Protein Supplementation For Athletes

Do athletes need to eat diets that are very high in protein to help gain muscle? Probably not. Eating protein can help people lose weight because it gives a sense of fullness during and after eating, which leads to less food consumption. A common thought is that, since muscles are made of protein, the diet should be high in protein to build muscle. However, too much protein can keep athletes from eating carbohydrates, which are a major source of energy.

Eating a diverse diet can help you get the fat, carbohydrates, and protein needed to build and maintain a healthy body. Plus, eating a variety of foods will help you get the nutrients (like vitamins and minerals) to allow your body to perform at its peak.

The problem with using protein supplements is that, while they may supply protein, they often do not supply any other nutrients like food does. Protein supplements are “empty” proteins, but real food is more “complete”.

Reports differ on the consequences of a high-protein diet. Although high-protein diets may hurt the kidneys, there is currently no proof to support this claim. Proteins require more water to be digested properly, and too much protein might make an athlete prone to dehydration. Muscles are about 75% water, so it is very important for athletes to be well hydrated to maintain or build muscle.

Why do people who take protein supplements seem to have more muscle than other athletes? We know that it is not the protein supplement that is responsible for the large muscles. It may be a placebo effect, when the belief that a treatment will work results in the treatment working.

An excellent web site to help determine a healthy diet is www.choosemyplate.gov. Most adults need between five and six ounces of protein daily. Three ounces of protein is equivalent to:

- 1 small chicken breast
- three eggs
- 1 can of tuna
- 1 small, lean hamburger patty
- 1 ½ cups of bean, pea, or lentil soup

If an athlete eats more calories in a day for their training program, they may need to eat more protein than a non-athlete.

By Tim Polacheck, PharmD Candidate

REFERENCES:

PATIENT INFORMATION: Stroke

How do you recognize a stroke?

Remember the word FAST to recognize a stroke quickly.

F for Face – Face drooping or laziness on one side can occur when a stroke happens.

A for Arm – Arm weakness on one side can occur when a stroke happens.

S for Speech – Trouble speaking or slurred speech can occur when a stroke happens.

T for Time – Getting help as fast as possible by calling 9-1-1 is very important.

Recognizing the signs of a stroke is very important. Quickly recognizing a stroke and calling 9-1-1 could prevent serious disability or even death.

How can you help prevent a stroke from happening to you?

Regular exercise can help lower stroke risk in several ways, including losing body weight, lowering blood pressure, and improving cholesterol.

Eating a healthy diet that consists of plenty of fresh fruit and vegetables, and less saturated fats, trans fats, and salt.

Quitting tobacco use will lower risk of stroke and improve health in many other ways.

Drinking less alcohol and limiting the amount of drinks to one per day for women and two per day for men can also help lower risk of stroke.

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Visit the following Web sites for more information about strokes:


http://www.cdc.gov/stroke/index.htm

http://www.strokeassociation.org/STROKEORG/

By Luke Schonsberg, PharmD Candidate

REFERENCES:


Vraylar® (cariprazine)

Vraylar® (cariprazine) was approved by the FDA on September 17, 2015, for treatment of schizophrenia and bipolar I disorder with acute mixed or manic episodes. Cariprazine is believed to be a potent partial agonist of D3, D2, and 5-HT1A receptors in the brain as well as an antagonist for 5-HT2B, 5-HT2A, and H1 receptors. Current antipsychotic medications do not have a strong affinity for D3 receptors. Cariprazine is unique because it is 10 times more potent for D3 receptors than D2 in vitro. D3 receptors are thought to have a role in mood regulation and cognition function. Therefore, cariprazine may have a broader effect on patients with bipolar and schizophrenia due to its unique mechanism of action.

Current antipsychotic therapies mainly target positive symptoms including hallucinations, delusions, and disorganized speech. However, better quality of life is associated with decreased negative (social withdrawal, decreased motivation, lack of emotion) and cognitive symptoms (lack of attention or memory deficit). In clinical trials, cariprazine not only improved positive symptoms, but also had some benefit on negative symptoms.

Cariprazine was more effective than placebo in patients with bipolar disorder and in study participants with schizophrenia in multiple trials.

