Pharmacy Benefit News

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What to Do If an Antidepressant Doesn't Work?

If an antidepressant doesn't work, one option is to add an antipsychotic. One recent trial, titled *VAST-D, analyzed patients with major depressive disorder (MDD) who were treated with an antidepressant, but did not respond. The conclusion is that more studies are needed to understand the benefit of adding Aripiprazole for treating patients with MDD who are unresponsive to the first antidepressant. This trial is the first head-to-head trial comparing the efficacy and safety of three common alternate treatments for MDD:

- Switching to bupropion (switch group)
- Adding bupropion to the current antidepressant (augment-bupropion group)
- Adding aripiprazole (augment- aripiprazole group), which is an atypical antipsychotic

Researchers found that the Aripiprazole group has 7% higher rate of remission than the switch group. In terms of safety, most patients from the two Bupropion groups experienced anxiety. For the Aripiprazole group, weight gain and akathisia – defined as motor restlessness – are the common side effects. Given the modest benefit and the added side effects from Aripiprazole to the treatment, it is still too early to draw a solid recommendation for this approach.

Commentary:
The goal of depression treatment is remission of symptoms and restoring baseline functioning of the patients. In patients who are treatment-resistant to their first antidepressant after dose optimization, conventional strategies include augmentation (adding another treatment) or switching to a different treatment. There is currently no evidence favoring switching or augmentation. A generally recognized duration of the treatment trial is 6-12 weeks at therapeutic dose.

It is not uncommon for patients to respond insufficiently to their first antidepressants. Measuring the effects of drugs in depression is complicated by the lack of concrete end-points that can be objectively measured. Antidepressant effects are measured using patient-reported outcomes (PRO) through survey and questionnaires. Historically, outcomes considered in clinical trials were often objectively measurable and interpreted by providers such as blood pressure or A1C.

In contrast, PROs are subjective reports of patient's health directly from the patient, without the interpretation of response by providers. The rise of PRO came with the FDA approvals of antidepressants using results from questionnaires rather than clinical outcome collected and measured by providers. It is worth mentioning that PRO questionnaires had been extensively tested and validated in both reliability and validity. The acceptance of PROs in clinical research is part of the increasing focus on patient-focused outcome measurements. With FDA releasing its guidance to the industry in 2009, the use of PROs had been widely accepted as a valid instrument to support labeling claims in clinical trials.
* VAST-D: VA Augmentation and Switching Treatments for Improving Depression Outcomes

References:
1. JAMA. 2017;318(2):132-145. doi:10.1001/jama.2017.8036
2. Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006;163(11):1905-1917.

Wouldn't It Be Great

Before spreadsheets, analytics was left to IT. After spreadsheets, everyone could analyze their own data.

Wouldn't it be great if everyone were a medical and medication analyst?
Wouldn't it be great to do your own medical/pharmacy analyses anywhere, anytime, all of the time?
Wouldn't it be great to get answers to your questions on your desktop, mobile device or phone?

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- Wouldn't it be great to track every pharmacy and/or physician on their CMR performance?

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What Does Cholera Have to Do with Opiates?

An article written earlier this month titled "Stopping Epidemics at The Source: Applying Lessons from Cholera to The Opioid Crisis" argued that a solution to the opioid epidemic is understanding its root cause. During the cholera outbreak in the 19th century, tackling cholera's mode of transmission, which is through contaminated water, was more effective in stopping the disease than merely treating patients. Now, the root cause of our current opioid crisis, according to the article, is poorly managed chronic pain and excessive reliance on opioid for pain management. One possible solution to the current crisis is through chronic pain management by incorporating safer non-pharmacologic pain management such as "acupuncture, massage, mindfulness, yoga, and manipulation therapies."

Coffee Lowering Death Rate – Truth or Myth?

