

ORIGINAL ARTICLE

Inter-observer reliability of the Onychomycosis Severity Index depending on clinical experience: A review of 50 cases

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Abstract

Background: Onychomycosis (ONM) is the most prevalent nail unit pathology, and its severity and monitoring are often based on the visual judgement of clinicians.

Objective: The objective of this study is to assess the reliability of the Onychomycosis Severity Index (OSI) classification when utilized by three clinicians with varying levels of clinical experience: an experienced podiatrist (with 5 years of experience), a moderately experienced podiatrist (with 2 years of experience) and an inexperienced podiatrist (a recent graduate familiar with the OSI classification but lacking clinical experience). Additionally, we compared the severity assessments made through visual inspection with those determined using the OSI by different clinicians.

Methods: We evaluated reliability using the intraclass correlation index (ICC), analysing 50 images of ONM.

Results: The OSI demonstrated a very high level of reliability (ICC: 0.889) across clinicians, irrespective of their experience levels. Conversely, a statistically significant increase in severity was observed when comparing visual assessments with the OSI ($p < .001$) for ONM severity evaluation.

Conclusion: The OSI proves to be a reproducible classification system, regardless of the clinical experience of the practitioner employing it.

KEYWORDS

classification, nail pathology, onychomycosis, severity index

1 | BACKGROUND

Onychomycosis (ONM) is a fungal infection affecting the nail unit and the surrounding tissue. It represents the most prevalent nail-related pathology, with a prevalence ranging from 4% to 13%. The responsible pathogens can include dermatophyte fungi, yeasts or non-dermatophyte moulds.^{1–5}

The most characteristic clinical signs include nail thickening, subungual hyperkeratosis, nail plate discolouration and onycholysis.^{1–4,6,7}

Traditionally, ONM is typically classified based on these clinical signs through visual assessment. However, it is worth noting that there are numerical classifications available, though not all of them are validated. Examples include the classifications proposed

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by Baran et al.⁸ and Sergeev et al.⁹ for evaluating the severity and treatment response of ONM.

The Onychomycosis Severity Index (OSI), introduced and validated by Carney et al.³ stands as the only validated score classification system available for effectively assessing the severity of ONM. This index serves as a valuable tool for guiding treatment decisions and predicting therapeutic outcomes.³

The OSI classification is based on specific clinical characteristics, including the affected area, the proximity of the lesion, and the presence of dermatophytoma or hyperkeratosis larger than 2 mm, which is used to categorize ONM as mild, moderate or severe (Table 1; Figure 1).

The presence of a dermatophytoma is characterized by the accumulation of fungal hyphae, manifesting as a yellow, white or orange longitudinal stripe or a white or yellow rounded patch near the nail fold (Figure 2). It is worth noting that antifungal treatments may have limited effectiveness against dermatophytomas.^{1,3}

Subungual hyperkeratosis is considered a prognostic factor associated with a poorer prognosis, as an increase of more than 2 mm in hyperkeratosis can reduce the penetration of antifungal drugs.

Given the subjective nature of visually assessing these clinical signs, our objective was to examine the concordance in utilizing the OSI classification, a validated scale, among three podiatrists with varying levels of clinical experience: an experienced podiatrist (with 5 years of experience), a moderately experienced podiatrist (with 2 years of experience) and an inexperienced podiatrist (a recent graduate familiar with the OSI classification but lacking clinical experience).

2 | MATERIALS AND METHODS

2.1 | Participants and samples

This study was conducted in accordance with the Declaration of Helsinki and the current national legislation governing research involving the use of patients.¹⁰

TABLE 1 The Onychomycosis Severity Index (OSI) scale³ is calculated by multiplying the value of 'Area of Involvement' by the value of 'Proximity of infection to the matrix'. To this result, 10 points would be added in case of hyperkeratosis or dermatophytoma. Figure 1 shows an example of how to calculate the severity of the infected nail using the OSI scale.

