# PREFERENCES FOR TOENAIL ONYCHOMYCOSIS TREATMENTS AMONG CANADIANS WITH AND WITHOUT DIABETES MELLITUS: A DISCRETE CHOICE EXPERIMENT

# **PCR146**

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## **BACKGROUND & OBJECTIVE**

- Toenail onychomycosis (fungal infection) affects approximately 7% of Canadians.<sup>1,2</sup>
- Comorbid type I/II diabetes mellitus is associated with both an increased risk of onychomycosis infection and of experiencing associated complications.<sup>3,4</sup>
- Pharmacotherapies that have received a Notice of Compliance by Health Canada include topicals (ciclopirox, efinaconazole) and oral agents (terbinafine, itraconazole).
- Toenail onychomycosis treatment selection is multifactorial;

### RESULTS



#### Figure 1. Discrete choice experiment - attributes and associated levels

considerations may include severity of nail involvement, mode of administration, efficacy, and side effects. However, little is known about preferences from patients in the management of onychomycosis.

- Presence of diabetes may also affect an individual's preferences for toenail onychomycosis treatment given their need to manage comorbidities, challenges with adverse events (AEs) and polypharmacy, and that such individuals are at higher risk of onychomycosis-related complications.<sup>5</sup>
- The objective was to understand patient preferences regarding onychomycosis treatment features and how preferences vary among those with and without diabetes.

### **METHODS**

- A discrete choice experiment (DCE) was conducted; attributes and levels were informed by: a targeted literature review, qualitative interviews with 14 toenail onychomycosis patients (7 with diabetes), and consultation with one clinical expert.
- The DCE comprised 16 choice scenarios developed using the Hahn Shapiro catalogue.<sup>6</sup> Both, choice questions and attribute order within choices were randomized to minimize impact of respondent fatigue.

			r	nail debris monthly
Mild adverse effects	No side effects			<b>2 of 10 patients</b> will experience at least one of the following temporary side effects: headache, stomach upset, diarrhea, rash, itch, or loss of taste
Severe adverse effects	No side effects			<b>1 of 100 patients</b> will experience liver, kidney, or heart damage which may require hospitalization
Efficacy	will hav will h	<b>35 of 100 patients</b> we no evidence of fungus with lab test year from initiating treatment, if medication is used as prescribed	<b>15 of 100 patients</b> will have no evidence of fungus with lab tes 1 year from initiating treatment, if medication is used as prescribed	st 000000000000000000000000000000000000
Interaction with alcohol consumption	No interactions with alcohol consun	nption	Your doctor will strong while you are on treatm suc	ly advise against alcohol consumption ent to reduce the risk of complications ch as liver damage
Interaction with other medications	No risk of the toenail fungus medication inte other medications	eracting with your	Because there is a ris interacting with your change or temporarily othe	sk of the toenail fungus medication other medications, your doctor may stop your other prescriptions for your er health conditions

\* Descriptions represent Canada-approved products and recommended use: 2 pills = itraconazole, 1 pill = terbinafine, topical applicator = efinaconazole, lacquer = ciclopirox

- Three hundred and nine participants completed the DCE; 160 had comorbid diabetes. The diabetes group included a slightly higher proportion of males and was slightly older (**Table 1**).
- More patients with diabetes were currently using prescription medication for their toenail fungus (either topical or oral medications) than those without diabetes.
- Those with diabetes had stronger preferences regarding treatment efficacy, the risk of severe AEs, and interactions with other medications and alcohol, while those without diabetes had stronger preferences regarding the route and frequency of treatment administration.

- Adults residing in Canada with self-reported, physiciandiagnosed toenail onychomycosis were recruited online. The sample was stratified according to self-reported diabetes status and onychomycosis treatment experience.
- Clinical and demographic characteristics were summarized using frequency and percent, or mean and standard deviation (SD), as relevant. Data from the DCE were analyzed using conditional logit regression (presented as odds ratios [ORs] with 95% confidence intervals [CIs]) and stratified by diabetes status.
- Ethics approval was provided by Veritas IRB (qualitative: #16575-15:38:275-06-2020; DCE: #2022-2743-9764-1).

