French-Canadian linguistic validation of the NIH Chronic Prostatitis Symptom Index

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Introduction: *The NIH Chronic Prostatitis Symptom Index (CPSI) is recommended in the clinical evaluation of men with chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS). However, its use is not possible in French speakers, as it has not been validated in this population. We performed a linguistic validation of the CPSI.*

Methods: *Linguistic translation followed the forward-backward-forward technique and relied on professional medical translators, bilingual health professionals, and patient input. Along with the SF-12, the translated version was administered to a convenience sample of men presenting for pre-vasectomy visits (controls) and to consecutive patients with established CP/CPPS (cases). Men with CP/CPPS were subsequently asked to complete a 14-day retest questionnaire. Psychometric testing addressed standard reliability and validity characteristics.*

Results: *Thirty-six cases and 38 controls with respective mean ages of 46.5 and 44.0 years participated and 33 (91.2%) cases completed the retest questionnaire. Pain ($p<0.001$), urinary ($p<0.001$) and quality-of-life (QOL) scale ($p<0.001$) score means differed between cases and controls. For the same scales, Cronbach's alphas for cases were respectively 0.70, 0.72 and 0.79 versus 0.80, 0.57, and 0.88 for controls. The retest product-moments were 0.83 for pain, 0.55 for urinary, and 0.83 for QOL scales. In cases, strong correlation was noted between QOL and pain scales ($r=0.7$), and between urinary and pain scales ($r=0.6$), versus moderate correlation between QOL and urinary scales ($r=0.4$). Negative correlation was recorded between CPSI scales and SF-12 scales, which ranged from -0.2 to -0.4.*

Conclusions: *When applied to CPPS and control subjects, the French Canadian CPSI translation demonstrates excellent discriminant properties. Moreover, its reliability and validity characteristics confirm the qualities of the CPSI as a standard evaluative tool for men with CPPS.*

Key Words: prostatitis, questionnaire, validation, psychometrics

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Introduction

The burden of chronic prostatitis has been recognized internationally. The United States National Ambulatory Health Care Surveys demonstrated that prostatitis accounts for 8% of urology and 1% of primary care visits.[1] In Italy, up to 12% of men in outpatient urology practice have a diagnosis of prostatitis.[2] In Canada, primary care physicians and urologists respectively averaged 3.5

and 21.8 monthly chronic prostatitis diagnoses.[3] A population-based, cross-sectional survey indicated that 6.0% of Canadian men have moderate prostatitis-like symptoms.[4] In 1995, the National Institutes of Health (NIH) Workshop culminated in a structured and systematic prostatitis classification, to address the existing frustration related to diagnosis and management of this important disease.[5] In order to better understand its natural history and to improve treatment methods, the NIH also sponsored the development and validation of an index of symptoms and quality-of-life impact.[6] The chronic prostatitis symptom index (CPSI) has since been validated for use in Spanish speaking,[7] Finnish,[8] German[9] and Japanese[10] men. However, the use of this reliable and valid tool is impossible in several other populations, such as French Canadian men. The population of the province of Quebec, one of the largest North American linguistic minorities, accounts for the majority of French Canadians and its population exceeds 7 million. The unavailability of a French Canadian validated version of the CPSI limits systematic and structured assessment of men with chronic prostatitis, limits enrollment of French Canadian men in clinical trials, and precludes cross-cultural comparisons. To address these limitations, we performed a linguistic validation of the CPSI in French Canadian men from Montreal.

Methods

The Institutional Review Board of the University of Montreal Health Center provided study approval. The original NIH-CPSI questionnaire was translated into Quebec French by three independent medical translators. The three translations were subsequently reviewed and reconciled by five urologists, who are fluent in French and English. The reconciled version was subsequently back translated into English by a professional medical translator. The back translation was then compared with the original version. The two versions were virtually identical and no significant inconsistencies were identified. The translated French-Canadian version was subsequently reviewed by five men with chronic prostatitis and by five men presenting for a pre-vasectomy consultation, who confirmed the face validity of the instrument.