OSI					
Area of involvement (%)		Proximity of infection to the matrix		Presence of dermatophytoma or hyperkeratosis >2 mm	
1-10	1	<1/4	1	No	0
11-25	2	1/4-1/2	2	Yes	10
26-50	3	>1-2 to 3/4	3		
51-75	4	>3/4	4		
76-100	5	Matrix involvement	5		

A cross-sectional study was conducted involving 50 images of ONM from patients attending a specialized clinic dedicated to ONM management.

Previously, a primary clinical investigator reviewed the medical records of patients diagnosed with ONM between January and December 2022. He was tasked with gathering and blinding the photographs for evaluation. Furthermore, the clinical investigator was responsible for documenting the results in the data collection notebook and subsequently conducting statistical analysis using the collected data.

The inclusion criteria encompassed individuals aged 18 years and older who had received a diagnosis of ONM through a microbiological culture combined with PCR, as detailed in the study conducted by Navarro-Pérez et al.¹¹

Exclusion criteria applied to patients for whom there was no available image of ONM or in cases where the image was taken after the nail plate had been debrided.

The assessment was carried out using the OSI scale³ by three different research podiatrists with varying levels of clinical experience: an experienced podiatrist (with 5 years of experience), a moderately experienced podiatrist (with 2 years of experience) and an inexperienced podiatrist (a recent graduate familiar with the OSI classification but lacking clinical experience).

All images were captured as part of routine clinical practice, and they were taken before any nail plate debridement procedures were conducted as part of the ONM treatment in the clinic.

Before applying the OSI scale, the investigators independently assessed each photograph and visually classified the ONM based on their criteria, categorizing the infections as mild, moderate or severe. Subsequently, they compared these classifications with the results obtained using the OSI scale.

2.2 | Statistical analysis

ONM has a prevalence ranging from 4% to 13% and to determine the required sample size for this study, we utilized the Granmo Sample Size Calculator, version 7.12, developed by the Institut Municipal d'Investigació Mèdica in Barcelona, Spain. We aimed to establish a confidence level of 95% with a precision of ± 10 percentage units, resulting in a sample size of 50 individuals. Additionally, a 10% replacement rate was accounted for.

Statistical analysis was conducted using SPSS for MacOS, version 25.0, developed by SPSS, Inc. in Chicago, IL. The analysis was based on the intraclass correlation index (ICC) with a 95% confidence level. Concordance was considered high at 0.6 and very high at 0.81.

The chi-square test was employed to assess the association between visual classification and classification using the OSI scale.

Qualitative variables were presented based on their frequency and percentage, while quantitative variables were described using their mean and standard deviation.

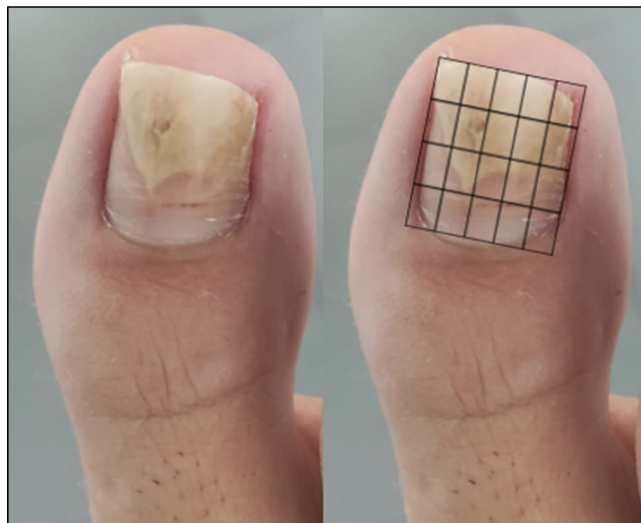


FIGURE 1 Example of assessment using the OSI scale. Area of involvement, 51%–75% (4 points); proximity of infection to the matrix, >1/2 to 3/4 (3 points); dermatophytoma, no (0 points) and hyperkeratosis, no (0 points). Calculation: $4 \times 3 + 0 = 12$ points. Moderate onychomycosis. OSI, Onychomycosis Severity Index.



FIGURE 2 Example of dermatophytoma.

