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Inside This Issue

Aspirin in High Risk CV Patients Using COX-2 Inhibitors

By: Nancy Rizkalla, PharmD Candidate c/o 2015

NSAIDs are effective agents used in the management of several types of pain. They mitigate the negative effects of inflammation by inhibiting two key enzymes called cyclooxygenase (COX)—COX-1 and COX-2—and their subsequent products. However, the inhibition of these enzymes' other beneficial functions is associated with negative side effects. In particular, COX-1 inhibition is associated with reduction in gastro-protective barriers, causing gastric irritation. To circumvent this unwanted effect and aim to only reduce the pro-inflammatory factors, selective COX-2 inhibitors that would reduce the formation of inflammatory mediators without compromising the beneficial effects of COX-1 byproducts were developed.

Unfortunately, it was soon discovered that this selective inhibition was not without risks. As it turned out, selective COX-2 inhibitors—while sparing patients of negative gastrointestinal (GI) effects—increased the risk for CV events, possibly due to the inhibition of vasodilatory products produced by COX-2 mechanisms without the balancing effect of reduced platelet aggregation that is afforded by COX-1 inhibition. This left clinicians with the following dilemma: how should high CV risk patients who opt for therapy with selective COX-2 inhibitors be treated? Is low-dose aspirin (used as prophylaxis for CV events) effective in counteracting the increased risk brought on by selective COX-2 inhibitors?

To date, no randomized controlled clinical trials have addressed this question. No studies have been conducted that directly compared selective COX-2 inhibitor use alone with the combination of a selective COX-2 inhibitor and low-dose aspirin to see if there was a subsequent reduction in CV events. Instead, randomized controlled clinical studies have been conducted to address the theoretical pharmacodynamic interaction that may exist with concomitant aspirin and selective COX-2 inhibitor use.

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NEWS

Use of Complementary and Alternative Medicine in Oncology Patients

By: Nicollette Pacheco, Staff Editor [Graphics-focused]

With an increase in the use of alternative medicine in the United States, the field of oncology is seeing a rise in the use of unconventional methods to treat symptoms in a wide range of cancers. Since 1990, it has been found that an increasing number of patients seek alternative treatment instead of mainstream medical care. It is imperative that oncologists become familiar with the risks and benefits involved with alternative treatments to provide the most appropriate and individualized care to their patients.[1] An estimated average of 35.9% of cancer patients reported using alternative therapy throughout treatment.[2] Most of these patients used alternative medicine to improve physical and emotional well-being as an adjunct to traditional chemotherapy. The most common therapies used include herbalism, homeopathy, hypnotherapy, and visualization. Patients turned to these methods due to their ability to improve overall sentiments of well-being and hope, both of which have been proven to extend survival.[2]

The benefits of complementary and alternative medicine (CAM) have been observed for thousands of years, and the benefits of particular therapies have been studied extensively. Aloe vera has been shown to possess antioxidant, anti-inflammatory, and even anti-proliferative effects when taken orally.[3] Qigong is a form of energy therapy that has been examined for its mood-enhancing effects that improve quality of life for many patients.[4] Long pepper is an agent used in ayurvedic therapy, a form of alternative medicine that has been used for thousands of years and focuses on plant-based medications. Long pepper has recently undergone studies that confirm its anticancer activity in colon cancers.[5] The search for less toxic oncolytic agents frequently points to such alternative treatments.

The barrier that exists between CAM and modern medicine is due to the lack of clinical trials to evaluate the efficacy of CAM therapy. A large portion of the alternative medicine market involves herbal supplements, many of which are not regulated by the FDA – meaning their efficacy and toxicity has not been extensively studied. Patients often hear of such therapies from resources that are not credible. This creates a sense of reluctance among prescribers when it comes to recommending CAM as an adjunct to chemotherapy. 58.8% of prescribers report they are not adequately educated in alternative therapies, and 79.2% of prescribers state they are not up to date with the most current studies involving alternative therapy methods.[6] When treating an oncology patient, only 17.2% of prescribers recommended continuation of CAM therapy.[6] Health care professionals that use CAM themselves were also found more likely to recommend CAM to their patients.[6] A survey of healthcare professionals revealed that 38.2% were asked about CAM use in the last 6 months, indicating a large increase in demand for knowledge about these therapies.[6] With adequate education of both patients and prescribers, the synergistic use of complementary and conventional medicine may propel oncology from a world of treating disease to curing it.

Pharmacists play an essential role in educating both patients and prescribers alike and in closing the information gap that often prevents the use of CAM. When using CAM in an oncology patient, several factors must be considered to determine the agent that will best supplement the patient's regimen. Agents should only be used if they have high efficacy, low toxicity, and an adequate amount of supporting research. While assessing the benefits of adding CAM to a patient's therapy may seem simple, it is also important to recognize the associated risks. Before adding an agent to a patient's regimen, it should be screened for drug interactions and possible adverse affects. For example, Aloe vera proved to have several beneficial properties that warrant its use in an oncology patient. However, it is metabolized by CYP3A4 and CYP2D6, which can cause severe interactions with several other drugs that the patient may be taking.[3] Despite its obvious benefit, long pepper has also been shown to affect liver function, which may also limit its use in therapy.[5]

To gather accurate and pertinent information on CAM therapies, pharmacists should refer to credible sources that provide objective information. The Integrative Medicine Service at Memorial Sloan Kettering Cancer Center provides a free resource which contains information on herbal supplements and their

unbiased studies. Databases such as Facts and Comparisons and Pharmacist's Letter also contain information on natural medicines and may help screen for drug interactions.[7,8]

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NEWS

Prevalence of Psychiatric Disorders in the United States

By: Jacqueline Meaney, PharmD Candidate c/o 2015
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Psychiatric disorders are common in the United States, as nearly half of all Americans will meet the criteria for an anxiety disorder, mood disorder, impulse-control disorder or substance abuse disorder at some point in their lifetime. It is estimated that 26.2% of adults in the United States suffer from a psychiatric disorder in any given year. In addition, mental disorders are the leading cause of disability in the United States, and many people suffer from multiple psychiatric disorders at one time.[1-3]