The translated French-Canadian version of the questionnaire was administered to 36 men with chronic prostatitis and to 38 control subjects, who presented for a pre-vasectomy consultation. Inclusion to the chronic prostatitis group (cases) was based on either established or new clinical diagnosis of chronic prostatitis. Inclusion to the pre-vasectomy group (controls) was based on a referral for a vasectomy in an otherwise healthy male. Controls were invited to a single questionnaire administration. Cases were invited to complete the questionnaire on two separate occasions: test and retest. Financial incentives were not used. The retest was administered 14 days after the test. In both groups, the CPSI was complemented by the 12-item short-form Health Survey (SF-12).[11] Finally, a section addressing socioeconomic status and comorbidity completed the survey,Table 1.[11]

Psychometric testing focused on reliability and validity.[12] Reliability addressed internal consistency of functional scales, which was quantified with the Cronbach's alpha coefficient.[13] For retest respondents, temporal reliability was quantified with Pearson product-moment coefficient. The validation process focused on construct validity testing, where correlation between scales was quantified. Criteria for quantitative assessment of correlation coefficients (r) define the degree of convergence as insignificant if $r < 0.3$, as moderate if $r = 0.3$-0.450, as substantial if $r = 0.451$-0.6 and as high if $r > 0.6$.[14] Finally, independent sample t-tests were used to test score means between cases and controls, with the intent of assessing known groups validity. In all tests a two sided significance level of 0.05 was used and all statistical analyses were performed using the Statistical Package for Social Sciences version 11 (SPSS Inc. Chicago Ill).

Results

The descriptive characteristics of cases and controls are shown in Table 1. The two groups exhibited similar characteristics with regard to age, race, linguistic preference and comorbidity status. In general, fewer patients with prostatitis had a household income in excess of CDN$75,000, relative to men presenting for a pre-vasectomy visit.

The CPSI and the SF-12 questionnaire reliability statistics are shown in Table 2. Control subjects fared significantly better in all areas that were explored with the CPSI and SF-12 questionnaires. CPSI scale scores, as well as single and combined item combination scores were significantly lower when pain, urinary symptoms and quality-of-life were assessed. Cronbach's alphas recorded for the eight-item pain domain ranged from 0.7 to 0.8, for controls, cases and for cases, who completed the retest questionnaire after 14 days (retests). The quality-of-

TABLE 1. **Descriptive characteristics for 36 prostatitis cases and 38 vasectomy controls**

	Cases: Prostatitis (n= 36)		Controls: Vasectomy (n= 38)	
	No of patients (%)	**Missing values (%)**	**No of patients (%)**	**Missing values (%)**
Age				
Mean (median)	46.5 (45.0)	1 (2.8)	44.0 (40.0)	1 (2.6)
Range	24-79		40-77	
Race		0 (0.0)		1 (2.6)
White	33 (91.7)		35 (92.1)	
Black	1 (2.8)		0 (0.0)	
Hispanic	1 (2.8)		2 (5.3)	
Asian	1 (2.8)		0 (0.0)	
Linguistic preference		0 (0.0)		0 (0.0)
French	34 (94.4)		37 (97.4)	
English	2 (5.6)		1 (2.6)	
Education level		0 (0.0)		0 (0.0)
High School	9 (25.0)		15 (39.5)	
College	12 (33.3)		6 (15.8)	
University	15 (41.7)		17 (44.7)	
Household income ($)		3 (8.3)		2 (5.3)
0-10,000	0 (0.0)		3 (7.9)	
10,001-20,000	1 (2.8)		1 (2.6)	
20,001-30,000	2 (5.6)		4 (10.5)	
30,001-50,000	15 (41.7)		5 (13.2)	
50,001-75,000	4 (11.1)		6 (15.8)	
75,001 and higher	11 (30.6)		17 (44.7)	
Comorbidity		1 (2.8)		0 (0.0)
Mean (median)	0.51 (0.0)		55 (0.0)	
Range	0-3		0-2	
Comorbidity				0 (0.0)
Diabetes	1 (2.8)	1 (2.8)	2 (5.3)	
Heart attack, chest pain	0 (0.0)	1 (2.8)	4 (10.5)	
Stroke	1 (2.8)	1 (2.8)	0 (0.0)	
Amputation	0 (0.0)	1 (2.8)	0 (0.0)	
Circulation problems	1 (2.8)	1 (2.8)	3 (7.9)	
Asthma	3 (8.3)	1 (2.8)	5 (13.2)	
Ulcer	5 (13.9)	1 (2.8)	3 (7.9)	
Renal disease	2 (5.6)	1 (2.8)	0 (0.0)	
Depression	2 (5.6)	1 (2.8)	1 (2.6)	
Epilepsy	0 (0.0)	1 (2.8)	0 (0.0)	
Alcoholism	2 (5.6)	1 (2.8)	2 (5.3)	
Drug problems	1 (2.8)	1 (2.8)	1 (2.6)	

