ONYCHOMYCHOSIS TREATMENT WITH LOW CONCENTRATIONS OF FOOD-GRADE HYDROGEN PEROXIDE: A CASE STUDY

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Summary: An 80-year-old woman with a 25-year history of onychomycosis of all finger nails that had not responded to conventional treatment was placed on three times daily oral therapy of 0.5% concentration of food-grade hydrogen peroxide (FGHP) for one month, 1% concentration for another month, and 0.5% for the third month. All the darkly discolored, brittle, and firmly attached nails extending from the lunula to the distal end dislodged by the end of the therapy. Histopathology confirmed the presence of fungal hyphae in the shed nails. A month after the therapy, the patient complained of swelling and itching at the roots of three nails which responded to a repeat of the food-grade hydrogen peroxide oral therapy for 3 months, but not to antibiotic treatment. There has been no evidence, however, of new nail growth, even after the second cycle of FGHP therapy. This suggests that the germinal matrix of the nails had been permanently damaged by the fungi. No consequential adverse effects of the therapy were noted.

This case study provides evidence that orally administered very low concentrations of food-grade hydrogen peroxide is effective and safe for the management of chronic onychomycosis. Offered early, it might even prevent pathogen damage to the nail germinal matrix.

Introduction: Hydrogen peroxide (H_2O_2) (HP), a naturally occurring chemical, is produced by immune and other cells of the body to destroy microorganisms such as bacteria, fungi, and viruses (Ong et al., 2018). Exogenous (manufactured) forms of this chemical had been used for over 200 years in the management of several medical conditions, including treatment of wounds (Zhu et al., 2017), ulcers, and dental infections (Mtenga et al., 2019), and as an antiseptic in general (Lin Shih-Ming et al., 2011). In vivo, its mechanism of action is through the Fenton reaction, where HP reacts with a ferrous ion to form a potent free hydroxyl radical (-OH) to damage and destroy anaerobic bacteria, fungi, and viruses (Winterbourn, 1995)(Halliwell et al., 2000). This same mechanism is employed in targeting and destroying tumor cells (Ou et al., 2023). In vitro, the oxygen molecule of HP has also been shown to target the membrane walls of bacteria, viruses, and fungi to deactivate them (Di et al., 2020), (Kaushik et al., 2023), (Raval et al., 2022).

During the COVID-19 pandemic, the role of exogenous HP in protecting against the coronavirus was investigated by several researchers (Carrouel et al., 2021)(Domenico et al., 2021) (Amoah et al., 2021)(Amoah et al., 2022). This solution, indeed, proved quite effective in protecting health workers from all the variants of SARS-CoV-2 that emerged in the period of the COVID-19 pandemic (Peng et al., 2020)(Banakar et al., 2020). It is now well accepted that the topical use of this off-the-counter medication has the potential of protecting mankind from virulent pathogens that enter the body through the oronasal pathway. Its safety has been investigated by many. Topical use of HP, in dentistry for over 70 years, had not revealed any deleterious effects (Marshall et al., 1995) (Walsh, 2000). More importantly, there has been no conclusive evidence of oncogenic effect in the oral cavity in individuals who had used the solution daily for rinsing over several decades (Marshall et al., 1995)(Walsh, 2000).

Over the years, parenteral oxygen therapy, including HP and medical ozone therapies, have been applied in alternate medical practice referred to as bio-oxidative therapies. The first such therapy was recorded in 1818 (Armogida et al., 2012)(Marcial-Vega et al., 2015)(Shabanov et al., 2022). This mode of treatment, however, has not been widely accepted yet. Indeed, it had even been regarded controversial and risky (Rzepczyk et al., 2023), mainly with reference to the use of high concentrations of HP especially in teeth whitening, ranging 3% to 35%. However, for oral and parenteral use in medical practice, food-grade hydrogen peroxide (FGHP) is diluted to around 1% or less. In the United States where special clinics exist for bio-oxidative therapies for a variety of diseases, the concentration of HP used is extremely low. Of note, in the 1918 influenza pandemic, which ultimately killed close to 50 million people worldwide, parenteral HP saved many critically ill patients, reducing the death rate (Levy Thomas E., 2021). Also, aside from nausea and evidence of gastritis with oral use, no adverse effects have been noted in parenteral (Brownstein, 2020) and nasogastric use of FGHP (Katsinelos et al., 2006).