Psychiatric disorders are currently diagnosed based on the Diagnostic and Statistical Manual of Mental Disorders (DSM-V).[4] A psychiatric disorder is defined as a pattern of behavioral and psychological symptoms that impair a person's ability to function or increases their risk of pain, disability, or death. Psychiatric disorders include eating disorders, anxiety disorders, autism spectrum disorder, mood disorders, attention deficit hyperactivity disorder (ADHD), and personality disorders. People often suffer from multiple psychiatric disorders at a time, as 45% of people with any mental disorder meet the criteria for two or more mental disorders, with disease severity being directly related to comorbidity. If left untreated, mental disorders can result in negative consequences; 90% of people who commit suicide have a mental disorder, most commonly a substance abuse disorder or a depressive disorder. [5-7]

Mood disorders affect 9.5% of adults in the United States each year.[1, 2] Mood disorders include major depressive disorder (MDD), dysthymic disorder, bipolar disorder, and schizophrenia. MDD is the leading cause of disability in the United States for people aged 15 to 44 and is more common in women than in men.[3, 8, 9] Dysthymic disorder involves a chronic mild depression that persists for at least two years and affects 1.5% of Americans aged 18 years and older.[1, 2] Bipolar disorder affects 2.6% of adult Americans, while schizophrenia affects 1.1% of adult Americans.[9-11] Major depressive disorder, dysthymic disorder, and bipolar disorder all have an average age of onset between 25 and 32 years of age, while schizophrenia is often diagnosed in the late teens or early twenties.[12]

Anxiety disorders are another common type of psychiatric disorder, with 18.1% of American adults experiencing an anxiety disorder each year. Anxiety disorders include panic disorder, post-traumatic stress disorder (PTSD), generalized anxiety disorder (GAD), obsessive-compulsive disorder (OCD), and various phobias. The majority of patients who have one anxiety disorder will also have a second anxiety disorder, and the age of onset is typically in the early twenties.[1, 2, 8]

Eating disorders include anorexia nervosa, bulimia nervosa, and binge-eating disorder, which respectively affect 0.6%, 1% and 2.8% of adult Americans at some point during their lifetime. Women are three times as likely as men to develop anorexia nervosa or bulimia nervosa and are 75% more likely to develop binge-eating disorder.[14] The mortality rate for eating disorders in the United States is 0.56% per year.[14, 15]

Autism is a pervasive developmental disorder that is part of a group of disorders known as autism spectrum disorders. These disorders vary in severity, with autism being the most debilitating form of the disorder. Autism generally develops early in childhood and is four times more common in males than in females. However, females with autism tend to have a more severe disorder than males.[16, 17]

Personality disorders include antisocial personality disorder, avoidant personality disorder, and borderline personality disorder, among others. Antisocial personality disorder is a mental disorder in which a person tends to treat others with indifference, and often seeks to manipulate or antagonize others. People with antisocial personality disorder often become criminals and rarely show guilt or remorse for crimes committed. In contrast, avoidant personality disorder is a mental condition in which a person tends to feel overly shy, inferior, inadequate, or sensitive to rejection. Borderline personality disorder is characterized by unpredictable emotions and impulsive actions that lead to chaotic relationships with others. Personality disorders tend to represent patterns of behavior that substantially deviate from the expectations of the individual's culture and negatively affect the person's day-to-day life. Among adult Americans, 9.1% have a diagnosable personality disorder.[18]

Although there are many guidelines currently available for the treatment of these disorders, there is a constant need for new clinical trials that can re-evaluate the safety and efficacy of various treatment strategies, especially when compared to new or alternative options. A running understanding of the safety and efficacy of psychiatric treatment strategies could help health care providers better select an appropriate treatment approach for patients with psychiatric disorders.

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Harvoni™- First Combination Pill to Treat Hepatitis C

By: Sebanti Bhowmik and Elissa Tam, PharmD Candidates c/o 2015

On October 10, 2014, the Food and Drug Administration approved ledipasvir-sofosbuvir (Harvoni™) to treat chronic hepatitis C virus (HCV) genotype 1 infection in adults. Harvoni™, marketed by Gilead Sciences, consists of Gilead's sofosbuvir (Sovaldi™) and a new drug, ledipasvir.[1] Harvoni™ is the first combination pill to be approved to treat HCV, and is also the first approved regimen that does not require co-adminsitraton with interferon or ribavirin.[1]

HCV is a blood-borne disease that can be spread through blood transfusions, organ transplants, sharing needles and syringes, needlestick injuries in healthcare settings, and birth from a mother who is infected.[2] Though unlikely, transmission via sexual contact may occur, especially in those who have multiple partners or who are coinfected with human immunodeficiency virus (HIV).

HCV is highly heterogeneous; there are eleven HCV genotypes with several distinct subtypes.[3,4] Genotype 1 is most common, affecting 70% of the HCV-positive U.S. population. Although different strains have not been shown to differ dramatically in their virulence or pathogenicity, different genotypes do vary in their responsiveness to interferon and ribavirin combination therapy. Such heterogeneity has hindered both the development of vaccines and the effectiveness of treatments.[4]

An estimated 3.2 million people in the U.S. have chronic HCV, though many patients do not know they are infected until symptoms appear. In 2009, an estimated 16,000 acute HCV infections were reported. Approximately 75-85% of people who become infected with the virus develop chronic infection, which can lead to severe complications such as cirrhosis, liver cancer, liver failure, and even death.[2] HCV is the leading cause of cirrhosis and liver cancer, and is the most common reason for liver transplantation in the U.S. Approximately 15,000 people die every year from HCV related liver disease.[2]

