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Comparison of Headache-Related Impact (HIT-6) by Migraine Status: Results from the American Migraine Prevalence and Prevention (AMPP) Study Dawn C. Buse, PhD<sup>1,2</sup>; Aubrey Manack, PhD<sup>3</sup>; Daniel Serrano, PhD<sup>4</sup>; Sepideh F. Varon, PhD<sup>3</sup>; Catherine Turkel, PharmD, PhD<sup>3</sup>; Richard B. Lipton, MD<sup>1,2</sup> 1. Albert Einstein College of Medicine, Bronx, NY; 2. Montefiore Headache Center, Bronx, NY; 3. Allergan Inc., Irvine, CA; 4. Vedanta Research, Chapel Hill, NC





### BACKGROUND

- Chronic migraine (CM) has been demonstrated to have even greater impact than episodic migraine (EM) on socioeconomic status,<sup>1,2</sup> headache-related-disability,<sup>2,3,4</sup> health-related quality of life,<sup>2,5</sup> direct and indirect costs,<sup>6</sup> and comorbid medical and psychiatric conditions.<sup>1,2</sup>
- The Headache Impact Test (HIT-6), a well validated measure of headache impact, has been used extensively in research and clinical practice with EM.<sup>7</sup>
- A recent publication validated the HIT-6 for use with persons with CM.<sup>8</sup>
- We sought to further explore the validity of the HIT-6 to assess the impact of CM within the general population and report rates of headache-impact between persons

## RESULTS

• In 2009, 27,253 questionnaires were fielded, 20,107 were returned (73.8%). 11,792 (69.4%) of surveys sent to headache suffers were returned, of which 9,215 (78.2%) respondents reported at least one headache in the preceding year. 373 met criteria for CM (2.4%) and 6,554 met criteria for EM (41.9%).

#### Sociodemographics:

• The majority of respondents in both groups were female (80.7% of CM and 78.3% of EM) and Caucasian (92.0% of CM and EM 89.3% of EM).

#### with EM and CM.

## OBJECTIVES

To assess HIT-6 as a useful measure of headache-impact among persons with CM.
 To report rates of various levels of headache-related impact among persons with EM and CM.

## **METHODS**

• The AMPP study has a longitudinal, population-based, survey design. Respondents were identified in 2004 by screening 120,000 US households. An annual follow-up survey has been sent to a sample of 24,000 severe headache sufferers identified from the 2004 survey in the years 2005-2009. In 2009, the survey was sent to a sample of 16,983 severe headache sufferers, and 10,270 control subjects (non severe headache sufferers identified in 2004.)

• Surveys include questions regarding headache symptomology which allows for the computation of headache type according to ICHD-2 criteria<sup>9</sup> and sociodemographic data. Body mass index (BMI) was calculated from respondent reported height and weight using a standard formula. The Headache Impact Test (HIT-6) was included in the 2009 survey.

The HIT-6 is a self administered, six-item questionnaire that measures headache-impact in lost time in work, school or social activities, pain severity, fatigue, frustration, and difficulty with concentration. Total sum scores range from 36-78 in the following categories: "no/little impact" (<50), "some impact" (50-55), "substantial impact" (56-59), and "severe impact" (60+).</li>
To be eligible for analyses, subjects were respondents to the 2009 survey who endorsed experiencing at least one severe headache in the preceding year and either:

• Both groups had an above average mean BMI (CM=30.4, EM=29.6) placing EM respondents in the "overweight" category and CM respondents in the "obese, class 1" category.

• CM respondents tended to be slightly older than EM respondents though differences were not significant.

• Those with CM reported lower average annual household income levels (38.3% of CM and 26.5% of EM <\$30,000/year; 17.4% of CM and 28.3% of EM >\$75,000/year).

#### HIT-6 Scores:

• HIT-6 scores in the CM and EM groups were normally distributed. (Fig. 1)

• Average HIT-6 scores were significantly different (b=5.75, 95%CI=4.9-6.6, p<.0001) between CM (64= "severe impact") and EM (58= "substantial impact").

