Pharmacy Benefit News

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Specialty Spotlight

Use of Proton Pump Inhibitors Linked to Increased Dementia Risk?

Older adults who use proton pump inhibitors (PPIs) may be at increased risk for developing dementia, according to an observational study in *JAMA Neurology*. Researchers studied nearly 74,000 adults aged 75 and older without dementia in 2004 using claims from a large German health insurer. By 2011, roughly 40% were diagnosed with dementia, After adjustment for confounding variables, including age, polypharmacy, stroke, and depression, PPI use was associated with a 44% increased risk for incident dementia.

As potential mechanisms of action, the authors cite evidence suggesting that some PPIs can cross the blood-brain barrier and affect brain enzyme levels. They may increase both production and degradation of amyloid which was shown in animal models. There is also evidence of reduced levels of vitamin B12 and other nutrients among PPI users that could possibly relate to an increased risk of dementia. However, the mechanism of action of PPIs contributing to increased risk of developing dementia is still unknown and requires more research. Randomized clinical trials are needed to confirm these observational findings.

Gomm W, Von holt K, Thomé F, et al. Association of Proton Pump Inhibitors With Risk of Dementia: A Pharmacoepidemiological Claims Data Analysis. JAMA Neurol. 2016, Kuller LH. Do Proton Pump Inhibitors Increase the Risk of Dementia?. JAMA Neurol. 2016; www.upi.com/Health_News/2016/02/15/Heartburn-medications-associated-with-higher-dementia-risk/8821455567164/?spt=sec&or=hn. Accessed February 26, 2016.

Commentary

Observational studies in addition to studies on animal models indicate that PPI use is associated with an increased risk of incident dementia. Thus it is thought that the avoidance of PPI medication may help prevent dementia. Even though, a few important risk factors of dementia such as ApoE allele carrier, lifestyle and diet and lower educational levels were not integrated in the prospective cohort study using observational data from 2004 to 2011, I believe it is safe to consider a reduction in the extended use of PPIs, especially among elderly. Proton pump inhibitors are among the most frequently used classes of drugs. Observational studies have shown that about 40% to 60% of all PPI prescriptions were considered to be detected as inappropriate, without adequate documentation for a gastrointestinal diagnosis. Therefore, it is safer not to use PPIs unless it is necessary especially in patients with family history of Alzheimer and dementia until more robust evidence is found confirming the results of these observational studies.

Find out more

Why is the Risk of Dementia Decreasing?

Analysis of over 30 years of Framingham Heart Study data challenges long held assumptions about dementia. Conventional wisdom believes that the incidence of dementia should increase as people live longer; however, analyses of the Framingham study suggest the rate is actually falling in high-income nations. Researchers published data in the New England Journal of Medicine that "of 5,206 persons tracked since 1975—all aged 60 years or older—the risk of dementia has gradually slipped over the years to achieve a 44% decline by the late 2000s and early 2010s". For comparison purposes, the rate was 2.0 per 100 persons compared with 3.6 per 100 person in the early years of the project. Factors contributing to the downward pattern remain unknown.

New England Journal of Medicine (02/11/16)

Commentary
Researchers compared the observed lower risk tied to stroke, atrial fibrillation, or heart failure over the years but this did not completely explain the overall trend. It is important for us to note that this is an observation from analysis of the data. It is not a proven fact. Associations like this are commonly found in analyses of data. However, causation or validation require additional analyses and confirmation over comparative data sets as well as evaluation of the methodology used in the analyses.

This is where statistical tests like regressions are used to further analyze how "tight" the association is and probabilities are used to give some idea of how possible the results actually are. Ultimately, validation by other groups in other situations is crucial. Perhaps health plans like Kaiser and others with large volumes of patients studied over years can help to validate these results. Yet, it is hard to compare against Framingham, as it is a special case with longitudinal data over decades. That amount of data is hard to find.

Interferon-Free Therapy for Hepatitis C?

In a recent study published in the Annals of Internal Medicine, researchers evaluate the efficacy of Grazoprevir 100mg/Elbasvir 50mg combination therapy in the treatment of cirrhotic and non-cirrhotic, treatment-naïve adults presenting with a genotype 1, 4, or 6 Hepatitis C infection. The randomized, blinded, placebo-controlled trial consisted of a treatment group that received an oral, once-daily, dose of the NS3+4a protease inhibitor/NS5a inhibitor (respectively) drug for 12 weeks. The other cohort in the study received a placebo drug; active treatment was delayed until week 16.