Currently, there are no vaccinations available for HCV. However, there are several medications available to treat chronic HCV, and more therapies are currently being investigated. Harvoni™ is the third drug approved by the FDA in the past year, following simeprevir (Olysio™) in November 2013, and sofosbuvir in December 2013.[1] Guidance for treatment in adults is changing constantly due to the advent of new therapies. Before the approval of simeprevir and sofosbuvir, oral twice-daily ribavirin with once-weekly subcutaneously injectable peginterferon was the main regimen prescribed. Side effects

of ribavirin include anemia, depression, and low neutrophils counts. Peginterferon can cause flu-like symptoms, hair thinning, and injection site reactions (redness and irritation). This regimen is administered over a period of 24 to 48 weeks, depending on co-infection with HIV, treatment status, and genotypes.[3] With use of simeprevir and sofosbuvir, therapy duration has been shortened to 12 to 24 weeks with less requirements for interferon and ribavirin.[3]

Harvoni™ is a fixed-dose combination product containing 90 mg of ledipasvir and 400 mg of sofosbuvir in a single tablet. The recommended dosage of ledipasvir-sofosbuvir is one tablet taken orally once a day. This drug should be taken with food to reduce the incidence of gastrointestinal side effects such as nausea and diarrhea. Ledipasvir is a HCV NS5A protein inhibitor that interferes with viral replication. Sofosbuvir is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, an enzyme that is required for viral replication.[5]

"...it is taken once a day, which increases compliance in a patient population in which adherence to therapy is crucial to a treatment response."

The efficacy of ledipasvir-sofosbuvir was evaluated in three randomized Phase 3 trials for patients with genotype 1 chronic HCV with compensated liver disease: ION-3, ION-1, and ION-2. All three Phase 3 trials evaluated the efficacy of ledipasvir-sofosbuvir with or without ribavirin. Serum HCV RNA values were measured. The primary endpoint was sustained virologic response (SVR), which was defined as HCV RNA of less than 25 IU/mL at 12 weeks after the cessation of treatment. ION-3 evaluated treatment-naïve adults without cirrhosis and showed that the SVR was 94% (95% confidence interval [CI], 90 to 97) with 8 weeks of ledipasvir–sofosbuvir, 93% (95% CI, 89 to 96) with 8 weeks of ledipasvir–sofosbuvir plus ribavirin, and 95% (95% CI, 92 to 98) with 12 weeks of ledipasvir–sofosbuvir.[6] ION-1 evaluated 12 and 24 weeks of treatment with ledipasvir-sofosbuvir with or without ribavirin in treatment-naïve adults with or without cirrhosis. The rates of SVR were 99% (95% confidence interval [CI], 96 to 100) in the group that received 12 weeks of ledipasvir–sofosbuvir; 97% (95% CI, 94 to 99) in the group that received 12 weeks of ledipasvir–sofosbuvir plus ribavirin; 98% (95% CI, 95 to 99) in the group that received 24 weeks of ledipasvir–sofosbuvir; and 99% (95% CI, 97 to 100) in the group that received 24 weeks of ledipasvir–sofosbuvir plus ribavirin.[7] ION-2 evaluated previously-treated adults with or without cirrhosis for 12 or 24 weeks of treatment with ledipasvir-sofosbuvir with or without ribavirin. The rates of sustained virologic response were high in all treatment groups: 94% (95% confidence interval [CI], 87 to 97) in the group that received 12 weeks of ledipasvir–sofosbuvir; 96% (95% CI, 91 to 99) in the group that received 12 weeks of ledipasvir–sofosbuvir and ribavirin; 99% (95% CI, 95 to 100) in the group that received 24 weeks of ledipasvir–sofosbuvir; and 99% (95% CI, 95 to 100) in the group that received 24 weeks of ledipasvir–sofosbuvir and ribavirin.[8] Results of all three Phase 3 trials indicated that ledipasvir-sofosbuvir was associated with a high SVR in both treatment-naive and previously-treated adults with or without cirrhosis with HCV genotype 1 infection, and that no additional benefit was seen when ribavirin was added.

At the moment, clinical trials have only shown the efficacy of ledipasvir-sofosbuvir in adult subjects. Ledipasvir-sofosbuvir has not been studied adequately in pregnancy or during breastfeeding. Thus, use during pregnancy is only recommended if the potential benefits justify the potential risks to the fetus. Efficacy has not been established in pediatric patients, and no dosage adjustments are necessary in the geriatric population.[5]

The use of ledipasvir-sofosbuvir with P-glycoprotein inducers such as rifampin or St. John's wort is not recommended due to decreased ledipasvir and sofosbuvir plasma concentrations, leading to reduced therapeutic effects. The use of ledipasvir-sofosbuvir with other products containing sofosbuvir is also not recommended. Acid reducing agents such as antacids, H2-receptor antagonists, and proton-pump inhibitors decrease ledipasvir concentration, and administration of these agents should therefore be separated by a minimum of four hours. Furthermore, concomitant use of antiretrovirals containing tenofovir and ledipasvir-sofosbuvir may lead to in-

creased tenofovir concentration. As a result, tenofovir -associated adverse reactions such as lactic acidosis, decreased bone mineral density, and gastrointestinal effects must be monitored in patients with HCV and HIV co-infection.

As the first single-tablet regimen for HCV infection, Harvoni™ presents many advantages. Primarily, it is taken once a day, which increases compliance in a patient population in which adherence to therapy is crucial to achieving treatment response. In addition, it may decrease HCV treatment length to as little as 8 weeks for patients who do not have cirrhosis, are treatment-naive and have a baseline HCV RNA below 6 million IU/mL.[5] Ledipasvir-sofosbuvir also has the advantage of not requiring treatment with interferon or ribavirin, thus freeing those undergoing treatment from side effects of those medications and the need for weekly injections. The most common adverse effects of ledipasvir-sofosbuvir are fatigue and headache, which are far more manageable than adverse events caused by interferon and ribavirin. Additionally, clinical trials have shown that study participants achieve SVR rates of 94-99% [6,7,8], bringing ledipasvir-sofosbuvir the closest to a potential cure. However, the cost of this medication ranges from approximately $63,000 for an 8-week course of treatment, to $94,500 for a 12-week course of treatment, and to $189,000 for a 24-week course of therapy, which is approximately $1,125 per tablet.[9] When compared to combination regimens, however, the cost for ledipasvir-sofosbuvir (Harvoni™) becomes arguably comparable. Regardless, cost-effectiveness should be assessed on an individual basis.