Having noted evidence of the efficacy of HP in protecting against COVID-19, and noting also from the literature that parenteral and enteral administration of it has benefits in the management of a variety of diseases (Levy Thomas E., 2021)(Fu et al., 2012), we set out to find out if there is any merit in that claim. If orally and parenterally administered FGHP is effective, we must see that in a challenging clinical state where conventional therapy for that disease has failed or has not

been too successful. We hypothesized that orally administered low concentrations of FGHP would eliminate pathogens difficult to deal with, such as in chronic onychomycosis.

An opportunity presented to test this hypothesis when an 80-year-old female patient with a 25-year history of onychomycosis consented to try the diluted FGHP oral medication, after explaining to her the possible benefits and risks to be expected. Considering that this is the first time such a study was being conducted in a patient with such condition, we had the following questions: Would our hypothesis hold in this challenging situation? Would diluted FGHP deactivate or eliminate fungi? Would this solution administered over a period of three (3) months or longer have any deleterious effects?

Materials and Methods: An 80-year-old housewife developed a fungal infection of her right middle finger in the year 2000. In five years the infection spread to involve all her ten fingers. About 10 years ago she started attending the dermatology clinic at the Korle Bu Teaching Hospital, Accra, Ghana. Over this period, she had been on a variety of antifungal agents, including oral itraconazole 200mg twice daily, taken in two (2) pulses (one week dose followed by a rest period of three weeks and then repeated for another week), oral griseofulvin given daily for a maximum period of six weeks. During the oral therapies and after, topical miconazole tincture was applied to the lunula and sides of the nail twice daily for a prolonged period without improvement. In January 2023, clinical examination of the nails, just before initiating oral FGHP, showed edematous and hypertrophic changes in the skin and tissues adjacent to the root and sides of the nail. The nails appeared dystrophic, being dark in coloration, dry, brittle, and cracked in places (Figure 1).

FGHP Preparation and Treatment:

She, subsequently, agreed to try the oral FGHP for the first time. One percent (1%) and 0.5% concentrations of FGHP solutions were prepared from a stock solution of 35% FGHP obtained from www.wellnesshoproducts.com in the US. Commercially bottled drinking water was used for the dilutions.

The topical antimycotic therapy the patient had been on for years was discontinued, before initiating the FGHP regime. The prescription for the patient was ingestion of 40mL of the 0.5% diluted FGHP, three times daily (morning, afternoon, and evening) for one month, followed by the 1% FGHP for another month, and back to the 0.5% solution for the third month. She was instructed to ingest the FGHP on an empty stomach (four hours after the last meal, and an hour before each meal); she was advised not to take any snacks in between meals. She could drink water in between meals, when thirsty. She was also asked to report any health issues immediately by phone. Specifically, she was asked to note nausea, vomiting, abdominal pain, or discomfort associated with the therapy. As this was on an outpatient basis, the patient was followed weekly by phone for adverse reports.

Results

Three weeks into the therapy, the patient called in excitement to say she was beginning to notice some improvement in the state of her nails: The nails were not as dark as before, and they appeared to be dislodging. On examination, we saw pale areas in the otherwise darkened nails. The surrounding skin tissue of the nails, however, remained hypertrophic and edematous. Five weeks later when she had just started using the 1% FGHP therapy, we examined the fingers again and observed a marked improvement in not only the state of the fingernails but also in the surrounding skin; the edema was resolving, and the nails had become loose and had begun detaching from the bed. At the end of the 3-month therapy, all ten fingernails had detached from the nail bed (Figure 2). Samples of the separated nails sent for histopathology showed fungal hyphae, confirming Onychomycosis.

