UTILITY VALUES DERIVED FROM CANADIAN ADULTS WITH TOENAIL ONYCHOMYCOSIS WITH AND WITHOUT COMORBID DIABETES MELLITUS: A STUDY USING THE HEALTH UTILITIES INDEX®

PCR28

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BACKGROUND & OBJECTIVE

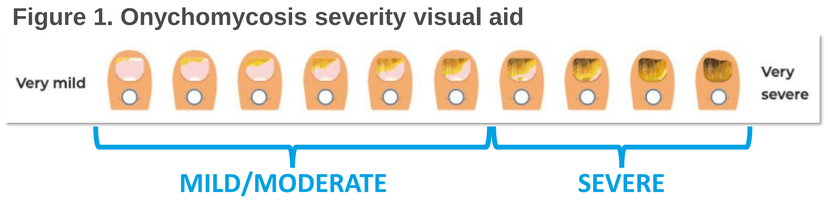
- Toenail onychomycosis (fungal infection) affects approximately 7% of Canadians.[1,2]
- Comorbid type I/II diabetes mellitus is associated with both an increased risk of onychomycosis infection and of experiencing complications secondary to onychomycosis.[3,4]
- Physical and social consequences of onychomycosis include pain, paresthesia, difficulties performing activities of daily life, and impaired social interaction, all potentially impactful on health-related quality of life (HRQoL) and associated utility estimates.[5]
- At the time of commencing this research, only one published mean estimate of health state utility existed for onychomycosis, at 0.99 (n=6).[6] This value is higher than Canadian adult population normal mean (0.86).[7] No utility values stratified by onychomycosis severity have been presented.

This study sought to estimate utility values for health states associated with toenail onychomycosis among adult patients in Canada, overall and stratified by onychomycosis disease severity and the presence or absence of comorbid diabetes.

METHODS

- Adults residing in Canada with self-reported, physician-diagnosed, toenail onychomycosis were recruited online. The sample was stratified according to onychomycosis severity and the presence or absence of diabetes.
- Ethics approval was provided by Veritas IRB (#2022-2743-9764-1)
- The survey comprised a customized clinical & demographic questionnaire to capture patient characteristics, including onychomycosis disease severity (mild/moderate or severe; assessed based on the extent of disease of the most affected toenail; **Figure 1**), the presence of physician-diagnosed comorbid diabetes (yes or no; self-reported), and the Health Utilities Index 15-item questionnaire (HUI-15Q®).[8]
  - Clinical and demographic characteristics were summarized using percent or mean (standard deviation [SD]), where relevant.
  - Utility values were mapped from HUI-15Q® scores using the HUI Mark 3 (HUI3®) health status classification system, and presented as mean (95% confidence interval [CI]).[9]
  - Tests for between-group differences were conducted using the Wilcoxon Rank Sum test.

