

Impact of Onychomycosis and Treatment on Patient Reported Quality of Life **Outcome Measures: A Systematic Review**

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Abstract

Background: Onychomycosis is the most common nail disorder, often causing physical, emotional, and aesthetic consequences. The impact of both the condition itself and treatment on quality of life has not been well studied. Objective: The objectives of this study were to systematically review the available literature describing the impact of onychomycosis and treatment on quality of life. Methods: We performed a search of the onychomycosis literature published prior to April 13, 2020. Articles were included in the review if primary data were presented, patient-reported outcome measures were used, and onychomycosis was specifically examined.

Results: Thirty studies were included in the final analysis. Poorest QoL scores were associated with females and fingernail involvement. QoL scores improved from baseline with all treatment types; there were greater improvements reported with orals compared to topicals.

Conclusions: This review affirms that onychomycosis causes significant impact on quality of life, warranting effective treatment. All treatments resulted in quality of life improvements, however studies on oral and topical therapies were of higher quality than those evaluating devices. Increased efforts are needed to understand the impact of the disease and therapy as assessed by validated, nail-specific outcome measure that accurately assess patients' cosmetic, physical and social difficulties.

Introduction

Onychomycosis is a nail fungal infection caused by dermatophytes, nondermatophytes, and yeasts. It is the most common nail condition, comprising an estimated 50% of all nail disorders in the outpatient setting [1]. Prevalence increases with age; onychomycosis affects approximately 50% of adults over 70 years [2]. Onychomycosis may lead to pain, discomfort, limited dexterity and mobility in daily activities [3]. The impact of the condition and its treatment on quality of life (QoL) has not been well studied. The objective of this study was to systematically review the available literature describing the impact of onychomycosis and its treatment on quality of life. We performed a search of the literature published prior to April 13, 2020.

Methods and Materials

A search of the English-language literature published prior to April 13,2020 for studies reporting QoL in nail conditions was performed with the search terms "nail" and "quality of life" in Pubmed and Embase. Exclusion criteria included: not an original article, no PROM data, not nail specific, not accessible, not onychomycosis-specific.

- 3289 abstracts screened
- 430 full-text articles reviewed
- 30 articles for data extraction [4]

Results

Fifteen studies utilized ad-hoc measures to assess PROMs. Validated PROMs used included the:

- International Onychomycosis-specific Questionnaire (n=5)
- Quality of Life Questionnaire for Toenail Onychomycosis (OnyCOE-t) (n=5)
- Dermatology Life Quality Index (DLQI) (n=2)
- Bristol Foot Score (n=1)
- NailQoL score (n=1)

Fifteen studies investigated the impact of onychomycosis on QoL (Table 1). Mean ages in the studies were 39.4 - 63.2 years and ranged from 16 - 92 years. The composition of females in study samples varied from 24.7 to 76.0%. Fifteen studies analyzed the impact of treatment on pre- and post-intervention QoL (Table 2). Patient demographics were varied with mean ages from 9.7 to 59.9 years and a range of 2 to 98 years. Percentage of female subjects ranged from 30.1 to 57.8%.

Table 1. Review of studies reporting the impact of onychomycosis on quality of life.

Table 1. Heview	of studies reporting the impact of onycholligeosis on quality of life.		
Reference	Key Findings in Patients with Onychomycosis		
Lubeck 1993 and Lubeck 1998	 Poorer general health, social functioning and mental health More bodily pain, health concerns, appearance problems, and symptoms 		
Elewski 1997	92% of reported negative psychosocial and/or physical effects		
Schein 1997	 Females reported poorer QoL than males in burden of symptoms, appearance, and problem with activities 		
Whittam 1997	 Significant overall problem of nails, pain with walking and discomfort limiting abilities 		
Drake 1998	 Females were more embarrassed than males Fingernail involvement had poorer QoL than those with only toenail disease 		
Drake 1999	 Longer duration of disease, greater involvement of individual nails, and greater number of nails involved were associated with poorer QoL. 		
Lubeck 1999	 Females reported a poorer QoL than males in areas of symptom frequency, appearance, physical activities and overall problems. 		
Lubeck 1999	Significant pain and discomfort		
Turner 2000	 Worse severity of onychomycosis was associated with more distress, functional impact and social stigma 		
Szepietwoski 2007	 Females reported poorer QoL than males Fingernail and toenail involvement had poorer QoL than those with only toenail disease 		
Szepietowski 2009	 Fingernail and toenail involvement had poorer QoL than those with only toenail disease 		
Milobratovic 2013	Females reported poorer QoL than males		
Bunyaratavej 2015	Mean DLQI in onychomycosis patients was 3.6 ± 3.75		
Kayarkatte 2020	 Females had higher mean DLQI than males (6.97 vs. 5.73) Females had a greater proportion reporting DLQI >11. Patients with toenail-only or fingernail and toenail disease reported poorer QoL than fingernail-only disease 		