Only a year ago, the limited number of available treatment options for HCV required administration with interferon and ribavirin. With the introduction of sofosbuvir and simeprevir, patients and healthcare professionals were provided with new alternatives. With the advent of ledipasvir-sofosbuvir (Harvoni™), there is now a combination medication that can increase compliance, reduce pill burden and need for injections, and lead to high SVR rates with minimal side effects. Although other medications are in the process of development for chronic HCV genotype 1 infection, such as AbbVie's investigational, all-oral, interferon-free three-drug regimen, it is likely that with the advantages and simplicity of treatment with Harvoni™, Gilead's product is here to stay.

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Aspirin in High Risk CV Patients Using COX-2 Inhibitors (Continued)

By: Nancy Rizkalla, PharmD Candidate c/o 2015

CLINICAL

The basis for this interaction is that the selective COX -2 inhibitor may exhibit some affinity for COX-1 and compete with aspirin for binding sites, thereby reducing the effectiveness of aspirin-induced irreversible COX-1 inhibition.

A study conducted by Greenberg *et al* analyzed whether the concomitant use of rofecoxib and low-dose aspirin reduced the antiplatelet activity of aspirin.[1] It was found that this combination did not, in fact, reduce the antiplatelet activity of aspirin, and it was noted that this combination was well tolerated—alleviating the fear that it may produce unwanted GI effects due to the addition of aspirin. On the other hand, in a study conducted by Jermany *et al*, the concomitant use of lumiracoxib and low-dose aspirin was assessed; and while the antiplatelet activity of aspirin was not found to be compromised, three adverse events (not classified as "serious") occurred in the group receiving both lumiracoxib and aspirin.[2]

Two noteworthy studies were conducted that begin to shed light on the aforementioned question: the Celecoxib Long-term Arthritis Safety Study (CLASS) conducted by Silverstein *et al*, and the comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET) conducted by Farkouh *et al*.[3,4] In the CLASS trial, the use of celecoxib, ibuprofen, or diclofenac for six months was compared to assess rates of CV events—aspirin use up to 325mg/day was permitted. In regards to the question at hand, there was no noted increase in the incidence of cardiovascular events associated with celecoxib or NSAIDs, irrespective of aspirin use. Amongst patients not taking aspirin concomitantly, however, there was a greater reduction in upper GI toxicity.[3] In the TARGET trial, treatment with lumiracoxib, naproxen, or ibuprofen was compared in respect to cardiovascular morbidity, and groups of patients on concomitant aspirin therapy were further stratified. At the 1-year follow up, the results did not show a statistically significant difference between patients in the aspirin population vs. the non-aspirin population. Still, among patients taking aspirin, those receiving lumiracoxib showed a trend toward fewer cardiovascular events as compared to patients receiving ibuprofen. This result may be due to the well-known pharmacodynamic interaction between ibuprofen and aspirin—which results in reduced aspirin efficacy— if their administration is not properly staggered.[4]

The Adenoma Prevention with Celecoxib (APC) trial demonstrated that high-dose, long-term celecoxib use was associated with an increase in the risk of thrombotic cardiovascular events.[5] In the beginning of the trial, 30% of patients reported aspirin use. Thirty-three months after the trial was started, it was stopped by the National Cancer Institute because of an increase in the risk of cardiovascular events observed in both celecoxib arms. A number of *post hoc* analyses of the APC data examined whether patient factors could identify those at particularly high or low risk for thrombotic CV events. Of relevance, the aspirin user subgroup did not have a lower risk of CV events than those not using aspirin.[5] This data was not statistically significant, and it still must be emphasized that we have inadequate evidence to determine whether concomitant administration of aspirin with selective COX-2 inhibitor therapy will provide any cardio-protection.

A similar finding was observed for an oral COX-2 inhibitor valdecoxib and its intravenous formulation, parecoxib, in two trials in patients undergoing coronary artery bypass graft (CABG): CABG I and CABG II.[5] In the CABG I trial, treatment with valdecoxib vs. placebo was assessed, and in the CABG II trial, treatment with intravenous parecoxib followed by valdecoxib, intravenous placebo followed by valdecoxib, or intravenous placebo followed by oral placebo was assessed. It was found that valdecoxib with concomitant aspirin treatment in the CABG I and CABG II trials was associated with an increased cardiovascular risk compared with placebo. Both of these findings suggest that the increased CV risk associated with selective COX-2 inhibitor use may not simply be due to an imbalance between COX-1 and COX-2 inhibition.[5]

Based on this limited evidence failing to demonstrate any benefits provided by concomitant treat-

ment with aspirin, clinical experts and practice guidelines have favored the side of caution and not recommended this combination in patient care. In addition to the lack of cardio-protection afforded by the aspirin, as previous studies have demonstrated, aspirin may negate any GI-protective effects of selective COX-2 inhibitors—causing more harm than good.[2,4] A 2007 statement from the American Heart Association® commented regarding the use of a selective COX-2 inhibitor and aspirin: "Of note, the combination of aspirin (necessary for protection against cardiovascular events) and a coxib may ameliorate the gastric mucosal protective effect of COX-2 inhibition. The combination of the two may also prolong the time for recovery from gastric mucosal injury."[6] Moreover, the 2012 American College of Rheumatology® Recommendations for the Use of Non-Pharmacologic and Pharmacologic Therapies in Osteoarthritis of the Hand, Hip, and Knee state the following: "In the clinical scenario where the patient with OA is taking low-dose aspirin (≤325 mg per day) for cardioprotection and the practitioner chooses to use an oral NSAID, the TEP (Technical Expert Panel) strongly recommends using a nonselective NSAID other than ibuprofen in combination with a proton-pump inhibitor. This recommendation is based, in part, on the FDA warning that the concomitant use of ibuprofen and low-dose aspirin may render aspirin less effective when used for cardioprotection and stroke prevention because of a recognized pharmacodynamic interaction. Studies have not demonstrated this same type of pharmacodynamic interaction with diclofenac or celecoxib; nonetheless, the TEP strongly recommends that a COX-2 selective inhibitor should not be used in the above situation."[7] Consistent with this approach, product labeling for Celebrex® (celecoxib) states that it can be used with low-dose aspirin but that there is no evidence to support that this combination will reduce the risk of serious thrombotic CV events, and that the combination of celecoxib and aspirin will increase the rate of GI complications compared to celecoxib use alone.[8]