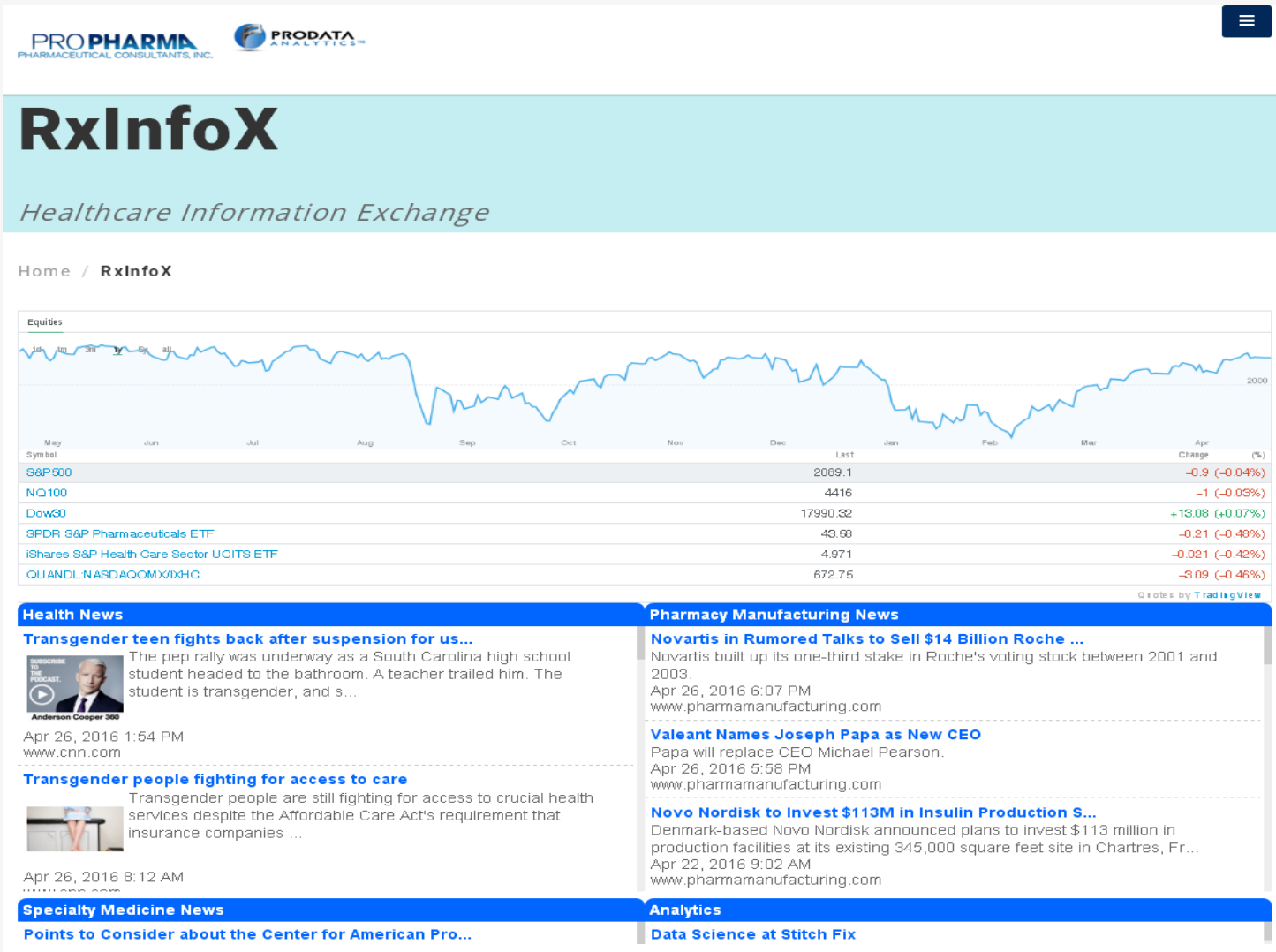
The authors reported that 95% of patients in the treatment arm achieved sustained viral suppression 12 weeks after the conclusion of therapy, as compared to the 73% of patients in other studies who have received Simepravir/Peginterferon + Ribavirin. Consequently the authors concluded that the drug regimen tested in their study offers a potent new therapeutic option for those with chronic HCV infections.