3 | RESULTS

High concordance was achieved using the OSI scale when aggregating the results of the three clinical researchers ($ICC=0.889$). When comparing two by two, a higher concordance was observed between the most experienced and moderately experienced clinician ($ICC=0.873$), whereas the concordance between the moderately experienced and inexperienced clinician was lower ($ICC=0.781$), although it still demonstrated a strong level of concordance.

The mean OSI scores varied among the different clinicians, with an average of 23.23 ± 10.72 for the most experienced clinician, 18.24 ± 11.09 for the moderately experienced clinician and 17.4 ± 10.87 for the inexperienced clinician.

When comparing the results between the visual scale and the OSI scale, statistically significant differences were observed. In the case of the expert clinician, the p -value was .01, and for the intermediate expert and inexperienced clinicians, it was less than 0.001. The OSI scale resulted in a higher percentage of severe ONM cases compared to the visual assessment. Specifically, the most experienced clinician increased from 38% to 80% in severe ONM cases, the moderately experienced clinician from 42% to 68% and the inexperienced clinician from 28% to 52% (Figures 3 and 4).

4 | DISCUSSION

In the current study, we observed a significant level of concordance ($ICC=0.889$) on the OSI scale among various podiatrists, even those with varying levels of clinical experience. It is recommended that these assessments be conducted by professionals who are either experts or possess moderate expertise. While a reasonably high level of concordance was also observed between the expert and non-expert assessors, it was slightly lower ($ICC=0.781$).

Sergeev et al.⁹ introduced the Clinical Index of Onychomycosis Score (SCIO) as a composite score to evaluate the severity of ONM. This score takes into account various factors, including the clinical form, extent of nail involvement, thickness of subungual hyperkeratosis, the location of the condition and the patient's age. In contrast, Baran et al.⁸ introduced Baran-Hay's Severity Index in 2008, which assesses ONM severity based on 10 different parameters.

The OSI scale, introduced by Carney et al.³ in 2011 and later consolidated by Gupta et al.¹² in their 2018 update on the diagnosis and treatment of ONM, offers distinct advantages over prior classification systems. Unlike previous methods, this scale evaluates only three key parameters, minimizing subjectivity by focusing on the presence or absence of dermatophytoma and hyperkeratosis exceeding 2 mm. Additionally, its formula is easy to calculate and can be done promptly.

Various studies, including those conducted by Watjer et al.⁴ Elewski et al.⁷ and Gupta et al.¹² have conducted pre- and post-treatment assessments using the OSI scale. However, none of these studies specify the number of professionals who administered the OSI scale. It is crucial to determine whether the results may vary based on the assessor's level of expertise.

On the other hand, we observed statistically significant disparities when categorizing severity through visual classification compared to utilizing the OSI scale. This discrepancy may be due from the omission of the affected nail quarter in some cases, a variable that can amplify the OSI scale's final value by up to fivefold. To the best of our knowledge, prior studies have not explored this aspect. Consequently, it implies that an ONM case with a more favourable visual appearance but greater proximal involvement could be

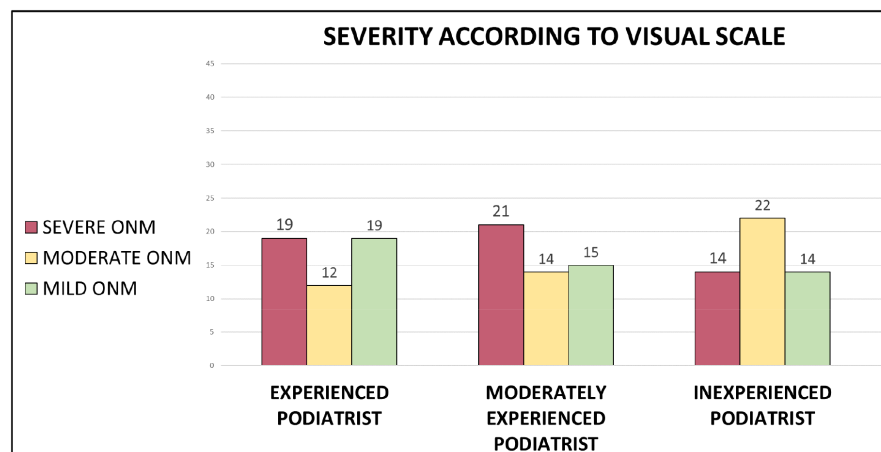


FIGURE 3 Researchers' visual assessment of the photographs, classifying them as mild, moderate or severe. The most experienced clinician classified 38% (19/50) as severe, 24% (12/50) as moderate and 38% (19/50) as mild. The moderately experienced clinician classified 42% (21/50) as severe, 28% (14/50) as moderate and 30% (15/50) as mild. The inexperienced clinician classified 28% (14/50), 44% (22/50) as moderate and 28% (14/50) as mild. ONM, onychomycosis.