Cariprazine significantly decreased the severity of mania symptoms after three weeks in 312 participants with bipolar disorder. The randomized, double-blind study evaluated various cariprazine doses between 3 mg and 12 mg. The use of benzodiazepines as a rescue medication in the study did not significantly decrease in any of the treatment groups. Because the use of benzodiazepines was similar between placebo and cariprazine, this drug may not decrease agitation in patients. The study results may not be generalizable to all populations since 57% of participants were Asian. Additionally, participants were excluded if they had received electroconvulsive therapy within the last three months, a depot neuroleptic within the last three months or had been previous clozapine treatment within the last ten years.

Often antipsychotics are linked to weight gain, cardiovascular events or metabolic changes. In a three-week clinical trial, the effects of cariprazine were similar to placebo in weight gain, QTc prolongation, metabolic changes, and changes in prolactin, which may suggest cariprazine as an alternative to other antipsychotic medications to avoid these side effects.

Cariprazine 3 mg to 9 mg significantly decreased positive schizophrenia symptoms in 446 participants compared to placebo. In this double-blind, six-week study, doses of 3 mg to 6 mg of cariprazine and 6 mg to 9 mg of cariprazine were compared to placebo. Regardless of cariprazine dose, positive symptoms improved compared to placebo. Participants on higher doses of cariprazine also had a significant decrease in negative symptoms, but this was not seen with lower cariprazine doses. Schizophrenia Quality of Life Scale (SQLS-R4) scores and vitality scores significantly improved in participants taking lower doses of cariprazine, but the improvement was not significant with higher doses. Study participants were excluded if they had treatment-resistant schizophrenia, electroconvulsive therapy in the past 3 months, or used clozapine within the last ten years, which may limit the generalizability of the results.

Adverse effects of akathisia, extrapyramidal symptoms, somnolence, restlessness, induction, and vomiting were commonly seen in clinical trials. It is important to note that full effects from dose increases do not develop in patients for several weeks since cariprazine has a long half-life (2–4 days) and multiple metabolites. Therefore the relatively short clinical trials may not be an adequate representation of long-term adverse effects of cariprazine.

The initial starting dose for cariprazine is 1.5 mg per day. The dose can be increased by 1.5 mg as needed to see effect. The maximum dose of cariprazine is 6 mg per day. The maintenance dose for treatment of schizophrenia is 1.5 mg to 6 mg daily, and the maintenance dose for treatment of bipolar disorder is 3 mg to 6 mg daily.

When used in conjunction with a strong CYP3A4 inhibitor (ketoconazole, clarithromycin, etc.), cariprazine dose should be decreased by 50% due to decreased metabolism and elimination of cariprazine. Cariprazine is also partially metabolized by CYP2D6 so it may interact with medications such as celecoxib or amiodarone.

The use of cariprazine in patients with severe hepatic impairment or creatinine clearance less than 30 mL/min has not studied, and it is not recommended to use cariprazine in these populations.

Cariprazine is a novel agent with the effects on D3 receptors as well as D2 receptors. Since D3 receptors promote mood regulation and cognition function, cariprazine may help advance therapy in patients with schizophrenia and bipolar disorder. Cariprazine clinical trials did not include an active control, which limits the ability to evaluate cariprazine’s therapeutic advantages compared to other agents. The clinical trials for both bipolar and schizophrenia allowed use of rescue benzodiazepine therapy, which did not decrease with use of cariprazine. Therefore, cariprazine should not be expected to reduce agitation.

By Valerie Nauditt, PharmD Candidate

References on Page 6
RSV infections can cause bronchiolitis, pneumonia, inflammatory disorders, and secondary infections of the lungs. Infection with RSV can occur at any time of year, but the incidence of infection increases in the winter months (Figure 1). RSV is the most common cause of bronchiolitis in children less than one year of age. By the age of 2, nearly all children will have been infected with RSV. Reinfection is common throughout life. As the time from first infection increases, occurrence becomes less common and symptoms are usually less severe. Most RSV infections are not life-threatening and do not require health care interventions. However, interventions may be warranted in those with severe disease or in high risk groups.

