Pharmacy News

UNIVERSITY HOSPITAL
Newark, New Jersey

First Quarter 2020
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Special Points of Interest:

P&T Update

Formulary Additions

- **Melatonin Formulary Addition Request**
  Melatonin is an inexpensive, safe, and possibly effective medication for sleep and ICU delirium with little safety risk. In studies, it has a dosage range from 0.5-10 mg. The pharmacy stocks 1 mg and 5 mg tablets. Formulary addition approved with no restrictions.
- **Sodium phenylacetate/sodium benzoate** - gatekeeper follow up
  Sodium phenylacetate/sodium benzoate is indicated for the treatment of hyperammoneic crisis in the pediatric patients with urea cycle disorder. Formulary addition of sodium phenylacetate/sodium benzoate approved with the following gatekeepers: Dr. Pletcher/Dr. Shih-Approved.
- **Acetaminophen 325mg rectal suppositories**
  Formulary addition of acetaminophen 325mg rectal suppositories – Approved

Line Extension:

- **Formulary Extension Sodium zirconium**
  A house wide orderset for hyperkalemia is being developed that includes sodium zirconium. Discussion about adding warning in orderset to alert ordering user of monitoring and repeat lab recommendations. Motion to approve unrestricted for one time dose through order-set, maintenance dose will require cardiology and nephrology approval.
- **Dantrolene (Ryanodex®)**
  Formulary switch from dantrolene (Dantrium®/Revonto®) formulation to dantrolene (Ryanodex®) formulation – Approved

Formulary Deletions

Aspirin 325 mg, aspirin EC 81 mg, aspirin EC 325 mg

- Keep the following formulations: aspirin oral suspension (1 mg/mL), aspirin 81 mg chewable tablet, aspirin rectal suppository 600 mg - Formulary deletion approved

Activated charcoal with sorbitol

- Use with sorbitol is no longer recommended – Formulary deletion approved

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P&T Update

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Allopurinol IV

- The cost of one vial of IV allopurinol is almost $2000 which is significantly more expensive than the oral formulation which is about a dollar per day. The current hospital rasburicase protocol recommends using low doses of rasburicase after approval from the Oncology/Nephrology divisions. These departments have approved the deletion of IV allopurinol. – Formulary deletion approved

Abciximab

- Discontinued by manufacturer. Formulary deletion approved.

Dantrolene (Revonto®/Dantrium® - Formulation)

- Dantrolene formulation to be switched from Revonto®/Dantrium® to Ryanodex®
  Formulary deletion of dantrolene (Revonto®/Dantrium®) formulation- Approved
  Formulary addition of Ryanodex® - Approved

Policies & Procedures/Floorstocks

UH Hazardous Drug Management Policy Hospital wide policy for management of hazardous drug, reflecting USP 800 standards. Policy will be effective December 1st, 2019 – Approved

- 707-500-118 Titrating Medication Orders- Policy Update
  An update to the existing policy is presented to include comprehensive listing of titratable intravenous medication drips and the regulatory elements required to safely/effectively titrate the medications. – Approved
- 707-500-115 Standard Concentration for IV Infusion Medications- Policy Update
  An update to the existing policy is presented outlining the standard infusion concentrations for adults/pediatrics/ neonatal patient population. The standard concentrations have been also incorporated in Epic. – Approved
- 707-400-112 Standing Medication Orders for the Newborn - Policy Update
  The policy is updated to specify standing orders for certain standard medications at birth which are administered per protocol by the nurse. – Approved

Clinical Guidelines

- 2020 Buprenorphine Prescribing Guidelines Update
  An update to the existing guidelines is presented whereby buprenorphine does not require approval from a DEA waivered physician beyond 72hours if the primary diagnosis is NOT opioid use disorder. – Approved
- 2020 Antidepressant Class Review
  An annual class review of the antidepressant medications is submitted by the Psychiatry Subcommittee. – Approved
- 2020 Mood Stabilizer Class Review
  An annual class review of the mood stabilizers medications is submitted by the Psychiatry Subcommittee. – Approved
- 2020 Antipsychotic Class review
  An annual class review of the antipsychotic medications is submitted by the Psychiatry Subcommittee. – Approved
- 2020 Dangerous Cautionary Medication interaction List
  The cautionary psychiatry medication interaction list was presented. – Approved