In summary, if a patient already requires treatment with low-dose aspirin, concomitant treatment with a selective COX-2 inhibitor is not contraindicated. Clinicians should keep in mind, however, that the patient may not be reducing their risk for CV events, the risk for GI complications will be increased, and that the patient should be treated accordingly. Furthermore, in patients who do not ordinarily require treatment with low dose aspirin, but is considering treatment with a selective COX-2 inhibitor, the addition of low-dose aspirin is not required, as there is no concrete evidence of benefits resulting from this approach.

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Novel Therapies for the Treatment of Chronic Hepatitis C

By: Svetlana Akbasheva [Staff Writer] and Beatrisa Popovitz; Section Editor, [Clinical]

CLINICAL

	Components	Mechanism of Action	FDA- Approved Indications	Frequency of Dosing
OLYSIO®	simeprevir 150 mg	HCV NS3/4A protease inhibitor	Treatment of chronic Hepatitis C Genotype 1	One capsule once daily with food
SOVALDI®	sofosbuvir 400 mg	HCV NS5B RNA-dependent RNA polymerase inhibitor	Treatment of chronic Hepatitis C Genotypes 1, 2, 3, 4	One tablet once daily
HARVONI®	▪ ledipasvir 90 mg ▪ sofosbuvir 400 mg	▪ HCV NS5A inhibitor ▪ HCV NS5B polymerase inhibitor	Treatment of chronic Hepatitis C Genotype 1	One tablet once daily
VIEKIRA® PAK	▪ ombitasvir 12.5 mg ▪ paritaprevir 75 mg ▪ ritonavir 50 mg ▪ dasabuvir 250 mg	▪ HCV NS5A inhibitor ▪ HCV NS3/4A protease inhibitor	Treatment of chronic Hepatitis C Genotype 1	▪ Two ombitasvir/ paritaprevir/ ritonavir tablets once daily in the morning with food ▪ One dasabuvir tablet twice daily with food

	Contraindications	Warnings/Precautions	Adverse Effects	Additional Information
OLYSIO®	None	▪ Phototoxicity ▪ Skin reactions (rash) ▪ Sulfa allergy (contains sulfonamide moiety) ▪ Use with moderate and strong CYP3A4 inducers or inhibitors is NOT recommended.	▪ When used with sofosbuvir – fatigue, headache, nausea ▪ When used with ribavirin and peginterferon alfa-2a – rash, pruritis, nausea	▪ Swallow capsules whole ▪ If used with ribavirin and peginterferon, screening for virus with NS3 Q80K polymorphism strongly recommended – if present, use alternative therapy ▪ Use not recommended in severe hepatic impairment
SOVALDI®	Pregnancy (if used with ribavirin or PEG-IFN)	P-glycoprotein substrate – clinically significant drug interactions with potent P-gp inducers (e.g. rifampin, St. John's wort, carbamazepine)	▪ When used with ribavirin – fatigue, headache ▪ When used with ribavirin and peginterferon alfa-2a – fatigue, headache, nausea, insomnia, anemia	▪ Prodrug ▪ Has not been studied in patients with severe renal impairment (CrCl<30ml/min) thus no dose adjustment can be recommended
HARVONI®	None	▪ Sofosbuvir is a P-glycoprotein substrate – potentially significant drug interactions with potent P-gp inducers (e.g. rifampin, St. John's Wort) ▪ Effect of ledipasvir decreased by agents that increase gastric pH (antacids, H_2 blockers, proton pump inhibitors)	Fatigue, headache	▪ See Sovaldi® ▪ Separate antacids by 4 hours

	Contraindications	Warnings/Precautions	Adverse Effects	Additional Information
VIEKIRA® PAK	▪ Hypersensitivity to ritonavir (e.g. TEN/SJS) or any component ▪ Severe hepatic impairment ▪ Concurrent use of drugs that are highly dependent on CYP3A4 for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events ▪ Concurrent use of strong inducers of CYP3A and CYP2C8 or strong CYP2C8 inhibitors ▪ Discontinue ethinyl estradiol-containing medications prior to starting Viekira Pak® due to risk of ALT elevation	▪ Drug interactions with CYP3A substrates	▪ Nausea, pruritis, insomnia ▪ When used with ribavirin – fatigue, nausea, pruritis, other skin reactions, insomnia, asthenia	FDA approved in December 2014 – unknown when drug will be commercially available

	Mechanism of Action	Dosage	U.S. Boxed Warnings	Additional Information
ribavirin (Copegus®; Moderiba®; Rebetol®; Ribasphere®; Ribasphere RibaPak®; Virazole®)	Inhibits replication of RNA and DNA viruses	▪ <75 kg: 1000 mg by mouth daily in 2 divided doses ▪ ≥ 75 kg: 1200 mg by mouth daily in 2 divided doses	▪ Hemolytic anemia ▪ Not for use as monotherapy for chronic Hepatitis C ▪ Contraindicated in pregnant women or their male partners	▪ Take with food ▪ Hazardous agent – use appropriate precautions for handling and disposal ▪ Dose adjustment required if CrCl < 50 ml/min
peginterferon alfa-2a (Pegasys®, Pegasys ProClick®)	Part of a family of proteins that possess antiviral, antiproliferative, and immune-regulating activity	180 mcg injected subcutaneously once weekly	▪ Injection site reactions ▪ May cause or exacerbate life-threatening neuropsychiatric disorders; autoimmune disorders; infectious disorders; ischemic disorders and hemorrhagic cerebrovascular events	▪ Inject into the abdomen or thigh. Rotate injection site. ▪ Store in refrigerator at 2°C to 8°C
peginterferon alfa-2b (Peg-Intron®, Peg-Intron Redipen®, Peg-Intron Redipen Pak 4®, Sylatron®		Combination therapy with ribavirin: weight-based dosing based on an average weekly dose of 1.5 mcg/kg subcutaneously once weekly		▪ Inject into the thigh, outer surface of the upper arm, or abdomen. Rotate injection site. ▪ Prior to reconstitution, store Redipen® at 2°C to 8°C. Store intact vials at 25°C.