Source: Zeuzem S, et al. Grazoprevir-Elbasvir Combination Therapy for Treatment-Naive Cirrhotic and Noncirrhotic Patients With Chronic HCV Genotype 1, 4, or 6 Infection: A Randomized Trial. Ann Intern Med. 2015 Apr 24.

Commentary:
The authors of the aforementioned study, with funding from Merck & Co., reported the efficacy of Grazoprevir/Elbasvir in attaining a higher SVR12 rate as compared to other regimens (in other studies) that used Interferon therapy. Due to the lack of an active-comparator group, such a claim is difficult to validate. In order to assess the true efficacy of the regimen as compared to other potential regimens, a trial should contain the various treatment arms to be studied, so that researchers may be able to compare the results in a standardized, controlled manner.

Differences in population size, baseline characteristics between groups, dosing, frequency, duration of therapy, and primary/secondary endpoints tested, are all important factors to consider; these factors are difficult to control and standardize across studies. In addition, there were a relatively limited number of patients diagnosed with genotypes 4 (n=18) and 16 (n=10) as compared to genotype 1 (1a, n=157 and 1b, n=131).

As such, a concern is whether or not sufficient statistical power was achieved in the study to assess the efficacy of the drug regimen in patients diagnosed with genotypes 4 and 6. Further testing will help delineate the efficacy of Interferon-free drug therapies with those including Interferon in the treatment of Hepatitis C. Such former therapies may help spare the patients some of the adverse reactions commonly associated with Interferon therapy – such as hemolysis, decreased hemoglobin levels, myalgia, headache, and fatigue.



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Pro Pharma Introduces Information Exchange Hub: RxInfoX

CANOGA PARK, Calif. - April 27, 2016 - PRLog -- RxInfoX joins Pro Pharma's Pharmacy Benefit News (PBN) as one of the contributions to the health care news cycle. The exchange of ideas, questions, viewpoints, and analyses are at the heart of a rational approach to news.

RxInfoX grew out of Pro Pharma's need to centralize the collection of current, timely, and relevant information. This internal need is also applicable to a much broader audience of the general health care industry.

RxInfoX provides up-to-the minute news capsules relating to general and health care stock indices, health news, pharmacy manufacturing news, specialty medicine, and health care analytics, to name a few. RxInfoX is

updated throughout the day, every day, as relevant stories hit the news media. Pro Pharma is continually monitoring these new updates for relevancy and importance to the general healthcare population.

In the near future, Pro Pharma will look to expand the RxInfoX offerings relating to the basic science of disease and drug impact as well as links to articles that explain the complicated pathophysiology and pharmacology underlying today's health care. Similar to Pharmacy Benefit News, we will endeavor to comment on major topics which will provide some perspectives and potentially to stimulate conversations.

RxInfoX is dynamic and will be regularly expanded and improved.

Look to RxInfoX for a quick and objective daily read at
http://www.propharmaconsultants.com/RxInfoX.html

We encourage you to share your thoughts, questions, and suggestions for improvement to assist us in providing valuable information for all of our readers!

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PRO PHARMA is a multi-service, woman owned, privately held consulting firm offering a vast portfolio of services to public and private entities including self-insured employers, Taft Hartley Trusts and unions, public employers, for-profit hospitals and integrated health networks, health care insurance companies, worker's compensation insurers, small-to-medium sized HMO's, and physician groups.

As a primary service to plan sponsors for achieving below trend results, PRO PHARMA provides an integrated program of administrative process improvements, clinical quality oversight, and provider/member education.

PRO PHARMA's Consulting services are grounded in the use of data and the communication of that information to define benefit trends, drivers and other analytical indicators. PRO PHARMA markets Biotech Modeling™, Invoice Screening™, Quality Management Program™, and Treatment Calendar™. The Company directly markets its products in the U.S. and collaborates with partners to reach international markets.

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For more information about Pro Pharma contact:
Carol Stern, CEO
(888) 701-5438
carol.stern@propharmaconsultants.com

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