life domain Cronbach's alphas ranged from 0.7 to 0.8. Finally, the two-item urinary domain demonstrated the lowest inter-item correlation, which ranged from 0.6 to 0.7.

The SF-12 mental and physical function scales and item scores demonstrated borderline statistically significant differences, with the exception of two role-emotional items (p=0.09) and two role-physical items (p=0.06). SF-12 mental and emotional scales demonstrated Cronbach's alphas ranging from 0.7 to 0.8.

Temporal reliability was assessed with test-retest product moments. These were defined for cases that completed the test and retest surveys (retests). Of CPSI scales, the urinary symptom scale demonstrated the lowest temporal reliability (product moment of 0.55). Pain and quality-of-life domains demonstrated test-retest product moments of 0.8. SF-12 mental and

TABLE 2. **NIH CPSI and SF-12 reliability statistics**

			Controls: Vasectomy (n= 38) Principal sample		
Scales	**No items (max. score)**	**No completed question. (%)**	**Mean scores**	**SD**	**Cronbach's alpha**
Pain domain	8 items (21 points)	38 (100.0)	1.72[1a]	2.27	0.807
Pain location	6 items (6 points)	38 (100.0)	0.13[1b]	0.40	
Pain frequency	1 item (5 points)	38 (100.0)	0.29[1c]	0.80	
Pain severity	1 item (10 points)	35 (92.1)	1.43[1d]	1.31	
Urinary symptoms	2 items (10 points)	38 (100.0)	0.95[2a]	1.12	0.570
Quality of life domain	3 items (12 points)	33 (86.8)	0.76[3a]	1.81	0.884
Impact	2 items (6 points)	33 (86.8)	0.21[3b]	0.89	
Quality of life item	1 item (6 points)	33 (86.8)	0.58[3c]	1.12	
SF-12 mental function	6 items (100 points)	35 (92.1)	83.57[4a]	17.00	0.801
Vitality	1 item	37 (97.4)	79.05[ab]	15.04	
Social functionning	1 item	37 (97.4)	93.92[4c]	16.04	
Role-emotional	2 items	37 (97.4)	86.49[4d]	30.39	
Mental health	2 items	29 (76.3)	77.70[4e]	14.28	
SF-12 physical function	6 items (100 points)	35 (92.1)	92.74[5a]	12.35	0.711
Physical functionning	2 items	37 (97.4)	97.30[5b]	9.83	
Role-physical	2 items	29 (76.3)	94.59[5c]	22.92	
Bodily pain	1 item	37 (97.4)	94.59[5d]	15.74	
General health	1 item	37 (97.4)	79.05[5e]	21.66	

Principal sample: Mean scale scores comparison between prostatitis and vasectomy.
[1a] t= -10.205, p≤ 0.001; [1b] t= -8.669, p≤ 0.001; [1c] t= -9.648, p≤ 0.001; [1d] t= -6.814, p≤ 0.001
[2a] t= -4.997, p≤ 0.001;
[3a] t= -9.836, p≤ 0.001; [3b] t= -7.528, p≤ 0.001; [3c] t= -9.778, p≤ 0.001
[4a] t= 3.076, p= 0.003; [4b] t= 5.023, p≤ 0.001; [4c] t= 3.366, p≤ 0.001; [4d] t= 1.707, p= 0.092; [4e] t= 3.207, p= 0.002
[5a] t= 2.207, p= 0.031; [5b] t= 1.622, p= 0.109; [5c] t= 1.906, p= 0.061; [5d] t= 2.384, p= 0.020; [5e] t= 2.469, p= 0.016

physical function scales demonstrated test-retest product moments of 0.7. Role-emotional items demonstrated the lowest temporal reliability (product moment of 0.6).