### RESULTS

Six attributes (one with 4, and five with 2 levels) were constructed (Figure 1).

- Severe toenail fungus was more common among those with diabetes (70%) vs. those without (51%).
- Differences in treatment efficacy; treatment administration, frequency and duration; and risk of severe AEs, medication interactions, and interaction with alcohol had statistically significant impacts on patient preferences (Figure 2).
- Everything else being equal:
  - A 1% increase in efficacy increased the odds of the treatment being preferred by 4% (OR = 1.04 [95% CI: 1.02, 1.05]).
  - A treatment with 1% risk of severe AEs was 15% less likely to be preferred than one without risk of severe AEs (OR = 0.85 [0.80, 0.90]).
- Preferences estimated among those with diabetes were broadly similar to those from the overall sample.

### DISCUSSION

- Results from this DCE provide novel data on patient preferences regarding onychomycosis treatments, and how these differ by diabetes status. Similar data from patients with toenail fungus were previously unavailable.
- Another strength is the study's large sample size, overall and by diabetes status.
- Limitations to this study include self, rather than physician-confirmed onychomycosis and diabetes diagnosis and the recruitment of a convenience sample; however, effort was made to recruit patients from across Canada.
- Utilities were elicited alongside the DCE (results presented at ISPOR Europe 2022 [PCR28])

#### Table 1. Clinical and demographic characteristics of discrete choice experiment respondents

		Diabetes status			Overall	E
	Overall N = 309	No N = 149 (48%)	Yes N = 160 (52%)	Efficacy		
Demographic characteristics				Efficacy (per 1% ↑)	H	
ex, male	174 (56.3)	77 (51.7)	97 (60.6)			
je				Treatments		
Mean, SD	57.7 (14.6)	56.1 (16.5)	59.3 (12.4)	One pill*	┠={}	
Median, IQR	59.0 (50.0, 67.0)	59.0 (45.0, 67.0)	60.0 (52.0, 67.0)	Topical applicator*	┠■1	
Clinical characteristics				Two pills*	┣──━──┨	
Currently taking medication for diabetes	151 (48.9)	0 (0.0)	151 (94.4)	Adverse events (AEs)		
Surrently using toenail fungus prescription medication	112 (36.2)	42 (28.2)	70 (43.8)			
Dral prescription	26 (8.4)	1 (0.7)	25 (15.6)	Mild AEs		
Topical prescription	101 (32.7)	41 (27.5)	60 (37.5)	Severe AEs	<b>F-8-1</b>	
ime since diagnosis (in years) - Mean, SD	11.0 (12.3)	12.6 (13.8)	9.6 (10.7)	Oevere ALS		
umber of toenails affected - Mean, SD	3.6 (2.6)	3.4 (2.4)	3.8 (2.7)	Interactions		
ig toenail most affected	261 (84.5)	116 (77.9)	145 (90.6)			
Severity based on percent area affected of most affected		, , , , , , , , , , , , , , , , , , ,	· · · ·	Medication interactions		
penail				Alcohol interactions	<b>}-≡-1</b>	
Mild onychomycosis (0 to 20%)	7 (2.3)	5 (3.4)	2 (1.2)	l	0.50 0.75 1.00 1.25 1	50 0 50
Moderate onychomycosis (21% to 60%)	114 (36.9)	68 (45.6)	46 (28.7)		Odds ratio (95% CI)	.50 0.50
Severe onychomycosis (61%+)	188 (60.8)	76 (51.0)	112 (70.0)	CI = confidence interval		No Diabe
QR = interguartile range: SD = standard deviation.			<u>.</u>	* reference: lacquer		



#### CONCLUSION

Among patients with toenail onychomycosis from Canada, the presence of diabetes was associated with differences in treatment-related preferences.

#### Figure 2. Odds ratios and 95% CIs estimated from the results of the DCE

Those with diabetes were more likely to select a treatment with higher efficacy, no risk of severe AEs, medication or alcohol interactions; those without diabetes were more concerned with mode of administration.

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