Figure 1. Onychomycosis severity visual aid



RESULTS

Table 1. Clinical and demographic characteristics

	Overall	Onychomycosis severity		Presence of diabetes	
	All	Mild/Moderate	Severe	No	Yes
	n = 307	n = 119 (38.8%)	n = 188 (61.2%)	n = 149 (48.5 %)	n = 158 (51.5%)
Demographic characteristics					
Sex, male	170 (55.4)	65 (54.6)	105 (55.9)	76 (51.0)	94 (59.5)
Age					
Mean, SD	57.6 (14.7)	56.6 (16.5)	58.3 (13.4)	56.2 (16.7)	59.0 (12.5)
Median, IQR	59.0 (50.0, 67.0)	58.0 (46.0, 66.0)	59.5 (51.0, 67.2)	59.0 (45.0, 68.0)	60.0 (52.0, 66.8)
Marital status (n, %)					
Single	73 (23.8)	31 (26.1)	42 (22.3)	34 (22.8)	39 (24.7)
Married/common law	182 (59.3)	68 (57.1)	114 (60.6)	98 (65.8)	84 (53.2)
Widowed/divorced	51 (16.6)	20 (16.8)	31 (16.5)	17 (11.4)	34 (21.5)
Prefer not to answer	1 (0.0)	0 (0.0)	1 (0.01)	0 (0.0)	1 (0.01)
Gross household income (mean, SD)					
$0 - $40,000	85 (27.7)	27 (22.7)	58 (30.9)	29 (19.5)	56 (35.4)
$40,000 - $60,000	62 (20.2)	24 (20.2)	38 (20.2)	32 (21.5)	30 (19.0)
$60,000 - $80,000	45 (14.7)	15 (12.6)	30 (16.0)	21 (14.1)	24 (15.2)
$80,000 +	95 (30.9)	43 (36.1)	52 (27.7)	60 (40.3)	35 (22.2)
Prefer not to answer	20 (6.5)	10 (8.4)	10 (5.3)	7 (4.7)	13 (8.2)
Clinical characteristics					
Current toenail fungus prescription medication use (n, %)	110 (35.8)	36 (30.3)	74 (39.4)	40 (26.8)	70 (44.3)
Past toenail fungus prescription medication use (n, %)	74 (24.1)	30 (25.2)	44 (23.4)	46 (30.9)	28 (17.7)
Current diabetes medication use (n, %)	149 (48.5)	43 (36.1)	106 (56.4)	0 (0.0)	149 (94.3)
Years since diagnosis (mean, SD)	10.9 (12.3)	11.7 (14.9)	10.3 (10.4)	12.5 (13.8)	9.3 (10.6)
Number of toenails affected (mean, SD)	3.6 (2.5)	2.8 (2.1)	4.0 (2.6)	3.3 (2.3)	3.7 (2.7)

Abbreviations: CI = confidence interval; SD = standard deviation

RESULTS

The sample comprised 307 participants with onychomycosis, mean (SD) age 57.6 (14.7) years; 55.4% male; including:

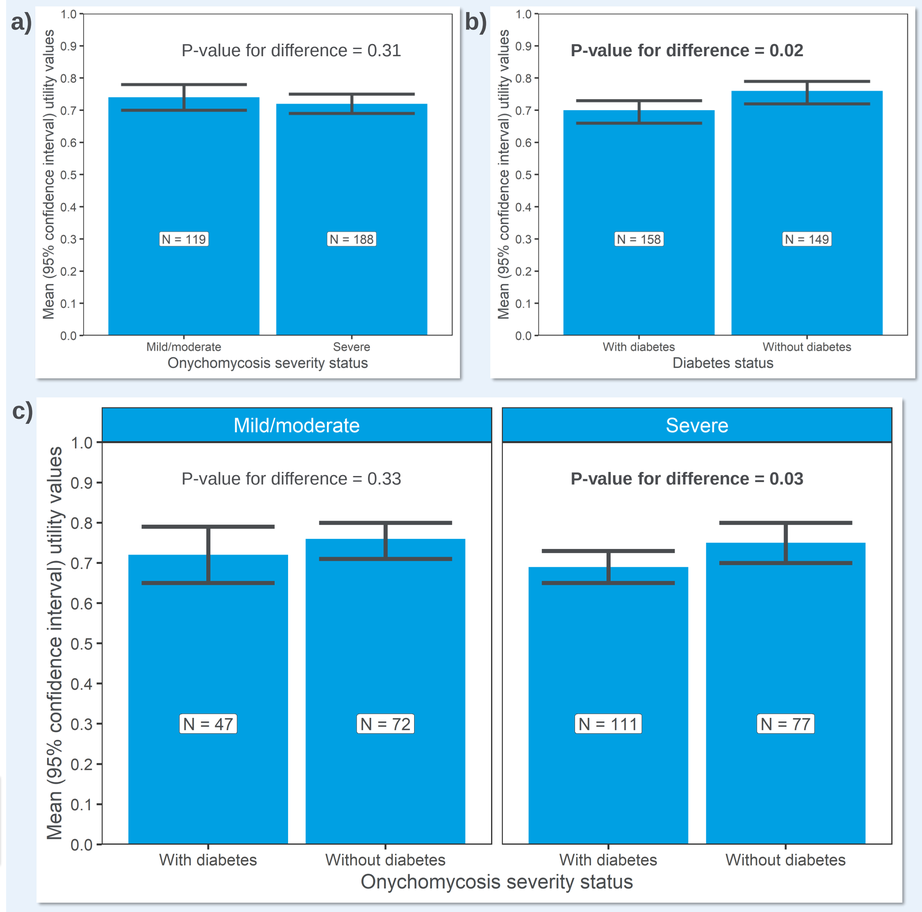
- 188 with severe onychomycosis; 158 with type I/II diabetes.
- Amongst onychomycosis severity and diabetes subgroups, clinical and demographic characteristics (e.g., marital status and household income) were similar; however, more patients with diabetes were taking prescription onychomycosis medication than those without diabetes (**Table 1**).

