THE FOOTPRACTICE

Title: Retrospective observational study of Amycot® in the treatment of commonly presenting foot and nail diseases.

Author Information: Tim Maiden, The Foot Practice, 144 Robinson Rd, #10-02 Robinson Square, Singapore 068908. Phone: +65 6909 0117. Email: tim@thefootpractice.com.

Abstract: Fungal infection and onychomycosis are common diseases or conditions impacting a significant proportion of the population. The disease may lead to physical pain and psychological angst. Whilst topical treatments are preferred the currently available options have poor efficacy. Amycot® is natural ingredient derived from *Arthrospira maxima* and early clinical trials have suggested high efficacy rates. In this retrospective observational analysis we reviewed 109 patients treated with Amycot® for various diseases of the nail and foot. The average duration of treatment was 3 months with routine follow up visits preformed via physical visits or telephone consultations. Overall, 117 (70%) patients had disease cleared, excellent or good response to treatment with only 18 (11%) having a poor response or worsening of disease. Within the cohort suffering from onychomycosis or nail damage, 76 patients were treated and 55 (72%) having disease cleared, excellent or good response to treatment with 7 (9%) having a poor response or worsening of disease. No adverse events were reported. These results are favourable when compared to currently available topical options which have clinical cure rates for onychomycosis below 20% and side effects which may limit use in some patients. Further research is warranted to confirm these findings.

Date of Report: 15 September 2020.

Introduction:

- Onychomycosis is a fungal infection of the nail unit caused by dermatophytes, yeasts, and nondermatophyte molds with a prevalence of ~10% in the United States.
- It may cause both physical and psychological problems, with patients complaining of pain, other infections and problems with daily functions secondary to nail dystrophy and/or the cosmetic appearance[1].
- The treatment objective is to eradicate the fungus and produce a normal nail with numerous treatment options available[2].
- Limited antifungal topical solutions exist with generally poor efficacy despite being a preferred treatment option for patients.
- Amycot® is a natural ingredient derived from a strain of spirulina (*Arthrospira maxima*) and pre-clinical data suggests anti-inflammatory, anti-bacterial, anti-fungal and skin regenerative properties.
- In a randomised, placebo-controlled trial of Amycot® 8% against severe tinea and onychomycosis, mycological cure was confirmed in 92.8% (13/14) of subjects in the treatment arm and none in the placebo group. Clinical cure was achieved in all subjects in the treatment arm 6-months after treatment initiation with no response in the placebo group. For the subset of onychomycosis patients, a 45% reduction in percentage of affected surface area for the active treatment group versus 15% for placebo arm was observed. There were no treatment-related adverse effects observed[3].
- An open label study performed on 10 onychomycosis subjects demonstrated complete cure among 7 subjects after 12 weeks and in 8 subjects after 6 months treatment. The other 2 subjects lost to follow-up (and hence unable to be assessed)[4].
- In this retrospective observational report, the effects of Amycot® are described.

Materials and Methods:

- Patients treated with Amycot® anytime between Jan-2019 and Jan-2020 were included in this retrospective review
- Treatment consisted of Amycot® 8% lotion for 3 months. Those presenting with suspected onychomycosis were also provided Amycot® 5% powder for concomitant use in shoes/socks.
- Amycot® is produced by Xerion Limited (Melbourne, Australia) and is listed in Australia as an OTC product for the treatment of onychomycosis.
- Anonymous data consisting of patient gender, age, race, significant medical history, condition, duration of treatment with Amycot® along with the outcome and any adverse reactions were transcribed from patient records to a case report form for statistical analysis
- In cases of patients with severe nail disease, debridement was conducted to aid in cosmetic appearance and reduce pain or discomfort.
- Standard practice was to contact all patients after 3 months with either a physical or tele-consultation. At this timepoint assessments were made on the outcome of treatment and categorised into following variables:
    - 100% remission except residual manifestations (disease cleared)
    - 90–99% improvement (excellent response)
    - 50–89% improvement (good response)
    - 25–49% improvement (fair response)
    - Less than 24% improvement (poor response)
    - deterioration from baseline (worsening disease)
    - Unknown

- Due to the retrospective nature of this study and use of anonymous data from a single centre as part of treatment improvement program, Ethics Approval was not required under Singapore regulations.