Two large observational studies – the EPIC study and the Multiethnic Cohort study – reached a similar conclusion: an inverse relationship between coffee consumption and mortality. This means that drinking more coffee might lower death rate. Both studies cautioned against generalizing the results to any causal relationship, given the possible influence of various confounding factors. Both studies concluded that moderate coffee intake can be incorporated into one's healthy diet. The EPIC study with 520,000 participants in 10 European countries and an average of 16 years follow up time showed significantly lower all-cause mortality for participants who consume the most caffeine. The Multiethnic Cohort study with 200,000 in various racial and ethnic groups and a follow-up period averaging 16 years also observed A similar effect. Another recent systematic review concluded that

Commentary:
A major gap in the current science of pain is the lack of research on alternative medicine and non-pharmacological therapies for chronic pain. Fortunately, the recent national attention on the crisis has revived interest in alternative therapy for managing chronic pain. The department of Health and Human Services (HHS) and National Institutes of Health (NIH) have placed major emphasis on supporting research on pain, addiction, and advancing better practices for pain management. One possible reason for the previous lack of interest is that opioids had been extremely effective in reducing patient's perceived pain level. An alternative approach would be utilizing safer alternatives to manage pain. However, given the shortage of evidence, providers are hesitant to recommend these alternatives over the extremely effective opioids. There is also the lack of reimbursement since payers are reluctant to cover services such as acupuncture and massage. Another factor for the lack of research interest is the limited patient exposure to alternative medicine.

With more resources and funding on solving the opioid problem, new emergent research will shed light to the effectiveness and safety of non-pharmacological approach to pain management.

Reference:
Schoomaker, Eric, and Chester Buckenmaier III. "Stopping Epidemics At The Source: Applying Lessons From Cholera To The Opioid Crisis." Health Affairs Blog, Health Affairs Blog, 4 Aug. 2017, http://healthaffairs.org/blog/2017/08/04/stopping-epidemics-at-the-source-applying-lessons-from-cholera-to-the-opioid-crisis/.

associated with acute toxicity and other adverse effects.

Commentary:
Observational studies are studies that draw correlations and inferences from a sample of the population; and allowed researchers to study relationships that might be unethical or impractical to study with randomized controlled trials. The relationship of interest is not controlled by the researcher. The subjects in the study are not randomly assigned. These observational studies suffer from bias and confounding factors that often cannot be eliminated using statistical techniques. In the two studies above, people who drink a lot of coffee can have other behaviors such as diets, socio-economic, and health-related factors that can lead to lower mortality. Since there are numerous known and unknown confounding factors, it is still too early to draw a solid conclusion regarding the relationship between caffeine consumption and mortality.

Dietary studies, such as the two studies discussed above, are often observational due to the nature of the subject. Researchers can attempt to control some known confounding factors in study design before data gathering, such as matching and restriction. Restriction means selecting subjects who have the same confounding factors such as age or gender. Matching is often used in case-control studies which match similar subjects in both control and experimental group. Other statistical methods, such as stratification and regression analysis, are often used to control known confounding factors after data gathering.

References:
Ann Intern Med. 2017;167:283-284. doi:10.7326/M17-1503
Mayo Clinic Staff, "Caffeine: How Much Is Too Much?" Mayo Clinic, Mayo Foundation for Medical Education and Research, 8 Mar. 2017, www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/caffeine/art-20045678.
Gastroenterol Hepatol Bed Bench. 2012 Spring; 5(2): 79–83.

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Prior Authorizations

Support for Specialty Medications and Benefit Compliance

Pro Pharma consultants evaluate benefit compliance as the reviewer, for numerous self-insured employers and Health Plans. Benefit compliance is based on benefit coverage, FDA approved indications and/or support for therapy for extraordinary circumstances. Specialty medications are reviewed daily, on an "as needed" basis, or as a pre-certification review process for FDA approved indications prior to Medical Director review.

Prior Authorizations for specialty medications usually cover, but are not limited to:

- *FDA approved indications versus supplied diagnoses*
- *Duplicate payments in medical and pharmacy*
- *Multi-dose vs. single use dose*
- *Opportunities for rebate capture*
- *Pricing vs. contract requirements*
- *Dosage compliance with prescribed indication(s)*
- *Quantities compliant with benefit limitations*
- *Genomic testing criteria*

Important client benefits are:

- *Authorization based on strict benefit and FDA criteria for medication usage*
- *Authorization based on fair and equitable cost reduction methodologies*
- *Identification of patients that will receive the greatest benefit from the proposed therapy*

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