



Patients Reluctant to Discuss Epilepsy Side Effects, Study Finds

Medication-related side effects are common in people with epilepsy but about half of patients aren't discussing them with their physician, according to a new study. And mere forgetfulness may not be the culprit for some, as 29 percent sometimes feel reluctant to discuss side effects.

The study, funded by Ortho-McNeil Neurologics, found that health care providers estimated that: only 45 percent of epilepsy patients express concerns about side effects; roughly one-quarter of their patients sometimes feel reluctant to discuss side effects and as many as 21 percent are sometimes reluctant to talk about other health conditions they have. Also, fewer than 30 percent of their patients express concerns over the impact of side effects on daily life.

"We need to increase the focus on individualizing treatment plans and strive for optimal balance between seizure control and minimization of side effects so that we can improve the overall well-being of people with epilepsy," says Georgia Montouris, MD, director of epilepsy services at Boston University School of Medicine and Boston Medical Center in a prepared statement.

The patients who do discuss side effects at least sometimes say it's typically a one-sided affair in which only the patient brings up the issue (36 percent of respondents) and/or how side effects

impact daily life (41 percent). Health care providers agreed with this assessment. Forty-six percent said patients initiated discussions of side effects. The most common side effects reported, and backed up by physicians, include:

- Fatigue (experienced by 39 percent)
- Poor memory (experienced by 33 percent)
- Weight gain or weight loss (experienced by 29 percent)
- Loss of concentration (experienced by 24 percent)

But also of importance are the effects patients were least likely to discuss with their doctor:

- Hair loss (40 percent not discussed)
- Loss of concentration (30 percent not discussed)
- Vision changes (26 percent not discussed)
- Reproductive issues or sexual problems (25 percent not discussed)

Patients gave several reasons for not discussing the side effects. Forty-eight percent of patients said they didn't realize it was a side effect, 25 percent said it didn't seem important enough to mention (despite having an impact on their lives), 15 percent said their doctor didn't raise the issue, and 12 percent didn't want to switch medications.

"These findings suggest treatment expectations among epilepsy patients are simply too low," says Epilepsy

Foundation CEO and President Eric Hargis in a release. "According to the survey, 61 percent of people with epilepsy believe that side effects are just something they have to live with." About half of patients—53 percent—say their physician has told them this in the past.

According to the survey, 85 percent of patients would like to have a more active role in making their treatment decisions. However, only 35 percent of patients say they give "detailed input into all treatment decisions with their physician." Other findings from the study include:

- About half (44 percent) wish they had more information about treatment options and epilepsy.
- Roughly one third of patients feel "very informed" about the different medications at their disposal.
- Physicians, however, say the above statistic is much lower: only 10 percent are very informed about epilepsy, and three percent of patients are very informed about the medications, in their estimation.

The study was conducted by Richard Day Research, a market research company. Healthcare professional data included 459 healthcare professionals—comprised of 155 primary care physicians (family, general, or internal medicine) and 304 neurologists. Patient data included 414 people diagnosed with epilepsy, screened for having seen a healthcare professional for epilepsy within the last two years. **PN**

SHORT TAKES

■ **Temporary Recall.** The maker of the PD patch Neupro is temporarily recalling the drug in the US and some consignments from Europe, according to the company. UCB Pharma says the decision for the recall was prompted by clinical performance of some samples, not a result of contamination or toxicity. "As a result, there will be an out-of-stock situation with Neupro in the United States in late April 2008. In the European Union and

most other regions, Neupro supply is sufficient," the company said in a statement. The duration of the recall is unknown. The patches have been available for just under a year, hitting pharmacies in July 2007.

■ **Test Helps Depression Diagnosis.** A new test could forecast the efficacy of antidepressant therapy within four to five days instead of weeks, according to a study published in the March 12th issue of *Neuroscience*. A change in the protein Gs alpha might be a biomarker for depression.

This would allow a simple, quick lab test to determine not only if a patient has depression, but whether a particular antidepressant therapy will be successful. Brain biopsies from depressed people who had committed suicide were compared against controls with no psychiatric disorder history. Researchers found that the total number of Gs alpha was the same in patients with depression and without, but those depressed had a higher proportion of the protein restricted to lipid rafts.

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PML Issues Likely to Persist in Tysabri Patients, CEO says

Progressive multifocal leukoencephalopathy will continue to be a concern in patients who take natalizumab (Tysabri), said the maker's CEO at a briefing to investors in mid-March. "We anticipate there will be some additional cases of PML," says Biogen Idec CEO James Mullen of the setback that forced the drug to be temporarily suspended in 2005 after a number of patients developed the disease. Mullen was speaking to a group of investors at a health conference in Boston, according to Reuters.