Validity of the CPSI was assessed in two ways. First, known groups validity was explored by comparing means differences between cases and controls, as described in Table 2. Subsequently, using the Pearson correlation coefficient, we assessed the degree of divergence or convergence between different scales, Table 3. The pain scale, where a higher score indicates a worse outcome, was strongly correlated (r = 0.7) with the urinary scale, where a higher score also indicates more

TABLE 2. **NIH CPSI and SF-12 reliability statistics**

Cases: Prostatitis (n= 36) Principal sample				Retest sample				Test Retest productmoment
No completed question.(%)	**Mean scores**	**SD**	**Cronbach's alpha**	**No completed question. (%)**	**Mean scores**	**SD**	**Cronbach's alpha**	
36 (100.0)	9.86[1a]	4.39	0.696	33 (91.7)	8.48	4.67	0.7217	0.835
36 (100.0)	2.50[1b]	1.63		33 (91.7)	2.15	1.52		0.716
36 (100.0)	2.75[1c]	1.34		33 (91.7)	2.09	1.40		0.650
36 (100.0)	4.61[1d]	2.44		33 (91.7)	4.24	2.29		0.853
35 (97.2)	3.11[2a]	2.43	0.716	33 (91.7)	3.33	2.31	0.592	0.546
33 (91.7)	6.30[3a]	2.72	0.787	33 (91.7)	5.39	2.84	0.843	0.832
33 (91.7)	2.45[3b]	1.46		33 (91.7)	1.97	1.49		0.778
33 (91.7)	3.85[3c]	1.56		33 (91.7)	3.42	1.64		0.795
35 (97.2)	69.43[4a]	21.23	0.825	33 (91.7)	69.43	21.23	0.845	0.728
35 (97.2)	59.29[4b]	18.28		33 (91.7)				0.862
36 (100.0)	79.17[4c]	21.13		33 (91.7)				0.875
36 (100.0)	72.22[4d]	40.43		33 (91.7)				0.599
36 (100.0)	65.28[4e]	18.45		33 (91.7)				0.692
35 (97.2)	84.14[5a]	19.45	0.820	33 (91.7)	84.14	19.45	0.816	0.744
36 (100.0)	92.36[5b]	15.61		33 (91.7)				0.352
36 (100.0)	80.56[5c]	38.32		33 (91.7)				0.667
36 (100.0)	83.33[5d]	23.90		33 (91.7)				0.837
36 (100.0)	67.36[5e]	18.73		33 (91.7)				0.798

severe symptoms. The pain scale also very strongly correlated (r=0.9) with the quality-of-life scale, where a high score indicates poor quality-of-life. Conversely, the pain scale showed an inverse correlation with the SF-12 mental and physical scales, where high scores are associated with good physical and emotional outcomes. Overall, the CPSI scales demonstrated a very strong degree of convergence with each other, as evidenced by product moments ranging from 0.6 to 0.9. All CPSI scales demonstrated strong divergence with the SF-12 physical function scale (r range from -0.4 to -0.5). The same degree of divergence was noted between the CPSI and the SF-12 mental health scale. The