Results:

- 109 patients, average age 43 years old and predominately of Caucasian descent, were treated with Amycot® during the observation period for a variety of conditions including onychomycosis and other conditions affecting the nail and/or foot (Table 1).

Table 1: Baseline Demographics	n= 109	%
Sex		
Male	63	58%
Female	46	42%
Age (mean)	43.26	
Race		
Caucasian	59	56%
Asian	40	38%
Other	2	2%
Missing	4	4%
Conditions		
Onychomycosis	66	61%
Nail Damage	10	9%
Psoriasis	1	1%
Skin Damage	2	2%
Verruga	7	6%
Other	4	4%
Missing	19	17%

- The average duration of Amycot® treatment was 3 months and follow up visits were preformed via face-to-face visits or telephone consultations
- Of the 90 patients with underlying condition documented, 62 (69%) had their disease cleared or an excellent or good response to treatment. 11 (12%) had a poor response or worsening of disease (Figure 1) and 15 (17%) had data missing or not available.
- 76 patients were treated with Amycot® for onychomycosis or nail damage. In this cohort, 55 (72%) had disease cleared or an excellent or good response to treatment. 7 (9%) had a poor response or worsening of disease and 12 (16%) had data missing or not available. (Table 2)

Figure 1: Summary of responses to Amycot 8% lotion in various conditions after 3 months treatment.