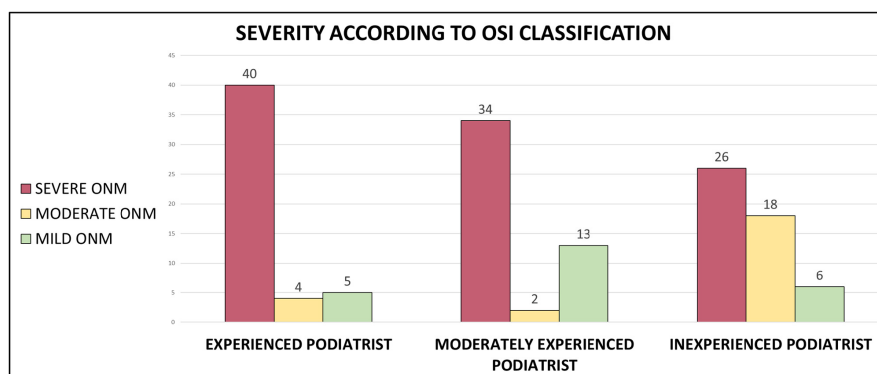


FIGURE 4 The investigators' OSI assessment of the photographs, classifying them as mild, moderate or severe. The most experienced clinician classified 80% (40/50) as severe, 8% (4/50) as moderate and 10% (5/50) as mild. The moderately experienced clinician classified 68% (34/50) as severe, 4% (2/50) as moderate and 26% (13/50) as mild. The inexperienced clinician classified 52% (26/50), 36% (18/50) as moderate and 12% (6/50) as mild. ONM, onychomycosis; OSI, Onychomycosis Severity Index.

classified as more severe than a lesion with a poorer visual presentation but more distal involvement.

In 2022, Dubljanin et al.⁶ conducted a study involving 417 patients, where they assessed the SCIO scale. They opted against using the OSI scale due to concerns about potential inter-observer variability. Nonetheless, in our study, we have achieved a sufficiently high level of concordance, making it a viable option for our purposes.

The primary limitation of this study stemmed from its single-centre design, where in only podiatrists affiliated with the same research group participated. Conversely, a key strength of our study lies in its novelty, as it is, to the best of our knowledge, the first to assess OSI by distinguishing levels of clinical experience among podiatrists to gauge concordance. It is worth noting that the 2011 study on OSI was conducted exclusively among dermatologists.

Based on the findings of this study, the OSI appears to be a reliable scale, demonstrating concordance among various clinicians with varying levels of clinical experience. Consequently, it would be interesting to consider conducting future studies that establish treatment guidelines based on the OSI score.

In this study, we can conclude that the OSI classification exhibits strong concordance agreement irrespective of the clinicians' level

of experience, demonstrating reproducibility among professionals with differing levels of expertise without significant variations. Additionally, the utilization of the OSI scale has revealed a higher incidence of severe ONM when compared to visual classification, regardless of the clinician's level of experience.

AUTHOR CONTRIBUTIONS

David Navarro-Pérez: Conceptualization; methodology; validation; investigation; data curation; writing – original draft. **Sara García-Oreja:** Conceptualization; methodology; software; validation; formal analysis; investigation; writing – original draft. **Aroa Tardáguila-García:** Data curation; writing – review and editing. **Diego León-Herce:** Conceptualization; methodology; software; investigation; writing – original draft; visualization. **Francisco Javier Álvaro-Afonso:** Visualization. **José Luis Lázaro-Martínez:** Validation; resources; writing – review and editing; supervision; funding acquisition; project administration.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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