Though he does not expect regulatory problems if the number stays small, "There is no doubt that will create a lot of excitement in the short-term given the history of this product," he says. He also expects for the MS drug's patient base to reach 100,000 patients by 2010, poten-

tially making it a billion-dollar-a-year therapy.

Anthony Reder, MD Associate Professor of Neurology at the University of Chicago, did not find the announcement alarming. "The whole purpose of the TOUCH program was to warn, and then closely monitor, anyone on Tysabri for potential PM," he says. "The risk was 2/2000 in MS with Avonex plus Tysabri, and possibly with Tysabri alone, over two years of therapy. Time will tell if there is a lesser risk with Tysabri alone, or if prior chemotherapy predisposes to PML."

In other news concerning Tysabri, a federal judge threw out a 2005 shareholder lawsuit against Elan Corp., the co-marketer of the drug, March 27th that alleged "misrepresentations regarding the safety, viability and potential market share" of

the drug, according to MarketWatch.

US District Judge Richard J. Holwell in Manhattan dismissed the case in its entirety "The court finds that plaintiffs' allegations are insufficient to state a claim for securities fraud based on defendants' failure to disclose information regarding the risk of non-PML opportunistic infections associated with Tysabri," the judge said. "Such risks did not become material until a casual link was established and neither opinion and speculation as to the degree of such risk nor the existence of adverse event reports were in themselves material."

The complaint said Elan's shares dramatically deteriorated after the drug was voluntarily pulled from the market, wiping out \$7.5 billion, or 70 percent, of shareholder value. **PN**

■ **Plaque Levels May Affect Hispanics Differently.** All it takes is a small buildup of plaque in the carotid artery in Hispanics to increase the likelihood of stroke or heart attack by a factor of four, compared to Hispanics who do not have plaque buildup, according to a new study. Published in the March 19th online edition of *Neurology*, study authors used ultrasound to read the thickness of plaque in 2,189 men and women in the multiethnic study. One hundred and twenty-one people suffered or died from ischemic stroke, 118 experienced or died from heart attack and 166 died due to other vascular causes during the study, which had an average follow-up of seven years. Maximum carotid plaque thickness was defined as more than 1.9mm plaque thickness, representing 25 percent of the group.

■ **Double Trouble.** Children who have both parents with AD are more likely to get the disease themselves, suggests a new report in the March issue of the *Archives of Neurology*. Having additional relatives with AD also increases the risk of developing the disease early. For the study, researchers gathered data on the adult children in 111 families where each parent had AD and found there to be 98 children who reached 70 years of age and of that group 42 percent developed AD. Of the total 297 children,

22.6 percent developed AD, comparing to an estimated 6 to 13 percent of the general population who would be likely to get the disease. AD normally started at roughly age 66 in children with two patients with the disease, the likelihood increasing as they aged.

■ **White Matter is What Matters.** A new study reveals that gait and balance abnormalities in old age are associated with the severity of white matter changes in the brain. Researchers followed 639 men and women between the ages of 65 and 84 who underwent CT scans as well as walking and balance tests, in their report published in the March 18th issue of *Neurology*. Results broke down like so: 284 had mild age-related white matter changes, 197 had moderate changes and 158 had severe changes. The study concluded that patients with severe white matter had their likelihood of scoring poorly on the walking and balance test doubled compared to those with mild white matter changes. Also, patients with severe changes had twice the risk as the mild group to have a history of falls.

■ **IH Blinds Blacks More Frequently.** Idiopathic intracranial hypertension is more likely to cause vision loss in blacks, according to a study published in the March 11th issue of *Neurology*. Records of 450 patients with the

disorder over a 17-year period were examined. There were 197 blacks, 246 whites, five Hispanics and two Asians in the study. Black patients were 3.5 times more likely to suffer severe vision loss in at least one eye and were nearly five times as likely to become legally blind than non-black patients. The study author added that the racial difference does not seem to be a result of differences in diagnosis, treatment or access to care.

■ **New Look at Sleep Apnea.** Researchers at the University of Pennsylvania say they've obtained an intimate glimpse at the molecular pathways underlying sleep apnea. Using an animal model, researchers found that poorly folded proteins accumulate in one compartment of a muscle nerve cell. This can send a signal to a cell to heal or destroy itself. Published in the February 27th *Journal of Neuroscience*, the study finds that motor neurons of the jaw and face had swollen endoplasmic reticula. This led the researchers to believe that misfolded proteins accrued as the endoplasmic reticula of mice were exposed to decreased oxygen and fluctuating oxygen during sleep over an eight week period. The association of the endoplasmic reticula had never been demonstrated before in elucidating the physiology of sleep apnea on a cellular level. **PN**