Onychomycosis

Introduction
Onychomycosis is a common fungal infection of the fingernails and toenails that accounts for about 30% of all fungal infections found on the surface of the skin. Although the world is full of yeasts, molds, and fungi, only a few cause skin problems. These agents, called “dermatophytes” or “skin fungi”, rarely invade deeper into the body and most live only on human skin, hair, or nails. Onychomycosis is an infection of the nail by fungi that include dermatophyte, non-dermatophyte molds, and yeast (mainly candida species). Onychomycosis makes the nails look white and opaque, thickened, and brittle, and can lead to ultimate destruction of the nail plate. Additionally, onychomycosis is capable of spreading to other toenails, fingernails, or even the skin. In rare occasions, if this fungal condition is ignored, its spread could impair one’s ability to work or even walk. This happens because it is frequently accompanied by thickening of the nails, which cannot be easily trimmed and may cause pain while wearing shoes.

Reasons for Treatment
The incidence of onychomycosis is high in the general population, especially in adults over 50 years of age. However, the frequency of onychomycosis is higher in patients with weak immune systems and those suffering from diabetes mellitus. When an individual suffers from diabetes, the blood circulation and the nerve supply to the feet can become impaired. Therefore, any relatively minor injury to their feet, including a nail fungal infection, can lead to a more serious complication, such as an open sore (foot ulcer) that is difficult to heal.

The cost of this disease has been extensively documented. For example, it has been reported that 662,000 Medicare patients made 1.3 million visits to physicians in 1989 for the treatment of onychomycosis, which cost the United States healthcare system $43 million. Onychomycosis also has a tremendous impact on an individual’s functioning and well-being. Rarely, in the elderly, onychomycosis can lead to complications such as cellulitis, an infection of the skin. If severe or if left untreated, it can spread into the lymph nodes and the bloodstream (lymph nodes filter the cells that help fight infection and disease). Onychomycosis can also further compromise the limbs in those with peripheral vascular disease, a condition where there is decreased circulation to the legs or arms.

Incidence
The incidence of onychomycosis has been increasing. This is attributed to increased awareness, the aging population, more people with a weak immune system, as well as changing lifestyles with tight clothing/footwear and communal bathing at public swimming pools.

Treatment of Onychomycosis
Fungal infections may be difficult to treat for several reasons. Depending on where and how serious the infection is, the length of treatment may range from three to six months. Therefore, it is important to obtain the correct diagnosis and select the appropriate antifungal agent.

Sporanox® (itraconazole) is a prescription medicine used to treat fungal infections of the toenails and fingernails. It is also used to treat some types of fungal infections in other areas of the body. Sporanox has been associated with rare cases of serious liver problems, including liver failure and death. Some of the individuals in these cases had neither prior liver disease nor a serious underlying medical condition. Common side effects of Sporanox include nausea, vomiting, rash, headache, and swelling of soft tissues.
as a result of excess water retention. Additionally, Sporanox should not be taken by individuals with heart failure or if they are on certain medications that can lead to abnormal heartbeats.\(^9\)

Another agent, Lamisil\(^\text{®}\) (terbinafine) tablets, is indicated for the treatment of fungal infections of the toenail or fingernail due to dermatophytes. Rare cases of liver failure, some leading to death or liver transplant, have occurred with the use of Lamisil tablets in individuals with or without prior liver disease. Common adverse effects include diarrhea, dyspepsia (upper abdominal pain, bloating, belching), abnormal liver tests, rash, hives, itching, and taste disturbances. In general, the adverse effects have been shown to be mild and transient.\(^10\)

Lamisil is dosed at 250 mg daily for 6 weeks and 12 weeks in fingernail and toenail infection, respectively.\(^3\) Sporanox is dosed at 200 mg daily for 12 weeks continuously in toenail infection. Alternatively, for fingernail infection, 200 mg twice daily is taken for one week in a “pulse” dosing schedule. For the next three weeks, no additional medication is required, since Sporanox is already at the site of infection. Two “pulses” are recommended for fingernail infection.\(^4,9\)

Improved nails may not be obvious for several months after the treatment period is finished since it usually takes about 6 months to grow a new fingernail or 12 months to grow a new toenail.\(^9\)

Of note, published clinical studies have shown Lamisil to be more effective than Sporanox for the treatment of dermatophyte onychomycosis. However, Sporanox is the most effective agent for the treatment of onychomycosis caused by candida. Both agents are generally well-tolerated.\(^11\)

**Clinical Initiatives**

The treatment of onychomycosis can be lengthy, challenging, and costly, often with limited success. One Caremark clinical program, SecureCare, helps to ensure that antifungal drugs are appropriately dispensed and utilized. This is accomplished through monitoring of refills, drug-drug interactions, and verification of high-dose prescriptions. Additionally, in the Caremark CustomCare Mail program, clinical pharmacists verify for appropriate diagnosis and limit drug quantity to appropriate length of therapy based upon which nails are affected. In the Prior Authorization program, Lamisil and Sporanox therapy is approved through diagnosis verification of “at risk” participants. Clients may choose coverage for these agents through their individual benefit designs. These programs, in collaboration with the expertise of the Caremark clinical team, can help ensure proper and cost-effective drug therapy for the participant with onychomycosis.

**References**