%
Impaired to Some Degree	22.6%	3.5%	4.4%	3.5%	3.1%	2.0%	39.1%
Severe Impairment Bed Rest Required	33.0%	4.6%	5.2%	4.1%	3.9%	2.9%	53.7%
TOTAL	60.0%	8.8%	10.3%	8.2%	7.8%	4.9%	100% (N=18670

Offer Preventive Treatment = 25.7%

Consider Preventive Treatment = 13.1%

Not Indicated = 61.3%

Prevention Need

- The prevalence of migraine cases where preventive treatment should be offered totaled 25.7%.
 - This = 7.7 mm cases in the US
- Migraine cases where prevention should be considered totaled 13.1%.
 - This = 3.8 mm cases in the US
- Total prevention need sums to 11.5 mm cases in the US.

4 in 10 migraineurs are candidates

Prevalence estimates based on 2003 US Census data

Demographic Characteristics

(1 of 2)

	Consider						
	Offer Preventive Treatment (N=4,799)	Preventive Treatment (N=2,437)	Prevention Not Indicated (N=11,438)				
Gender							
Male	21.3%	19.7%	24.4%				
Female	78.7%	80.3%	75.6%				
Race							
Caucasian	88.1%	86.4%	87.4%				
African American	5.5%	7.3%	6.1%				
Other/No Answer	6.4%	6.3%	6.4%				
Spanish/Hispanic	3.4%	3.5%	3.5%				
Age							
12-17	3.4%	3.6%	5.1%				
18-29	18.2%	18.3%	15.5%				
30-39	23.6%	25.4%	22.0%				
40-49	27.2%	27.0%	26.5%				
50-59	18.5%	16.9%	19.8%				
60+	9.1%	8.7%	11.1%				
Mean	41.3	40.8	42.1				

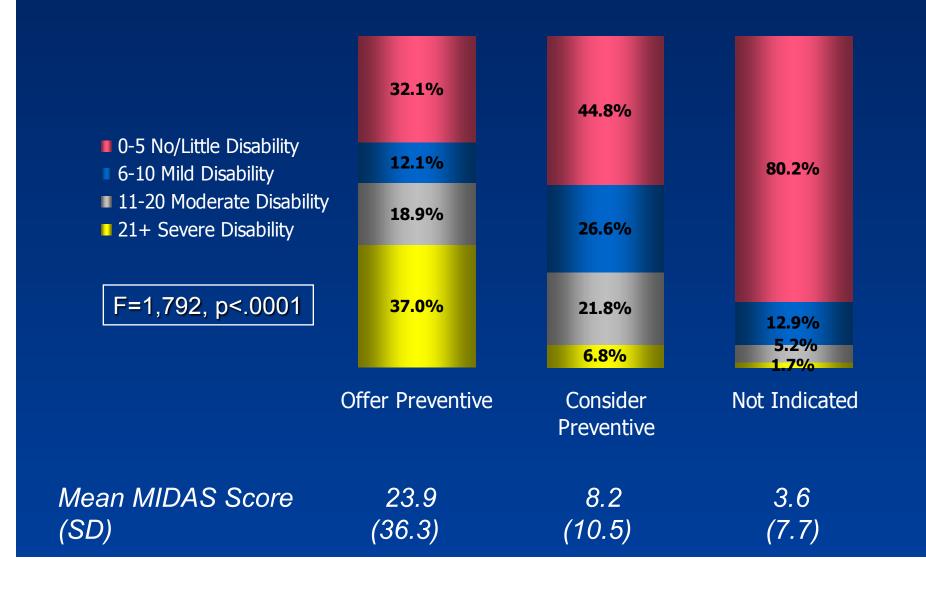
Demographic Characteristics

(2 of 2)

	Consider						
	Offer Preventive	Preventive	Prevention				
	Treatment	Treatment	Not Indicated				
	(n=4,799)	(n=2,437)	(n=11,438)				
Market Size							
<100,000	18.0%	16.9%	15.7%				
100,000-499,999	20.3%	18.3%	18.1%				
500,000-1,999,999	22.8%	22.5%	24.5%				
2,000,000+	38.9%	42.4%	41.7%				
Income							
Under \$22,500	33.2%	25.6%	24.6%				
\$22,500-\$39,999	20.2%	21.3%	19.5%				
\$40,000-\$59,999	16.9%	18.1%	18.0%				
\$60,000-\$89,999	15.2%	17.3%	19.4%				
\$90,000+	14.5%	17.6%	18.5%				

Chi-square testing is significant (p<.001) for all demographics comparisons. With the exception of income, where lower incomes are more common in the "offer prevention" group, there is a similar pattern across groups.

MIDAS Summary for Prevention Groups (Disability level is measured by summing 5 items that assess number of days in last 3 months participation/productivity in work, school or home activities were impacted due to headache)



Summary

 The need for preventive migraine care is high in the US population of migraine sufferers

# of Migraine Sufferers	% of US	Meeting Criteria for
7.7 MM	3.0%	Offer Preventive Treatment
3.8 MM	1.5%	Consider Preventive Treatment
11.5 MM	4.5%	Total Prevention Candidates

 Clearly, more dialogue between doctors and patients regarding prevention treatment options is needed.

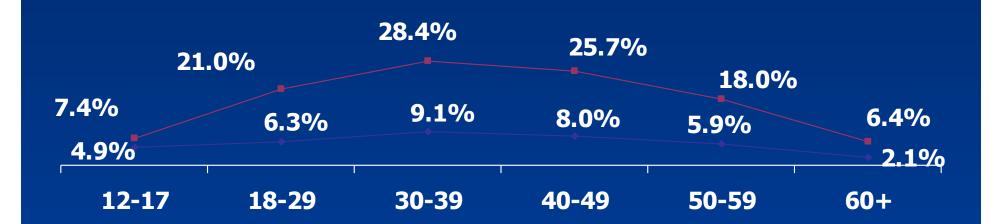
Back Up Slides

Sample Characteristics and Response Rates

	Sampled Individuals (N)	% of Sample	Responding Individuals (N)	Response Rate %
Total	257,339		162,576	63%
Gender				
Males	129,665	49%	77,292	62%
Females	132,674	51%	85,284	64%
Age				
12-17 yrs	23,933	8.0%	13,821	58%
18-29 yrs	45,238	15.1%	22,659	50%
30-39 yrs	42,947	14.3%	22,468	52%
40-49 yrs	47,242	15.7%	28,994	61%
50-59 yrs	41,870	13.9%	29,479	70%
60+ yrs	56,109	18.7%	45,155	80%
Total Headache Cases			30,721	
Total Migraine Cases			18,968	

Age and Gender Distribution for Migraine Cases

- Males - Females



One Year Period Prevalence for Those Age 12+

Preventive Rx Need Among Migraine Cases (Past week, month, year frequency)

How are you usually affected by severe	Monthly Migraine Days (# of Days Per Week, Month or Year)						
headaches?	≤1	2	3	4-5	6-10	11+	Total
Able to Work/ Function Normally	2.1%	1.0%	0.4%	1.3%	1.1%	1.2%	7.2%
Impaired to Some Degree	13.0%	6.5%	3.5%	6.3%	5.0%	5.0%	39.1%
Severe Impairment Bed Rest Required	22.1%	7.3%	4.2%	7.2%	5.9%	7.1%	53.7%
TOTAL	37.2%	14.7%	8.1%	14.7%	12.0%	13.3%	100% (N=1867

Offer Preventive Treatment = 43.0%

Consider Preventive Treatment = 18.4%

Not Indicated = 38.6%