Chondroitin and Glucosamine Use for Osteoarthritis Prevention

Osteoarthritis is the most common chronic condition of the joints, referred to as a "wear-and-tear" degenerative disease. Between 2013 and 2015, an estimated 54.4 million US adults, or 22.7% of the population, have been told by a doctor that they had some form of arthritis, gout, lupus or fibromyalgia. This represents an increase from 49.9 million adults between 2007 and 2009. By 2040, 26% of US adults aged 18 years or older are projected to have doctor-diagnosed arthritis.

In normal joints, a firm, rubbery material, known as cartilage, covers the end of each bone. Cartilage acts as a cushion between two bones and provides a smooth surface for joint motion. Cartilage is easily compressed, losing up to 40% of its original height when a load is applied. Normal cartilage turnover helps to repair and restore cartilage in response to physical activity and demands of joint loading as a result of obesity. Over time, changes that occur in the joint reflect compensatory processes to maintain function in the face of ongoing joint destruction.

Osteoarthritis begins with damage to articular cartilage, either through trauma, injury, overuse, genetics or other reasons. Depending on the degree of damage, the balance between the breakdown and resynthesis of cartilage over time can be lost. A vicious cycle of increasing breakdown leads to excess cartilage loss. Over time, as the cartilage increasingly breaks down, bones begin to rub against each other and develop growths called spurs. Bits of the broken down cartilage and bone float around the joint, triggering an inflammatory process and further damaging the cartilage.

Treatment modalities for knee osteoarthritis have been established, implemented, and documented in several guidelines. There is no cure for osteoarthritis, but there are numerous options available to manage symptoms. Optimal management of osteoarthritis is based on a combination of non-drug and drug treatments targeted towards prevention, risk modification and disease progression. Non-pharmacological treatments include maintaining a healthy weight, getting enough exercise, and, in severe cases, undergoing joint surgery. In terms of pharmacological treatment, analgesics and anti-inflammatory agents are typically prescribed for pain management. Although these medical

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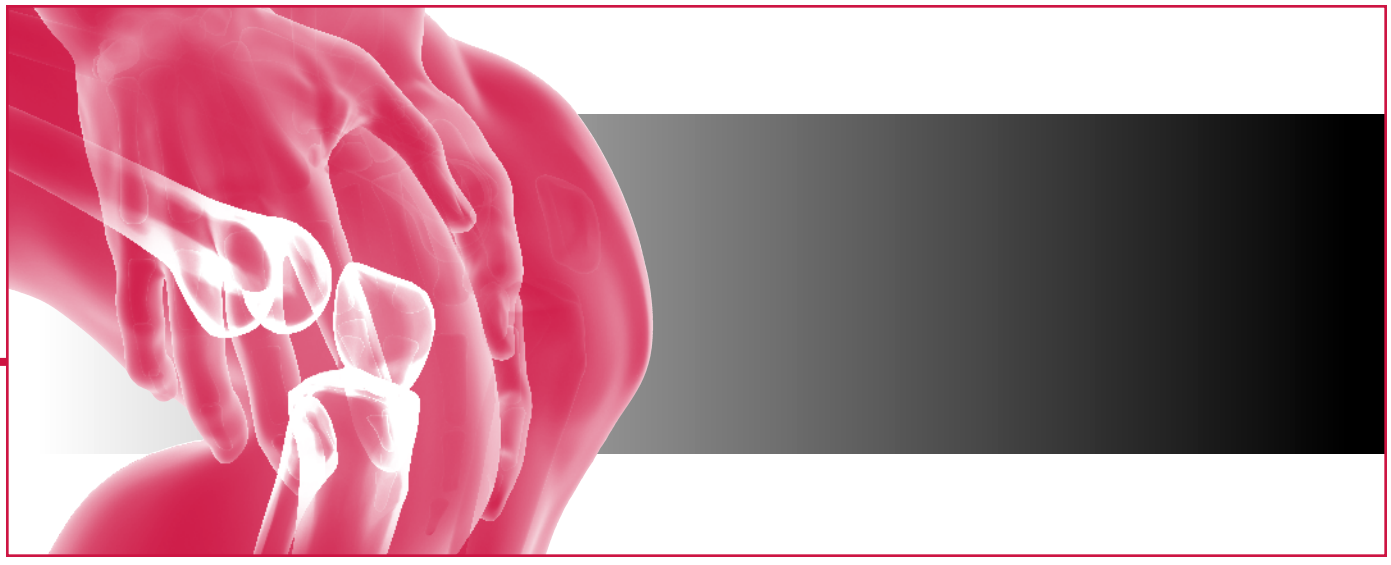