TABLE 3. **NIH CPSI and SF-12 covariance matrix**

		Pain scale				Urinary scale	QOL scale		
		Pain scale	**Pain location**	**Pain freq.**	**Pain severity**	**Urinary scale**	**QOL scale**	**QOL impact**	**QOL item**
Pain scale	Pain scale	1.00	-	-	-	-	-	-	-
	Pain location	0.87	1.00	-	-	-	-	-	-
	Pain freq.	0.91	0.72	1.00	-	-	-	-	-
	Pain severity	0.94	0.71	0.78	1.00	-	-	-	-
Urinary scale	Urinary scale	0.67	0.66	0.55	0.61	1.00	-	-	-
QOL scale	QOL scale	0.91	0.72	0.86	0.86	0.62	1.00	-	-
	QOL impact	0.86	0.63	0.82	0.84	0.62	0.94	1.00	-
	QOL item	0.87	0.73	0.82	0.81	0.57	0.97	0.82	1.00
SF-12 Physical scale	Physical scale	-0.40	-0.25	-0.37	-0.43	-0.40	-0.51	-0.60	-0.40
	Physical function	-0.38	-0.23	-0.37	-0.40	-0.42	-0.41	-0.53	-0.28
	Role-physical	-0.29	-0.19	-0.24	-0.32	-0.32	-0.42	-0.50	-0.32
	Bodily pain	-0.44	-0.33	-0.35	-0.48	-0.43	-0.44	-0.49	-0.40
	General health	-0.39	-0.33	-0.39	-0.32	-0.28	-0.50	-0.46	-0.48
SF-12 Mental scale	Mental scale	-0.41	-0.28	-0.44	-0.35	-0.37	-0.53	-0.61	-0.43
	Vitality	-0.50	-0.41	-0.53	-0.40	-0.37	-0.59	-0.60	-0.54
	Social function	-0.34	-0.23	-0.35	-0.32	-0.34	-0.50	-0.54	-0.43
	Role-emotion	-0.32	-0.22	-0.35	-0.29	-0.36	-0.40	-0.51	-0.28
	Mental health	-0.34	-0.25	-0.36	-0.31	-0.20	-0.45	-0.45	-0.42

SF-12 scales showed a strong convergence with each other (r = 0.6).

Discussion:

The results of our rigorous translation and validation study show that the French Canadian NIH-CPSI is a reliable and valid instrument for measuring the symptoms and impact of chronic prostatitis in French Canadian men. Our methodology was based on the accepted methodology for linguistic questionnaire validations.[7-10] Translation, back-translation, reconciliation and face validation of the translated version were enforced. These findings are consistent with previous work, where Spanish, German, Finnish and Japanese translations were developed.[7-10]

Reliability of the French-Canadian CPSI was assessed with Cronbach's alphas and with the test-retest product moments. Internal consistency of the French-Canadian scales ranged from 0.6 to 0.8. The two-item urinary scale demonstrated the lowest internal consistency (0.6). These findings are consistent with Litwin's original validation data, where of three CPSI scales, the urinary items also demonstrated the lowest internal consistency (0.79).[6] Our data are also consistent with the Spanish translation, where the urinary scale also scored the lowest relative to the other two CPSI scales.[7] Conversely, in Japanese men internal consistency of urinary items was the highest (0.97), relative to the other two scales.[9] Internal consistency data were not reported in the Finnish study.[8] These findings suggest that linguistic and cultural variables might affect questionnaire scales to a varying extent. This finding reinforces the need for population-specific validations prior to implementation.

Fourteen-day test-retest reliability findings showed that pain and quality-of-life scales are highly reliable in French Canadian men. Again, urinary items demonstrated lower reliability than other scales, which was consistent with findings in the original CPSI validation.[6] Opposite findings were reported in the Japanese validation, where urinary items demonstrated the highest test-retest reliability. These observations mirror internal consistency findings and substantiate the observation that different symptoms may show culture-specific psychometric properties. In face of internal consistency and temporal reliability data, the urinary scale appears the least reliable of the three CPSI scales, when tested in French Canadian men.

Validity testing was based on known groups and on convergent validity tests. In the current study

TABLE 3. **NIH CPSI and SF-12 covariance matrix**

	SF-12 Physical scale					SF-12 Mental scale			
Physical scale	**Physical function**	**Role physical**	**Bodily pain**	**General health**	**Mental scale**	**Vitality**	**Social function**	**Role emotion**	**Mental health**
-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-
1.00	-	-	-	-	-	-	-	-	
0.61	1.00	-	-	-	-	-	-	-	-
0.93	0.47	1.00	-	-	-	-	-	-	-
0.73	0.30	0.68	1.00	-	-	-	-	-	-
0.53	0.31	0.23	0.18	1.00	-	-	-	-	-
0.62	0.34	0.53	0.61	0.36	1.00	-	-	-	-
0.40	0.26	0.31	0.37	0.40	0.66	1.00	-	-	-
0.59	0.16	0.55	0.69	0.26	0.83	0.60	1.00	-	-
0.61	0.43	0.53	0.57	0.25	0.90	0.33	0.65	1.00	-
0.30	0.10	0.28	0.36	0.26	0.77	0.66	0.63	0.46	1.00