CLINICAL

CLINICAL

Initial Treatment Options for Chronic Hepatitis C Recommended by the AASLD/IDSA Guidelines

GENOTYPE 1a	• Daily ledipasvir/sofosbuvir x 12 weeks [Rating: Class I, Level A] • Daily ombitasvir/paritaprevir/ritonavir/dasabuvir + ribavirin x 12 weeks (no cirrhosis) or 24 weeks (cirrhosis) [Rating: Class I, Level A] • Daily sofosbuvir+ simeprevir +/- ribavirin x 12 weeks (no cirrhosis) or 24 weeks (cirrhosis) [Rating: Class IIa, Level B]
GENOTYPE 1b	• Daily ledipasvir/sofosbuvir x 12 weeks [Rating: Class I, Level A] • Daily ombitasvir/paritaprevir/ritonavir/dasabuvir (+ribavirin if cirrhosis) x 12 weeks [Rating: Class I, Level A] • Daily sofosbuvir + simeprevir x 12 weeks (no cirrhosis) or 24 weeks (cirrhosis) [Rating: Class IIa, Level B]
GENOTYPE 2	• Daily sofosbuvir + ribavirin x 12 weeks [Rating: Class I, Level A] *Extending treatment to 16 weeks is recommended in patients with cirrhosis
GENOTYPE 3	• Daily sofosbuvir + ribavirin x 24 weeks [Rating: Class I, Level B] *Alternative Regimen:* • Daily sofosbuvir + ribavirin + weekly peginterferon* x 12 weeks [Rating: Class IIa, Level A]
GENOTYPE 4	• Daily ledipasvir/sofosbuvir x 12 weeks [Rating: Class IIb, Level B] • Daily paritaprevir (150 mg)/ritonavir (100 mg)/ombitasvir (25 mg) + ribavirin x 12 weeks [Rating: Class I, Level B] • Daily sofosbuvir + ribavirin x 24 weeks [Rating: Class IIa, Level B] *Alternative Regimens:* • Daily sofosbuvir + ribavirin + weekly peginterferon x 12 weeks [Rating: Class II, Level B] • Daily sofosbuvir+ simeprevir +/- ribavirin x 12 weeks [Rating: Class IIb, Level B]
GENOTYPE 5	• Daily sofosbuvir + ribavirin + weekly peginterferon x 12 weeks [Rating: Class IIa, Level B] *Alternative Regimen:* • Weekly PEG-IFN + ribavirin x 48 weeks x 48 weeks [Rating: Class IIb, Level A]
GENOTYPE 6	• Daily ledipasvir/sofosbuvir x 12 weeks [Rating: Class IIa, Level B] *Alternative Regimen:* • Daily sofosbuvir + ribavirin + weekly peginterferon x 12 weeks [Rating: Class IIa, Level B]

*The AASLD/IDSA HCV guidelines do not specify peginterferon 2a or 2b, but the clinical trials are based on peginterferon 2a.

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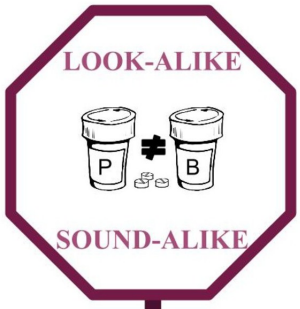


By: Sang Hyo Kim
Section Editor

Many drugs

LOOK – ALIKE

OR

SOUND– ALIKE

causing them to be easily mixed up in practice.

Can **YOU** match these facts with the correct medication?

Answers

Matching Column: Look-Alike Sound-Alikes

1. Works by killing the fungus and preventing its reproduction.

2. Hydrochloride salt of quinapril that comes in tablets of 5mg, 10mg, 20mg,or 40mg.

3. A carbonic anyhydrase inhibitor that reduces fluid pressure in eye-ball, increases the removal of water from the body by the kidney, and block certain nerve discharges that may contribute to seizures.

4. Patient must stay upright for at least 30 minutes after taking this medication.

5. Used to prevent asthma attacks

6. Combination of Lovastatin and Niacin that is used to lower cholesterol and triglycerides in the blood.

7. Generic name is Pioglitazone

8. Used together with diet and exercise to treat type 2 diabetes; belongs to FDA pregnancy category C.

9. To treat symptoms of gastroesophageal reflux (GERD) by decreasing the amount of acid produced in the stomach.

10. Is usually used as an injection intramuscularly or intravenously.

A. Abelcet

B. Amphotericin

C. Accupril

D. Aciphex

E. Acetazolamide

F. Acetohexamide

G. Actonel

H. Actos

I. Advair

J. Advicor

Lexi-Comp OnlineTM , Lexi-Drugs OnlineTM , Hudson, Ohio: Lexi-Comp, Inc.; January 1st, 2014