Results

Table 2. Review of studies reporting QoL impact of various treatments in onychomycosis.

Reference	Treatment	Key Findings
Ling 1998	Weekly fluconazole 450 mg for 4, 6 or 9 months	All treatment groups had greater treatment satisfaction vs. placebo
Pollak 2001	Terbinafine 250 mg/day for 12, 18 or 24 wks	68.8% of all patients were satisfied with appearance of toenails
Stier 2001	Not specified	Treatment with orals (terbinafine, itraconazole or fluconazole) had greater improvement in inconvenience, pain, embarrassment, self-consciousness and need to conceal nails vs. topical treatment
Warshaw 2003	Terbinafine 250 mg/day 12 wks vs. pulse-dose itraconazole 200 mg	Greater overall improvement in OnyCOE satisfaction scale with continuous terbinafine vs. pulse itraconazole
Firooz 2003	Itraconazole 200 mg BID for 1 wk every 4 wks for 12 wks	Mean change of 4.9 points of improvement in QoL score
Potter 2006 and 2007	Terbinafine 250 mg/day for 12 wks ± debridement	Similar improvements in OnyCOE-t scores were seen in both groups
Malay 2009	Topical ciclopirox 8% nail lacquer ± debridement	The combination of lacquer and debridement had a statistically significant improvement in Bristol Foot Score vs. debridement alone
Friedlander 2013	Weekly ciclopirox lacquer vs. vehicle	More than 90% of children reported treatment with ciclopirox was a positive experience
Snell 2013	Vicks VapoRub	Patients at an AIDS clinic had less embarrassment and discomfort/pain with treatment
Tosti 2014	Efinaconazole topical solution, 10%	Improvements were reported in all domains of the OnyCOE-t scale
Eertmans 2018	Acetic acid nail polish vs. 5% amorolfine lacquer	Improvements in an ad-hoc QoL score were reported with both the acetic acid polish and 5% amorolfine lacquer
lozumi 2019	Efinaconazole topical solution 10%	Improvements were reported in all domains of the OnyCOE-t scale
Ortiz 2014	4 treatments with a 1320- nm Nd:YAG laser vs. cryogen spray sham	Similar levels of improvements reported in treatment and placebo
Gilaberte 2017	3 sessions of urea 40% + MAL-PDT	Statistically significant improvements in QoL were reported with MAL-PDT treatment

Conclusions

Onychomycosis was associated with significant impact on QoL in multiple studies. The majority of studies reported higher impact in females than males, as well as in those with fingernail involvement. All treatments examined in the literature were associated with improvement in QoL with oral treatments having a greater impact than topicals. While reporting promising QoL results, devices for onychomycosis have not been approved for achieving neither mycological nor complete cure, limiting their use. Future studies should incorporate validated PROMs so that comparisons across treatment types may be performed.

Selected References

- 1. Lipner SR, Hancock JE, Fleischer AB. The ambulatory care burden of nail conditions in the United States. J Dermatolog Treat. 2019 Oct:21:1-4.
- 2. Gupta AK, Gupta G, Jain HC, et al. The prevalence of unsuspected onychomycosis and its causative organisms in a multicenter Canadian sample of 30000 patients visiting physicians' offices. J Eur Acad Dermatol Venerol. 2016;30(9):1567-
- 3. Lipner SR, Scher RK. Onychomycosis: Clinical overview and diagnosis. J Am Acad Dermatol. 2019 Apr;80(4):835-851.
- 4. Stewart CR, et al. The Impact of Onychomycosis and Treatment on Quality of Life: A Systematic Review. J Am Acad Dermatol 2020. Epub ahead of print.

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