At the end of the three-month treatment, the patient remarked that, after nearly 25 years of social stigmatization and embarrassment, she could now display her fingers confidently in public, even though no new nails had appeared. A month after this initial treatment, clinical examination revealed no evidence of regeneration of the nails. A second cycle of FGHP therapy followed. Twelve (12) months after that, still no new nail growth had occurred (Figure 3).

Adverse Effects:

Soon after the first dose of treatment, the patient complained of severe itch in the root area of some of the fingernails. Thinking that that could be from a secondary bacterial infection, the patient was placed on a course of antibiotics, but the itching continued. We, therefore, suspected that the irritation could be due to fungal activity. It was for that reason also that we extended the HP therapy for another three months. To our relief and that of the patient, the itching stopped, confirming the suspicion that some fungi localized in the roots of the nails had become active. The only other complaint the patient had in the six-month period of FGHP treatment was mild constipation when she started ingesting the 1% FGHP in the first cycle of treatment. This settled within a couple of weeks without any intervention.

Discussion:

The present study demonstrates that low concentrations of orally administered FGHP (0.5 and 1%) is helpful in the management of chronic onychomycosis. Notably, no major adverse effects of interest were reported or observed over the 6-month period of the first and second cycles therapy; within the period of eighteen (18) months of the study treatment and observation, there had been no consequential complaints of adverse effects, except mild constipation which self-resolved.

The results of this case study have far exceeded our expectations knowing how difficult it is to manage onychomycosis when the parasites are safely cocooned in the cuticle and nail matrix regions from the reach of antimycotic agents such as those used at the dermatology clinic at the Korle Bu Teaching Hospital.

The palpable and spontaneous joy of the patient who had lived with social stigma from infected fingernails for 25 years and who now is free to display her fingers publicly, is more than any reward

to be expected from this trial study. Even without new nails growing, she could use artificial nails or simply varnish her nail beds.

As noted, onychomycosis is a very troubling disease which is extremely difficult to treat. Even though the disease could originate from a topical infection or from an injury or contaminated fluid, the likelihood of it being from the oral cavity through periodontitis and other infections there should not be discounted. Indeed, the oral cavity has been known to be a reservoir of a variety of pathogens (Lrilop et al., 2011) (Parsek & Singh, 2003). Pathogens, including fungi, exist in the oral cavity tissues as chronic colonies of pathogens (Fanning & Mitchell, 2012). When we swallow saliva, especially after eating, tooth-brushing, or after a dental procedure, some of these colonies of pathogens protected by a biofilm of polysaccharides and proteins (Hall-Stoodley, L. et al., 2004), might escape into the gastrointestinal tract. Subsequently, they and the toxins they secrete, gain access to other parts of the body through the portal venous system and, from there, to the systemic circulation. A likely site for fungi especially to locate would be the cuticle region of the distal phalanges where the dead cuticle of skin meets the base of the germinal nail matrix to seal off the nail and its bed from the external environment. This region, naturally, has reduced blood flow and, therefore, becomes a preferred site for the growth of fungal pathogens. Being anaerobic in nature (Roy et al., 2018), fungal pathogens especially would prefer to locate at such sites to escape leukocyte detection and to survive. That all ten fingers were involved in the infection further supports our view that the source of the infection is likely from the oral cavity. Again, once the fungi are located in these suitable and preferential areas, they would go on to build a biofilm, re-cocooning themselves into chronic pathogen colonies. In that relatively secure place, these parasites could feed and survive for years, at the same time impeding nail growth in the germinal nail matrix.

The intervention of HP in onychomycosis without consequential clinical side effects in this study is significant. It should reopen the debate on the usefulness and safety or otherwise of this solution in the management of pathogenic and other diseases. Again, although this is a limited study, it shows that very low and non-toxic levels of FGHP could achieve more than what conventional treatment agents could in managing this disease.