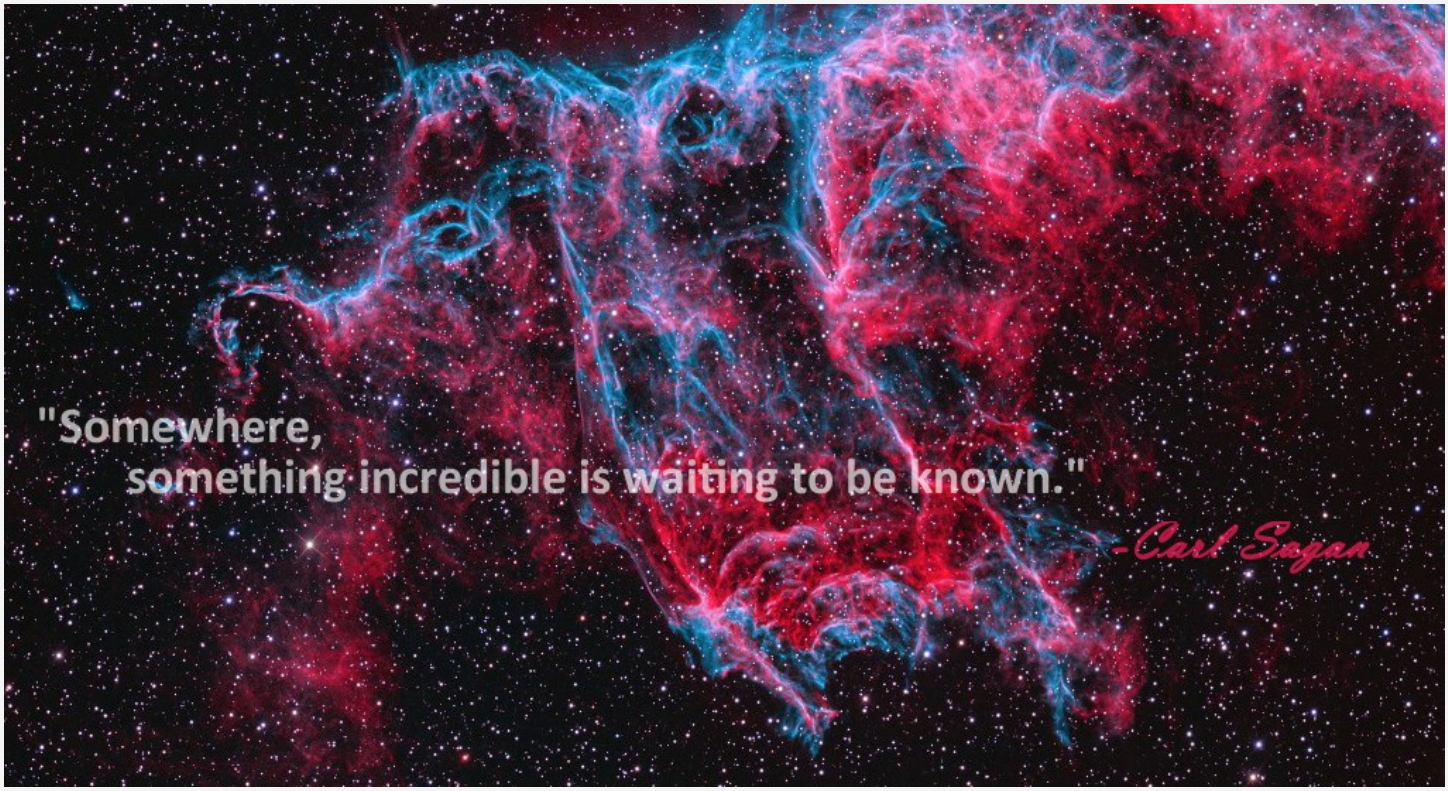
How Did You Do???

Answers to Look Alike and Sound Alike

A. 1 B. 10 C. 2 D. 9 E. 3 F. 8 G. 4 H. 7 I. 5 J. 6

Quote of Month

By: Sylva Ohanian, Staff Writer



PUZZLES

Do you enjoy our puzzle?

Send us a suggestion for a brainteaser at

RhoChiPost@gmail.com

We will feature your work in our next issue!

RHO CHI POST: TEAM MEMBERS

EDITORS

@ Tasnima Nabi ***(5th Year, STJ; Editor-in-Chief)***
Writing has always been my greatest outlet for experience and knowledge, through which I hope to keep you engaged and informed. It is imperative to keep up with our changing profession and community, and I look forward to bringing pertinent information to the newsletter.

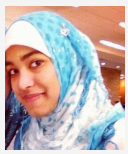
@ Katharine Cimmino ***(6th Year, STJ; Copy Editor [Content-Focused])***
I have always been an avid reader and writer. As a member of the Rho Chi Post I am able to merge my passions with the professionalism that comes with aspiring to be a healthcare provider. I am eager to be a part of a publication that promotes my interests and vocation.

@ Bharat Kirthivasan ***(PhD, Copy Editor [Content-Focused])***
I am a doctoral candidate in Industrial Pharmacy researching nanoparticles for delivery to the brain. The only thing I enjoy more than reading a well-written piece of work is writing it. I am glad to work for the Rho Chi Post, and I encourage others to do the same.

@ Hayeon Na ***(6th Year, STJ; Copy Editor [Content-Focused])***
Hello! My name is Hayeon Na. I am a 2015 PharmD Candidate and one of the Copy Editors for the Rho Chi Post. I hope the information I present will be helpful, or at least interesting. If you have any comments regarding my contribution, feel free to contact me at any time!

@ Erica Dimitropoulos ***(6th Year, STJ; Copy Editor [Content-Focused])***
As busy student pharmacists, we often fail to keep current with healthcare developments. My aim is to sort through the news and provide quick updates that are important to our profession. Feel free to contact me if there are any topics you would like to see covered in the next issue!

@ Davidta Brown ***(4th Year, STJ; Copy Editor [Content-Focused])***
My two great loves are innovative science and quality writing, and the Rho Chi Post is an insightful combination of both. As an editor, I look forward to bringing relevant information and fresh perspectives to the student and faculty of St. John's University, as well as to making the Rho Chi Post a newsletter that offers something new to every reader.