men with clinical diagnosis of chronic prostatitis reported substantially more pain (scale score 9.9 versus 1.7), more severe urinary symptoms (3.1 versus 0.9) and more quality-of-life detriments (6.3 versus 0.8) than their healthy counterparts, Table 2. The scale scores of men with chronic prostatitis are very comparable to those reported in Japan (pain 7.9; urinary 3.5; quality-of-life 6.3), Finland (pain 9.9; urinary 3.9; quality-of-life 6.5), and in the original validation cohort (pain 9.7; urinary 4.4; quality-of-life 7.0).[6-9] These findings suggest that across linguistically and culturally distinct populations, the three principal areas of concern are associated with measurable detriments that are of virtually the same intensity. Comparison of our findings in control men showed differences with Finish and Japanese data.[8,9] Our controls, men presenting for a pre-vasectomy consultation, reported small but measurable detriments on all three CPSI scales, Table 2. Data from Japan showed that normal men (individuals undergoing a general health checkup, aged 20 to 65 years) do not perceive any measurable pain or urinary symptoms, as evidenced by zero scale scores. Despite, zero pain and urinary scores, Japanese men reported more important quality-of-life scale (score 1.0) detriments than French-Canadian men (score 0.8).[9] This suggests that objective symptoms may be associated with different subjective ratings according to culture and linguistic background.

Data regarding convergence and divergence with other CPSI scales, show that in French Canadian men pain and quality-of-life are closely interrelated (r = 0.9). Conversely, urinary symptoms demonstrated a weaker relation with pain (r = 0.7) and a weaker relation with quality-of-life (r = 0.6). Our data are consistent with the Spanish validation, where urinary symptoms also exhibited a weaker correlation with quality-of-life (r = 0.76) than did the pain scale (r = 0.88).[7]

The above findings indicate that the French-Canadian translation of the CPSI is highly reliable when pain and QOL scales are considered. Our data suggest that the urinary items address a construct which may be different in French-Canadian men, relative to American, Spanish, Finnish, German or Japanese men.[6-10] This important observation underscores the importance of psychometric testing of linguistic questionnaire translations. Our data also indicate that the CPSI represents a reliable and valid tool, which may be safely used in French-Canadian men. Known psychometric properties of the French-

Canadian translation of the CPSI may serve as a foundation for its use in clinical trials.

Our study has several limitations. Area of recruitment of study subjects represents one of those limitations. Cases and controls have been recruited from metropolitan Montreal. Thus, their scale scores may not be reflective of cases from rural areas, where the perception of discomfort and the impact of discomfort on quality-of-life may be different. Moreover, men from Montreal are not fully representative of French speakers elsewhere in North America. They are even less representative of French speakers on other continents. Small differences exist between French spoken in other Canadian Provinces and that spoken in the Province of Quebec. Thus, the Montreal derived French-Canadian validation may be applicable to French-Canadians in New Brunswick or Manitoba. However, this version of the CPSI clearly cannot be used in France or French territories outside of Europe, where perception, culture and vocabulary differ from those of Montreal men. Finally, this study is based on a relatively small sample size, relative to previously published CPSI validations.[7-10] It may have contributed to spurious or chance observations. The Japanese validation was based on the largest sample, which consisted of 103 prostatitis cases, 60 benign prostatic hypertrophy controls and 87 men undergoing a general health checkup.[9] The Finnish validation was based on 155 prostatitis cases and 12 controls.[8] Finally, the Spanish validation was based on 37 cases from four different Spanish-speaking countries.[7] Based on sample size considerations, it is possible that we sampled an unusually high proportion of men whose urinary symptoms changed between the test and the retest questionnaires, which could explain the low test-retest product moment of the urinary scale. Presence of urinary symptoms that were omitted at the time of history taking represents another potential limitation of our control group. In a similar fashion, our cases might also have included men with unusually mild symptoms, as no gold standard exists for clinically diagnosis chronic prostatitis.

Conclusions

We have performed a rigorous linguistic validation of the CPSI in French-speakers from Montreal. The CPSI has demonstrated good reliability and validity characteristics. Therefore, the CPSI may be safely used in French Canadian populations. □

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