Chondroitin and Glucosamine Use for Osteoarthritis Prevention

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treatments have been proven to be effective, other therapeutic options have been proposed. These include biologic compounds and oral supplements, such as chondroitin and glucosamine. The possibility that these compounds may have a chondroprotective effect on knee osteoarthritis attracts significant interest among suffering patients.

The most commonly used alternative treatment for osteoarthritis is glucosamine. Glucosamine is a biological component of joint cartilage. It is an amino sugar, which is contained in the skin, cartilage, or the shell of a crustacean. The commercially manufactured glucosamine supplements are manufactured with chitin, which is disassembled with acids or enzymes from the shells of crabs or shrimps. This facilitates the production of cartilage cells (chondrite) and increases the secretion of synovial fluid, that acts as a lubricant of the joint to improve joint function. Joint cartilage consists of cells embedded in a matrix of fibrous collagen within a concentrated water-proteoglycan gel. The integrity of this matrix is crucial for the biomechanical properties of the joint cartilage. Glucosamine is the component that is used to make this proteoglycan. On the other hand, chondroitin is thought to enhance the shock absorbing properties of collagen and block the enzymes that break down the cartilage. Both of these supplements have been studied.

The most comprehensive long-term study of any supplement was called the Glucosamine/Chondroitin Arthritis Intervention Trial (GAIT). This study looked at the combination of chondroitin and glucosamine, both supplements individually, celecoxib (Celebrex) and placebo in patients with knee osteoarthritis. The first phase of GAIT found that the combination of glucosamine and chondroitin sulfate showed significant relief in a subgroup of participants with moderate to severe knee pain. There was no effect in the group with mild pain.[5] The second phase of the GAIT study looked at preventing joint damage in the knee. The combination of glucosamine and chondroitin appeared to be no more effective at preventing joint damage caused by osteoarthritis than a placebo. Participants who lost the least amount of joint space over two years were those in the groups taking either glucosamine or chondroitin alone. It was proposed that the combination of taking the two supplements together limits their absorption into the body. The third phase looked at a total of four years of data. It was shown that the supplements, either in combination or alone, had no greater benefit in knee pain relief than celecoxib or placebo. Celecoxib achieved the highest odds of attaining at least 20% reduction in pain.

Since both glucosamine and chondroitin are supplements, their production is not regulated by the U.S Food and Drug Administration (FDA). This means that the content can vary from brand to brand and these supplements may not be effective in all patients. It is important to discuss the use of such supplements with your doctor or pharmacist. Such products do not show immediate relief and it may take up to two to four months before the maximum benefits are seen.

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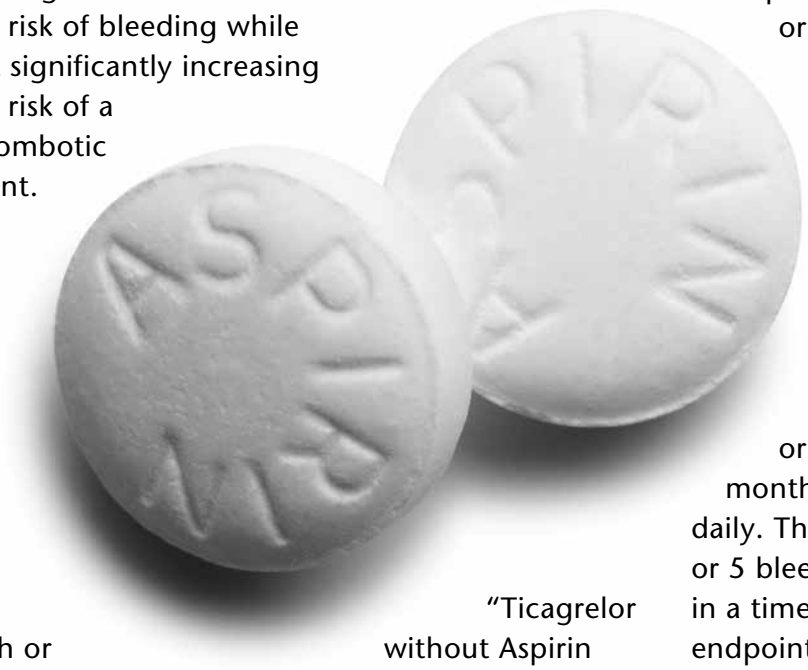
"Ticagrelor with or without Aspirin in High-Risk Patients after PCI"