@ Fatema Elias ***(5th Year, STJ; Copy Editor [Content-Focused])***
I am honored to be a part of the Rho Chi Post team. In this age of technology and the continuously changing healthcare profession, I hope to engage like-minded students and professionals. Writing is something that I hold dear to my heart and I hope with this newsletter we can all stay well informed, interested, and educated.

@ Melissa Roy ***(6th Year, STJ; Copy Editor [Graphics-Focused])***
We as future healthcare professionals owe it to our patients and ourselves to be aware and current on the events affecting our profession. The Rho Chi Post is our way to learn new things and stay in touch with the pharmacy world, on- and off-campus. Feel free to reach out to me with suggestions and comments.

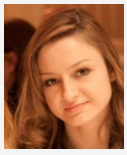
RHO CHI POST: TEAM MEMBERS

@ Tamara Yunusova *(4th Year, STJ; Section Editor: Clinical)*
My name is Tamara Yunusova, and I am a 4th year Pharm D candidate at St. John's University. I enjoy articulating information in a captivating and insightful way. I hope to make this publication more informative, student-friendly, and innovative.

@ Beatrisa Popovitz *(6th Year, STJ; Section Editor: Clinical)*
I am eager to relay current information on interesting topics making waves in the world of healthcare pertinent to the advancement of our profession. As student pharmacists, we are molding the future of our profession, and the Rho Chi Post facilitates the cultivation of a relationship (between students, faculty, and other members of the healthcare community) to share ideas and spread awareness of various issues.

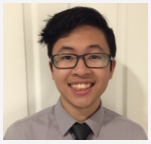
@ Sang Hyo Kim *(3rd Year, STJ; Section Editor: Puzzles)*
Advancements of technology and developments of new medicines, prolonging the lifespan and improving the quality of life, have increased the geriatric population. In years to come, pharmaceutical industries and healthcare systems will persistently work to find solutions to changing demands and new problems of the society. Through the Rho Chi Post, I wish to learn, educate, and prepare myself and others for the future.

@ Azia Tariq *(4th Year, STJ; Section Editor: News)*
The Rho Chi Post is a prominent and highly esteemed resource for pharmacy students and professionals. I am privileged to be a part of the team and hope to contribute informative and engaging pieces to the newsletter.

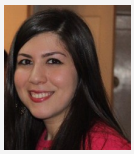


@ Ada Seldin *(6th Year, STJ; Staff Editor [Content-Focused])*
I am thrilled to have become a new member of the Rho Chi Post team. I hope to further strengthen the goals of this newsletter and make a lasting contribution. It is important, as future pharmacists, to collaborate with our peers, as well as accomplished professionals in the field. Rho Chi Post provides a vehicle to voice our opinions and share relevant news.

@ Nicollette Pacheco *(4th Year, STJ; Staff Editor [Graphics-Focused])*
As a new member of the Rho Chi Post team, I have a vast appreciation of what it means to be a future pharmacist in the rapidly evolving world of healthcare. I am looking forward to being on the team as a graphics-focused staff editor, and I hope to bring my passion for science and creativity to the Rho Chi Post.



@ Andrew Leong *(5th Year, STJ; Staff Writer)*
Students have to do more than what is required of us in classes to truly learn about our profession. That's why I joined the Rho Chi Post. This publication represents a channel by which our team members, faculty, and readership can share information - something I believe is important in this ever-changing pharmacy world.



@ Svetlana Akbasheva *(5th Year, STJ; Staff Writer)*
I am very excited and honored to be part of the Rho Chi Post! In a profession that is constantly evolving with new developments, it is so important to remain informed and current. The Rho Chi Post helps do just that, and I look forward to contributing to this unique publication.

?

@ You!
We are always looking for creative and motivated students to join our team!
If you are interested in becoming an editor for the Rho Chi Post, please visit:
http://rhochistj.org/RhoChiPost/EditorApplication

EDITORS

RHO CHI post

RHO CHI

The Rho Chi Society encourages and recognizes excellence in intellectual achievement and advocates critical inquiry in all aspects of Pharmacy.

The Society further encourages high standards of conduct and character and fosters fellowship among its members.

The Society seeks universal recognition of its members as lifelong intellectual leaders in Pharmacy, and as a community of scholars, to instill the desire to pursue intellectual excellence and critical inquiry to advance the profession.

THE RHO CHI POST

MISSION

The Rho Chi Post is an award-winning, monthly, electronic, student-operated, faculty-approved publication that aims to promote the pharmacy profession through creativity and effective communication. Our publication is a profound platform for integrating ideas, opinions, and innovations from students, faculty, and administrators.

VISION

The Rho Chi Post aims to become the most exciting and creative student-operated newsletter within St. John's University College of Pharmacy and Health Sciences. Our newsletter continues to be known for its relatable and useful content. Our editorial team continues to be known for its excellence and professionalism. The Rho Chi Post essentially sets the stage for the future of student-operated publications in pharmacy.

VALUES

Opportunity, Teamwork, Respect, Excellence

GOALS

1. To provide the highest quality student-operated newsletter with accurate information
2. To maintain a healthy, respectful, challenging, and rewarding environment for student editors
3. To cultivate sound relationships with other organizations and individuals who are like-minded and involved in like pursuits
4. To have a strong, positive impact on fellow students, faculty, and administrators
5. To contribute ideas and innovations to the Pharmacy profession

CURRENT EXECUTIVE BOARD

Anthony, Tyler, Sara, Tasnima, Joshua, Fawad at the 2014 Induction Ceremony

President: **Tyler Valente**
Vice President: **Fawad Piracha**
Secretary: **Tasnima Nabi**
Treasurer: **Anthony Nania**
Historian: **Sara James**
Media Relations Coordinator **Joshua Bliss**
Faculty Advisor: **S. William Zito, PhD**

UPCOMING EVENTS

April 21: Pharmacy Lobby Day
Albany, NY

April 27: RCP Workshop—How to Edit
St. John's University

April 27-29: 2015 Diabetes Summit
Boston. MA