Table 2. Utilities estimates, overall and stratified by disease severity and diabetes status

Group	n	Mean utility (96% CI)	P-value for difference
Overall	307	0.73 (0.70, 0.75)	-
Mild/moderate onychomycosis	119	0.74 (0.70, 0.78)	0.31
Severe onychomycosis	188	0.72 (0.69, 0.75)	
No diabetes	149	0.76 (0.72, 0.79)	**0.02**
With diabetes	158	0.70 (0.66, 0.73)	
Mild/moderate onychomycosis; *no diabetes*	72	0.76 (0.71, 0.80)	0.33
Mild/moderate onychomycosis; *with diabetes*	47	0.72 (0.65, 0.79)	
Severe onychomycosis; *no diabetes*	77	0.75 (0.70, 0.80)	**0.03**
Severe onychomycosis; *with diabetes*	111	0.69 (0.65, 0.73)	

Abbreviations: CI = confidence interval
Note: Statistically significant differences (p<0.05) are bold

Figure 2. Utilities estimates (mean, 95% CI), stratified by a) onychomycosis disease severity, b) the presence or absence of diabetes, and c) both onychomycosis disease severity and the presence or absence of diabetes



Note: Statistically significant differences (p<0.05) are bold

Overall and stratified mean (95% CI utility) estimates are presented in **Table 2**.

- After stratification by onychomycosis severity (**Table 2**; **Figure 2a**), utility estimates were higher amongst those with mild/moderate onychomycosis compared to those with severe disease; however, the difference between the groups was not statistically significant.
- When stratified by the presence or absence of diabetes (**Table 2**; **Figure 2b**), utility estimates were significantly lower amongst those with comorbid diabetes.
- After stratification by both onychomycosis severity and the presence or absence of diabetes **(Table 2; Figure 2c**), amongst those with mild/moderate onychomycosis, utility estimates amongst those with and without diabetes were similar. Amongst those with severe onychomycosis, the difference between those with diabetes and those without diabetes was statistically significant, again with lower estimates amongst those with comorbid diabetes.

DISCUSSION

- Utility value estimates for Canadians with toenail onychomycosis were lower than Canadian population normal values, and statistically significantly lower amongst those with comorbid diabetes mellitus type I/II.
- Utility estimates for those with severe onychomycosis trended lower than those with mild/moderate onychomycosis; however, the difference was not significant.
- Strengths of this study include a large sample size, onychomycosis- and diabetes comorbidity-specific estimates, and the use of an appropriate instrument validated for use in estimating health state utilities in Canadians (HUI3).
- Limitations to this study include self, rather than physician-confirmed onychomycosis and diabetes diagnoses and the recruitment of a convenience sample; however, effort was made to recruit patients from across Canada.
- Patient treatment preferences were elicited using a discrete choice experiment alongside the utilities elicitation (results presented at ISPOR Europe 2022 [PCR146])

CONCLUSIONS

These estimates highlight the reduced HRQoL amongst those with onychomycosis, with and without diabetes mellitus type I/II, and can be used to inform cost-utility analyses of new onychomycosis therapies for Canadians.

These data improve on those previously published by providing estimates across all relevant health states, with adequate sample sizes amongst all subgroups.

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Presented at ISPOR Europe 2022 ● Nov 6-9, 2022 ● Vienna, Austria

Sources of Support: The study was funded by Bausch Health, Canada Inc. and conducted by Broadstreet Health Economics and Outcomes Research.