Dual antiplatelet therapy, also known as DAPT, refers to treatment with both aspirin and a P2Y12 inhibitor, simultaneously. This combination is commonly used in post-percutaneous coronary intervention (PCI) patients in order to lower the risk of thrombotic events. However, monotherapy with a P2Y12 inhibitor after dual antiplatelet therapy has been on the rise lately in an attempt to reduce the risk of bleeding in patients after percutaneous coronary intervention (PCI). This trial was completed to test the hypothesis that after 3 months of DAPT in post-PCI patients, switching to ticagrelor alone will reduce the risk of bleeding while not significantly increasing the risk of a thrombotic event.



"Ticagrelor with or without Aspirin in High-Risk Patients after PCI" is a randomized, placebo-controlled trial that took place from July 2015 until July 2019 when the trial database was officially locked. The trial took place at 187 different sites across 11 countries. 9006 patients were originally enrolled and 7119 were randomly assigned after 3 months of DAPT to the ticagrelor/placebo or ticagrelor/aspirin groups. In order to be eligible, patients must have successfully underwent PCI with at least one drug-eluting stent and must have been intended to be discharged with a regimen of ticagrelor and aspirin. In addition, patients must have had at least one other clinical and one other angiographic feature associated with a high risk of bleeding or ischemic events. Qualifying clinical features included age >65, female sex, troponin-positive ACS, vascular disease, diabetes, or chronic kidney disease. Qualifying angiographic features included multi-vessel coronary artery disease, stent length >30 mm, a thrombotic target lesion, a bifurcation lesion treated with two stents, an obstructive main or proximal left anterior descending lesion, or a calcified target lesion treated with atherectomy.

Once patients were selected, they received 3 months of ticagrelor 90 mg twice daily plus aspirin 81-100 mg once daily. For those patients that did not have a major bleeding or ischemic event, they were then randomly assigned 1:1 to receive aspirin or matching placebo for an additional 12 months along with ticagrelor 90 mg twice daily. The primary endpoint was BARC type 2, 3, or 5 bleeding between randomization and 1 year in a time-to-event analysis. The key secondary endpoint was first occurrence of death from any cause, nonfatal myocardial infarction, or nonfatal stroke. Secondary bleeding endpoints were included to focus on BARC type 3 or 5 bleeding, which are more severe than type 2, and to extend to three other bleeding scales. Other secondary endpoints included death from cardiovascular causes, myocardial infarction, ischemic stroke, and probable or definite stent thrombosis.

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"Ticagrelor with or without Aspirin in High-Risk Patients after PCI"

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The primary endpoint was seen in 141 patients (4.0%) in the placebo group and 250 patients (7.1%) in the aspirin group. When analyzing just BARC type 3 or 5 bleeding, an event occurred in 1.0% of the placebo population and 2.0% of the aspirin population. Death from any cause occurred in 1.0% of the placebo group and 1.3% of the aspirin group. Incidences of myocardial infarction and probable or definite stent thrombosis were similar in both groups. Ischemic stroke occurred in 0.5% of the population in the placebo group and 0.2% of the population in the aspirin group.