**Figure 1: RSV seasons in US and Western regions**
(Adapted from the Center for Disease Control Web site)

### Treatment Recommendations by Patient Population

<table>
<thead>
<tr>
<th>Treatment for RSV in all groups</th>
<th>Supportive care is the mainstay of treatment, which includes supplemental oxygen, fluids, mucus removal and, in severe cases, intubation. Routine bronchodilator use has not shown a clear benefit in the treatment of RSV for any group.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infants and young children (less than 24 months)</strong></td>
<td>Supportive care is the mainstay of treatment for this group. Avoid corticosteroids, bronchodilators, ribavirin and immunoglobulins. One to two bronchodilator administrations may be warranted in severe disease, but routine use is not supported by the current literature.</td>
</tr>
<tr>
<td><strong>Older children and adults (over 24 months)</strong></td>
<td>Consider use of methylprednisolone. Provide supportive care as needed, though severity of symptoms is usually less than with younger patients.</td>
</tr>
<tr>
<td><strong>Special populations</strong></td>
<td>Immunocompromised patients: Consider ribavirin therapy. Ribavirin may be particularly beneficial when combined with passive immunotherapy and/or corticosteroids. Pregnant patients: Pregnant patients should receive management similar to other adults. Ribavirin is contraindicated in this group of patients. Male partners of pregnant patients should not receive ribavirin.</td>
</tr>
</tbody>
</table>

**By Kyle Ann Spinner, PharmD Candidate**
Continued on Page 5
## Treatment of Respiratory Syncytial Virus (RSV) Infection (cont.)

### Recommendations for Specific Therapies

<table>
<thead>
<tr>
<th><strong>Supplemental oxygen</strong></th>
<th><strong>Indication:</strong></th>
<th>Arterial oxygen saturations of $\leq 90%$(^1)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Delivery systems</strong></td>
<td></td>
<td>Masks or nasal cannula are recommended over other administration systems. Infants or children may also require enclosure systems. In severe cases, mechanical ventilation may be required.(^4)</td>
</tr>
<tr>
<td><strong>Discontinuation</strong></td>
<td></td>
<td>Discontinue upon consistent oxygen saturation of $&gt;90%$ and cessation of severe respiratory symptoms.(^3)</td>
</tr>
</tbody>
</table>

### Corticosteroids (methylprednisolone)

<table>
<thead>
<tr>
<th><strong>Adults</strong></th>
<th>500 mg oral methylprednisolone once daily for 3 days(^8)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children &gt;24 months</strong></td>
<td>No dose is currently established. Standard dosing for patients with inflammatory conditions are: Pediatrics: 0.5 to 1.7 mg/kg/day orally in 2-4 divided doses (^9). Adults: 2 to 60 mg/day in 1-4 divided doses (^9)</td>
</tr>
</tbody>
</table>

### Bronchodilators (albuterol and epinephrine)

| **Short term use** | Short term bronchodilator use has been found ineffective in all groups except those less than 24 months of age. A single study demonstrated a limited short term benefit of 0.1 mg/kg nebulized albuterol when given no more than 1-2 times, 30 minutes apart. All patients included in the study were under 24 months of age. Improvement occurred only in subjective clinical scores. Oxygen saturation was unaffected by this treatment.\(^5\) |
| **Prolonged use** | No benefit of long-term albuterol or epinephrine use has been found for all age groups.\(^1\) |

### Ribavirin

| **Formulations** | Nebulizer solutions have demonstrated efficacy in a greater number of trials than other formulations. Ribavirin is also supplied as a capsule, tablet and oral solution.\(^10\) No formulations have been directly compared or clearly established as the treatment of choice for RSV.\(^7,8,10\) |
| **Dosing** | Dosing of ribavirin for RSV has not been established. Treatment regimens that have shown success in trials have included: 2000 mg of inhaled ribavirin given over 2 hours and repeated every 8 hours for 4 to 10 days\(^7,8\). 15 to 20 mg/kg/day oral ribavirin in three divided doses for 7-10 days\(^11\). 10 mg/kg loading dose or oral or IV ribavirin, followed by 400 mg three times per day on day 2, and 600 mg three times per day on day 3. Treatment is discontinued when the patients become asymptomatic and RSV is undetectable by RT-PCR.\(^12\) |
| **Concomitant treatments** | In most studies, ribavirin was used concomitantly with both 500 mg/kg RSV IVIG and 15 mg/kg palivizumab. Both medications were given as a single dose at admission for treatment.\(^1,7,8\) Several studies demonstrated efficacy when ribavirin was administered with 500 mg of methylprednisolone daily for 3 days.\(^1,7,8\) |

References on Page 6
RSV Treatment References


Cariprazine References

What is the concern about pneumonia?2

“Pneumonia” is a common term used to describe a general lung infection. One cause of pneumonia is *Streptococcal pneumoniae* bacteria. There are more than 90 types of *S. pneumoniae*, and they are commonly found in the upper respiratory tract. Five to seventy percent of healthy adults are “carriers” of *S. pneumoniae*. Exposure to these bacteria can occur from an infected person expelling water droplets (coughing, sneezing). *S. pneumoniae* bacteria is also found in healthy people and can cause pneumonia if you are already ill or have a weakened immune system.