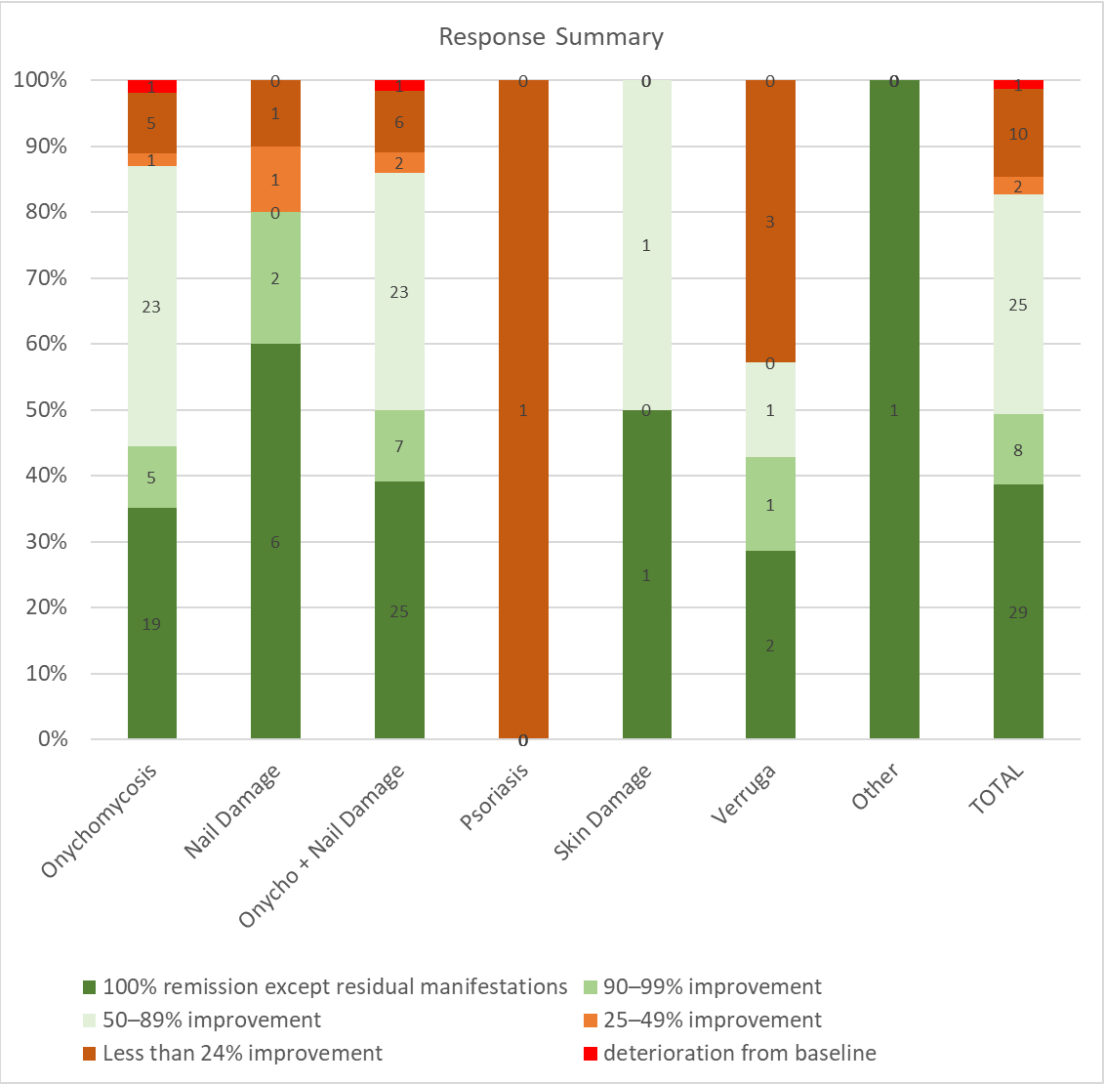

Table 2: Responses at 3 months post Treatment	Onychomycosis	Nail Damage	Combined
Response	**n= 66**	**n= 10**	**n= 76**
100% remission except residual manifestations	19 (29%)	6 (60%)	25 (33%)
90–99% improvement	5 (8%)	2 (20%)	7 (9%)
50–89% improvement	23 (35%)	0 (0%)	23 (30%)
25–49% improvement	1 (2%)	1 (10%)	2 (3%)
Less than 24% improvement	5 (8%)	1 (10%)	6 (8%)
deterioration from baseline	1 (2%)	0 (0%)	1 (1%)
Unknown	12 (18%)	0 (0%)	12 (16%)

- One mild adverse event was reported with a patient complaining of nail discolouration due to the treatment with Amycot®. No severe or serious reactions were observed.

Discussion

- Amycot® had a high response rate for patients with various foot and nail related diseases.
- Clinically relevant effectiveness was observed in the group with onychomycosis or nail disease with 86% of patients achieving greater than 50% improvement after 3 months with only 1 minor adverse event reported. Whilst not achieving the 100% clinical cure as observed with previous studies this was likely due to the shorter follow-up with assessments performed after 3 months compared with 6 months in other published data. This would also align with the time period required for an average nail with ~50% involvement to grow and achieve full clearance visually. Other conditions treated had too few patients included for any conclusions to be reached.
- These results are favourable when compared to currently available topical options which have clinical cure rates below 20% and side effects which may limit use in some patients.
- The simple topical application which does not require filing or other nail preparation permits the product to be easily used by patients.
- Limitations: the study did not use any mycological assessments to confirm onychomycosis and debridement was used to differing degrees in the majority of patients. Follow up assessments were largely performed via phone or video with patients sharing photographs or video images to permit assessments to be made.
- The promising results observed warrant further research, especially for patients with onychomycosis or nail damage, in a prospective study with mycological characterisation and accurate serial assessments of this natural therapeutic option.

References:

1. Ghannoum MA (2000) A large-scale North American study of fungal isolates from nails: the frequency of onychomycosis, fungal distribution, and antifungal susceptibility patterns. J Am AcadDermatol 43(4): p. 641-8.
2. Scher RK, Rich P, Pariser D, Elewski B (2013) The epidemiology, etiology, and pathophysiology of onychomycosis. SeminCutan Med Surg 32: S2-4.
3. Parekh et al (2017) BMC complementary and alternative medicine, 17(1), 464. https://doi.org/10.1186/s12906-017-1970-2
4. Freeman AM, Freeman MG. Australasian Journal of Dermatology. 2011;52(Suppl 1):25.