As far as the distribution of patient characteristics between the two groups, it was fairly even. The majority of the patients were white males around the age of 65. Over half of the patient population was overweight and were diagnosed with hypercholesterolemia and/or hypertension. About a third of the patient population was diagnosed with diabetes. This trial enrolled a large population across many different locations, which is one of the main strengths of this study. In addition, they included patients (33%) who were in stable condition at the time of enrollment. This is important because current guidelines recommend ticagrelor in the context of acute coronary syndrome alone. The lowering of bleeding risk while maintaining ischemic benefit was consistent across both the stable and acute patient groups. The main limitation of this study was the inability to detect significant differences between the rare clinical events such as stroke and stent thrombosis. For example, as stated earlier, the risk of ischemic stroke (0.5% vs 0.2%) was higher in the placebo group. However, there were only a total of 24 ischemic strokes out of the 7119 patients who underwent randomization and the study does not have significant power to determine if this was due to chance or not.

This study shows that ticagrelor alone after three months of successful DAPT with ticagrelor and aspirin provided a clinical benefit of lower bleeding events without increasing the risk of ischemic events when compared to ticagrelor and aspirin. It is unknown at this time whether the same results will be observed in patients without the high-risk criteria that was required in this study and it cannot be recommended to apply these results to such patients. In addition, this study only looked at patients who were able to successfully complete three months of DAPT and should not be applied to those who have adverse events while on DAPT. Further studies are needed to look into such scenarios.

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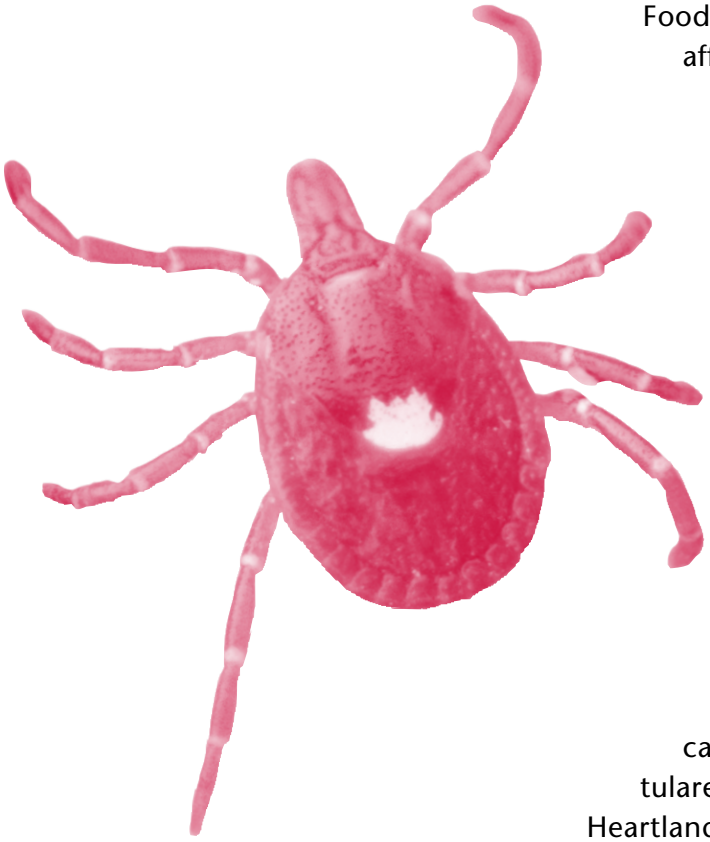
Lone Star Tick-Induced Red Meat Allergy



Food allergies are a growing public health concern affecting an estimated 4-6% of children and 4% of adults in the United States, according to the CDC. Although many food allergies are present amongst children and adolescents, food allergies can develop at any age. A unique example is the development of an allergy to red meat, or alpha-gal syndrome, caused by Amblyomma americanum, also known as the Lone Star tick. With the Lone Star tick expanding its geographic range, more people are at risk of coming into contact with it. Thus, it is important to understand the tick itself, the mechanism of the disorder, preventative measures, and how to live with the condition once it has been contracted.

Along with alpha-gal syndrome, other carried diseases such as human ehrlichiosis, tularemia, Southern tick associated rash illness, Heartland virus disease, and Bourbon virus disease are associated with the Lone Star tick. Female ticks bite humans more frequently than males and have a distinct white mark on the center of its back, or a "lone star". Conversely, males have white streaks or dots located around the border of their backs. The Lone Star tick is highly prevalent in the Southeast region of North America, but cases have been reported in regions ranging from Oklahoma and Texas to New England. This species is known to be highly populated in areas with high humidity and bites usually begin in early spring and span through late fall.