• Those with CM were more likely to be in the "severe" headache-related impact category (72.9% vs. 42.3%). Those with EM had lower levels of impact. The categories "no impact", "some impact", and "substantial impact" were higher for EM compared to CM by 11.0%, 13.1%, and 6.5%, respectively. (Fig. 2)

• An ordinal logistic regression multiple imputation model revealed that respondents with CM had significantly higher odds of greater impact (HIT-6 categories) compared with EM (OR=3.5, 95%CI=2.77-4.41, p<.0001).

- CM (ICHD-2 diagnosis of migraine and average ≥15 headache days/month) or
- EM (ICHD-2 diagnosis of migraine and average <15 headache days/month)
- Statistical analyses were conducted using the SAS (Cary, NC) system v. 9.2.1.

• Descriptive statistics along with a cumulative logistic imputation model were utilized to compare groups.

• Descriptive statistics such as means, standard deviations (SDs), and percents were computed using the MEANS and FREQ Procedures. A *p* value ≤0.05 was used to demarcate statistically significant effects.

Inferential statistics for HIT-6 models were complicated by the presence of HIT-6 item non-response, this was solved using multiple imputation (MI) techniques.<sup>10</sup>
In order to determine the difference between EM and CM with regard to HIT-6 score categories, post-imputation, scores in each imputed data set were categorized according to HIT-6 categories. An ordinal logistic regression model was fit to each imputed data sets and results were aggregated using the MIANALYZE procedure in SAS.

### Fig. 1 Distribution of Raw and Imputed HIT-6 Scores

### Fig 2. HIT-6 Categorical Scores for EM and CM Populations



# CONCLUSIONS

• Findings demonstrated that persons with CM experience greater headache-impact that persons with EM. Both univariate and ordinal logistic regression multiple imputation models demonstrated that CM respondents had significantly higher odds of greater headache-impact, as measured by the HIT-6 when compared with respondents with EM.

• This work also supports the use of the HIT-6 in a CM sample. HIT-6 scores were normally distributed among both EM and CM groups in this population-based sample.

### for EM and CM Populations



### REFERENCES

- 1. Buse D, Manack A, Serrano D, Turkel CC, Lipton RB. Sociodemographic and comorbidity profiles of chronic migraine and episodic migraine sufferers. J Neurol Neurosurg Psychiatry. 2010; 81(4):428-32.
- Blumenfeld AM, Varon SF, Wilcox TK, Buse DC, Kawata AK, Manack A, Goadsby PJ, Lipton RB. Disability, HRQOL, and Resource Use Among Chronic and Episodic Migraineurs: Results from the International Burden of Migraine Study. Cephalalgia 2010, in press.
- Bigal ME, Rapoport AM, Lipton RB, Tepper SJ, Sheftell FD. Assessment of migraine disability using the Migraine Disability Assessment (MIDAS) questionnaire. A comparison of chronic migraine with episodic migraine. Headache 2003; 3:336-342.
- 4. Bigal, M.E., Serrano, D., Reed, M., Lipton, R.B. Chronic migraine in the population: burden, diagnosis, and satisfaction with treatment. Neurology 2008;71(8):559-566.
- 5. Meletiche DM, Lofland JH, & Young WB. Quality of life differences between patients with episodic and transformed migraine. Headache 2001;41:573–578.
- 6. Stewart, W.F., Wood, G.C., Manack, A., Varon, S.F., Buse, D.C., Lipton, R.B. Employment and work impact of chronic migraine and episodic migraine. J Occup Environ Med. 2010;52(1):8-14.
- 7. <u>Headache Impact Test-6™. www.headachetest.com/HIT6/PDFS/English.pdf. Accessed August 2010.</u>
- 8. Yang M, Rendas-Baum R, Varon S, Kosinski M. Validation of the Headache Impact Test (HIT-6) across episodic and chronic migraine. Cephalalgia 2000;in press.
- 9. The International Classification of Headache Disorders: 2nd edition. *Cephalalgia* 2004;24(Suppl 1):9-160. 10. Rubin, D. B. (1987), *Multiple Imputation for Non-response in Surveys*, New York: John Wiley & Sons.

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