The claim of toxicity of HP which had been based mainly on the high concentrations used especially in teeth whitening, must be reviewed. All therapeutic medications are dose-administered for safety. Overdose or higher-than-normal concentrations of conventional drugs have adverse effects, as would high doses of hydrogen peroxide.

Another important view of toxicity of HP, for which reason its use in disease management has been rejected by many for years, is the oxidative stress it produces in cells in the Fenton reaction. Recent reviews on this subject suggest that this reaction targets cells and pathogens with higher-than-normal iron content (Ou et al., 2023)(Schaible & Kaufmann, 2004). This important property of parasitic agents makes them particularly vulnerable to HP (Skaar, 2010) (Schaible & Kaufmann, 2004) compared to aerobic microbial agents and normal cells, which do not accumulate large amounts of iron (Schaible & Kaufmann, 2004) (Root & Metcalf, 1977). In the Fenton reaction (Winterbourn, 1995)(Ou et al., 2023) (Yoon et al., 2011), both intracellular and extracellular iron in the form of ferric releases an electron to become ferrous. This electron interacts with HP to

convert it into the powerful antioxidant hydroxyl radical (-OH), which destroys pathogens and tumor cells. The final products of this hydroxyl radical are oxygen and water, both of which are vital for the body's metabolic activities for healing and repair. This means that normal cells, which have a lower content of iron than abnormal cells or pathogens, are not targeted by exogenous HP. It also means that HP is selective in its actions within the body, targeting pathogenic cells. It is to be noted again that normal cells are protected from apoptotic actions of radical hydroxyl by the prompt action of catalase and peroxidase enzymes which facilitate the conversion of the hydroxyl radical to safe products of water and oxygen in the Fenton reaction (Glorieux & Buc Calderon, 2024)(Zalewska-Ziob et al., 2019).

The findings in this study reveal a number of things. First, it establishes without doubt that very low concentrations of FGHP effectively eliminates fungi which are buried within the nail, and which cannot be easily eliminated by the innate immune system of the body or by systemic or topical anti-mycotic agents. Second, it demonstrates that exogenous HP is more efficient in managing nailbed infections than the standard therapeutic agents, dealing quicker also with fungi that had escaped therapeutic agents for decades. Third, as exogenous HP is only a fraction of the cost of treating nailbed infections, this result offers hope for access to treatment of onychomycosis for the ordinary patient who cannot afford the more expensive mycotic treatment agents.

We acknowledge the limitations of this case study, it being the first of such report we are aware of. There is a need therefore, for further studies to demonstrate that low concentrations of FGHP will have similar effects in other cases of onychomycosis. More importantly, we need to establish the minimum concentration of HP that achieves clinical effect. It is likely that even lower concentrations of FGHP can effect a cure, and limit further risks that could be associated with prolonged periods of its use; It is to be noted that the first observation of HP effect on the nails of this patient was made three weeks into the first cycle of therapy, when FGHP concentration was 0.5%.

Based on these preliminary observations, we plan to conduct full clinical studies on hydrogen peroxide use in the management of onychomycosis.

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Appendix

Figure 1: Shows severely dystrophic nails

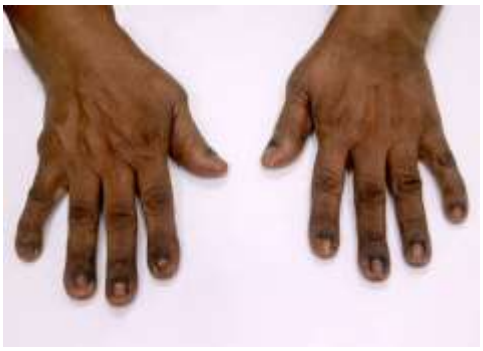

Figure 2: Dead nails have been shed

Figure 3: No evidence of new nail growth after 18 months

Close up picture of patient's ring and little finger after 18months showing dry nail beds without new nails