Alpha-gal syndrome is caused by the Lone Star tick's bite. Although it has not been confirmed, it is hypothesized that once bitten, the tick may transfer the carbohydrate galactose-alpha-1,3-galactose (αgal) into the person's body. Lone Star ticks are believed to carry this carbohydrate from the blood of the animals they commonly bite. Alpha-gal is found in the blood of beef, lamb, pork, and food products derived from all mammals other than catarrhine primates such as humans or apes. In some people, the injected alpha-gal results in a delayed-type IgE allergic response with histamine release. The resulting side effects include: hives, shortness of breath, angioedema, congestion and wheezing, as well as diarrhea/abdominal cramps, hemodynamic instability, and anaphylactic shock in severe cases. Unlike most food allergies, these symptoms do not appear for three to six hours after the ingestion of red meat; a common case would be a patient waking up in

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Lone Star Tick-Induced Red Meat Allergy

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the middle of the night with anaphylaxis after eating red meat for dinner. Lastly, it is important to note that symptoms of alpha-gal syndrome may lessen over time, with some people being able to eat red meat again within one to two years, as long as they do not receive additional bites.

Currently there is no treatment for those bitten by the Lone Star tick but preventative measures can be taken. Before going outdoors, EPA-registered insect repellents with a DEET concentration of at least 20% can be applied to the skin. Another viable option is to avoid skin exposure to grassy and wooded areas by covering up with permethrin-treated clothing. Once returning indoors, be sure to check for ticks on any clothing. If any ticks are seen, remove them immediately with tweezers rather than squeezing them. Maintaining a clean yard by removing leaves and brush is another preventative matter that can be taken. Once alpha-gal syndrome has developed, it is imperative to avoid eating any form of red meat; other animals such as chicken and fish are safe to eat. If anaphylaxis occurs, epinephrine autoinjectors can be used to avoid possible fatality.

Awareness is key to preventing alpha-gal syndrome related accidents. A growing number of physicians and other healthcare providers are becoming aware of this condition and the possible link it has to the Lone Star tick. It is important that patients are educated, especially those in highly tick-populated areas, of the risks and side effects of alpha-gal syndrome to avoid putting anyone's life at risk. With proper preventative measures, the Lone Star tick's bite can be a danger of the past.

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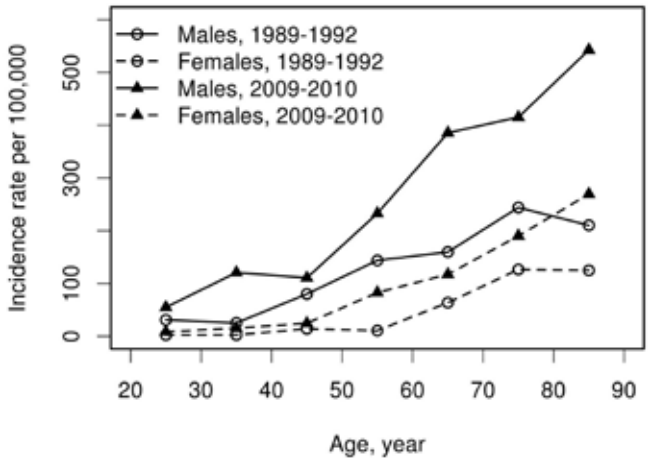
Management and Prevention of Acute Gout Flare-Ups

Epidemiology

Gout is a prevalent inflammatory arthropathy, affecting about 8.3 million people in the United States. Over the last few decades, the occurrence of gout has risen steadily, mainly due to trends in lifestyle and diet choices. Epidemiological studies have confirmed that the consumption of animal purines, alcohol, and fructose are clinically relevant risk factors for gout, and overindulgence in foods containing such elements will lead to a gout attack. In the US, 4.8 out of 1,000 patients have



The Journal of Rheumatology April 2018, 45 (4) 574-579; DOI: https://doi.org/10.3899/jrheum.170806

reported a gout attack in 1999, compared to 2.9 out of 1,000 in 1990. This syndrome is also more prevalent in men (5.9%) as opposed to women (2.0%). As people age the difference between genders decreases, how men still outnumber women with gout even amongst older patient populations.