Who is at risk?

People most at risk for *S. pneumoniae* infections are the young (< 5 years old) and the elderly (≥ 65 years old). People who have a weakened immune system (cancer, HIV/AIDS), lung disease (including asthma and smoking), or liver disease are also at risk.

How *S. pneumoniae* becomes deadly is not completely known, but lung diseases, such as asthma and COPD, are thought to play a role.

What is the pneumonia vaccine?

There are 2 vaccines which protect against the most common types of *S. pneumoniae* bacteria that cause pneumonia.

- Prevnar 13®—the “conjugate” vaccine was approved in 2010
- Pneumovax® 23—the “polysaccharide” vaccine was approved in 1983

The table below has information about who should get which pneumonia vaccine.

By Chris Migliaccio, PharmD Candidate

REFERENCES:


2015 Pneumococcal Vaccination Guidelines from the Advisory Committee on Immunization Practices (ACIP)

<table>
<thead>
<tr>
<th>Special populations</th>
<th>Prevnar 13®</th>
<th>Pneumovax® 23</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine type</td>
<td>Conjugate</td>
<td>Polysaccharide</td>
</tr>
<tr>
<td>Patient ages for vaccine use</td>
<td>≥ 65 years old*</td>
<td>≥ 65 years old*</td>
</tr>
<tr>
<td></td>
<td>2-59 months old</td>
<td>2-64 years old§</td>
</tr>
<tr>
<td>Special populations</td>
<td>≤ 64 years old§</td>
<td>+ chronic heart disease</td>
</tr>
<tr>
<td></td>
<td>+ asplenia</td>
<td>+ asplenia</td>
</tr>
<tr>
<td></td>
<td>+ cochlear implant</td>
<td>+ lung disease</td>
</tr>
<tr>
<td></td>
<td>+ cerebral spinal fluid leaks</td>
<td>+ asthma</td>
</tr>
<tr>
<td></td>
<td>+ decreased immunity (transplant, cancer, HIV)</td>
<td>(if &gt; 19 years old)</td>
</tr>
<tr>
<td></td>
<td>+ decreased immunity</td>
<td>+ liver disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+ alcoholism</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+ cigarette smoker</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(if &gt; 19 years old)</td>
</tr>
</tbody>
</table>

* Prevnar 13® should be given at least 1 year before receiving Pneumovax® 23

§ Prevnar 13® should be given at least 8 weeks before receiving Pneumovax® 23
Updates to Clozapine REMS Program

Previously, each manufacturer of clozapine had their own risk evaluation mitigation strategy (REMS) program, resulting in six independent programs. In an effort to reduce potential sources of error, the FDA has released a central REMS program, consolidating the previous programs into one program. Patients enrolled in previous programs have been transferred to the new REMS program. This update changes prescriber and pharmacist duties and eliminates the National Non-Rechallenge Master File (NNRMF).

Prescriber duty changes:
- Prescribers are required to be registered and certified with the new clozapine REMS program before they can dispense.
- Only prescribers or their registered designees can enroll patients into the program.
- Monitoring must be done with absolute neutrophil count (ANC); white blood cell (WBC) counts are no longer accepted.
- Notable updates to treatment guidelines include lower ANC thresholds, new guidelines for patients with benign ethnic neutropenia, removal of the NNRMF, and flexibility to continue treatment if benefits outweigh risks.

Pharmacist duty changes:
- Pharmacies must have a designated authorized representative who is registered with the program. This can be a pharmacist, pharmacy director, or corporate executive.
- Pharmacists can no longer enroll patients, unless they are a prescriber’s registered designee.
- A pre-dispense authorization (PDA) must be obtained before a pharmacy may dispense clozapine, to ensure all checks have been passed. PDAs can be obtained through the pharmacy management program (if your program is set up to interact with the registry) online through www.clozapinerems.com or by phone.
- Inpatient pharmacies do not need a PDA.

May 20, 2016 Update:
The initial PDA launch was implemented on May 20, 2016. If the prescriber and/or pharmacy is not certified with the REMS program, then a warning message will appear. However, dispensing will still be authorized. Dispensing will still be authorized if the patient’s ANC is not current.

Once the second phase of the PDA implementa-