Pathophysiology

Gout is a form of arthritis, causing pain and tenderness in the joints, most commonly affecting the big toe. Hyperuricemia is the major risk factor for the cause of gout. Hyperuricemia is defined as an excess of uric acid in the blood and has a direct correlation to the incidence and prevalence of gout. An increased serum concentration of uric acid leads to deposition of urate crystals in and around tissues, leading to inflammatory response, painful distal monoarthritis, and even joint destruction characteristic to gout. Hyperuricemia can be due to overproduction or poor excretion of uric acid. Overproduction of uric acid results when abnormalities occur with two enzymes in the body, phosphoribosyl pyrophosphate synthetase (PRPP synthetase) and hypoxanthine-guanine phosphoribosyl transferase (HGPRTase). PRPP synthetase is an enzyme that produces uric acid and HGPRTase is an enzyme that assists in breaking down substrates that make uric acid. When the body has either an increase in the activity of PRPP synthetase, or a deficiency in HGPRTase, serum uric acid increases and results in gout. However, overproduction of uric acid occurs in only 10% of patients and 90% of patients with gout have problems stemming from inefficient excretion. Lack of uric acid renal elimination is typically due to enhanced reabsorption in the proximal convoluted tubule, thus retaining it in the bloodstream and causing hyperuricemia.

Treatment Approaches

Patients that are afflicted with gout syndrome should initiate their management efforts with lifestyle and dietary modifications. To begin with, patients should limit their intake of purine rich foods (including red meat, organ meats, seafood) and high fructose corn syrup-sweetened drinks. Encourage patients to consume vegetables and lower the intake of dairy. Additionally, reducing alcohol consumption and abstaining from alcohol during an acute attack is the best course of action to prevent the onset or worsening of a gout attack. Uric acid levels can be reduced by 10-20% with weight management alone by reducing inflammation and tension on joint muscles. Following attempts to implement lifestyle changes, acute attacks can be treated with a combination

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Management and Prevention of Acute Gout Flare-Ups

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of high-dose/short-term NSAIDs + colchicine + glucocorticoids. To reduce the risk of future attacks associated with hyperuricemia, patients can prophylactically take a combination of xanthine oxidase inhibitors, uricosuric agents, low dose NSAIDs, and low dose colchicines.

Acute Gouty Attack Treatment

During an acute gouty attack, treatment with NSAIDs, colchicine or corticosteroids should be initiated within 24 hours of onset of symptoms. If treatment begins within 24 hours, the patient should see relief in 12 hours and complete resolution of symptoms within 24-48 hours. For severe or refractory attacks with inadequate response to monotherapy, consider dual therapy with colchicine + NSAIDs, colchicine + oral corticosteroids, and intra-articular steroids + first line agent. NSAIDs should not be taken together with steroids due to the risk of gastrointestinal side effects such as ulceration, worsening inflammation and bleeding, as well as fluid retention. Urate lowering therapy should be continued throughout the course of an acute attack.

Flare-Up Prophylaxis

For patients living with intercritical gout (Serum urate level >10mg/dL with palpable tophi), urate lowering therapy should be utilized. Xanthine oxidase inhibitors (XOIs) are considered first line therapy and should be used to target a serum urate level of <6mg/dL. If this target level is not achieved with xanthine oxidase inhibitors alone, a uricosuric agent should be added to the treatment plan. If serum urate levels are being reduced, a low dose anti-inflammatory medication can be used to prevent or control flare ups and acute attacks alongside low dose colchicine.

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Welcome our New Pharmacist

Dr. Alexander Ma, Pharm. D, is a graduate from the University of the Sciences – Philadelphia College of Pharmacy in 2018. Prior to starting at University hospital, he has worked in Rite-Aid, and as a pharmacist in Saint Barnabas Medical Center. He enjoys being passionate about providing and clarifying medications and medication orders with nurses and doctors. Outside of work, he likes to go jogging, fishing, and does watercolor and acrylic paintings from time to time. He looks forward to meeting and getting along with everyone in the team