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Empirical Validity of Canadian-weighted health utilities for the VR-12 in Patients with Life-Limiting Illness and their Family Caregivers

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Why validate this instrument?

Canadian Health Technology Assessment (HTA) guidelines recommend using *population* health-state values

- Available: EQ-5D-3L; EQ-5D-5L; HUI mark 2/3
- Since 2022 → the Veterans RAND 12-Item Health Survey (**VR-12**)

VR-12 validation evidence is limited in the Canadian context, and more generally for *family caregivers*

- Studies include population in long-term residential care and ED settings → with a focus on summary components
- No studies with a caregiver focus

Data source: Quality of Life and Practice Support System (QPSS) trial

Participants:

- Older adults with a life-limiting illness receiving home-based care (n = 331)
- Family caregivers (n = 111)

Follow-up:

Baseline and every 2 months over a year

Instruments:

- VR-12 (patients + caregivers)
- **Patients:** McGill Quality of Life Questionnaire – Expanded (*MQOL-E*) + Edmonton Symptom Assessment System Revised (*ESAS-r*)
- **Caregivers:** Quality of Life in Life Threatening Illness - Family Carer Version 3 (*QOLLTI-Fv3*)

Data source and outcome measures



VR-12 description



A generic measure
of health-related
quality of life
(HRQoL)

14 item questionnaire



8 attributes:

- Physical functioning
- Role limitations (physical and emotional)
- Bodily pain
- Vitality
- Mental health (Anxiety and Depression)
- Social functioning



Uses a 3-to-6 point
scale



Responses
converted into
preference-based
utility scores using
a Canadian
valuation algorithm

Other reference instruments

Patients

MQOL-E → Multidimensional QoL
(e.g., physical, psychological, existential, social)

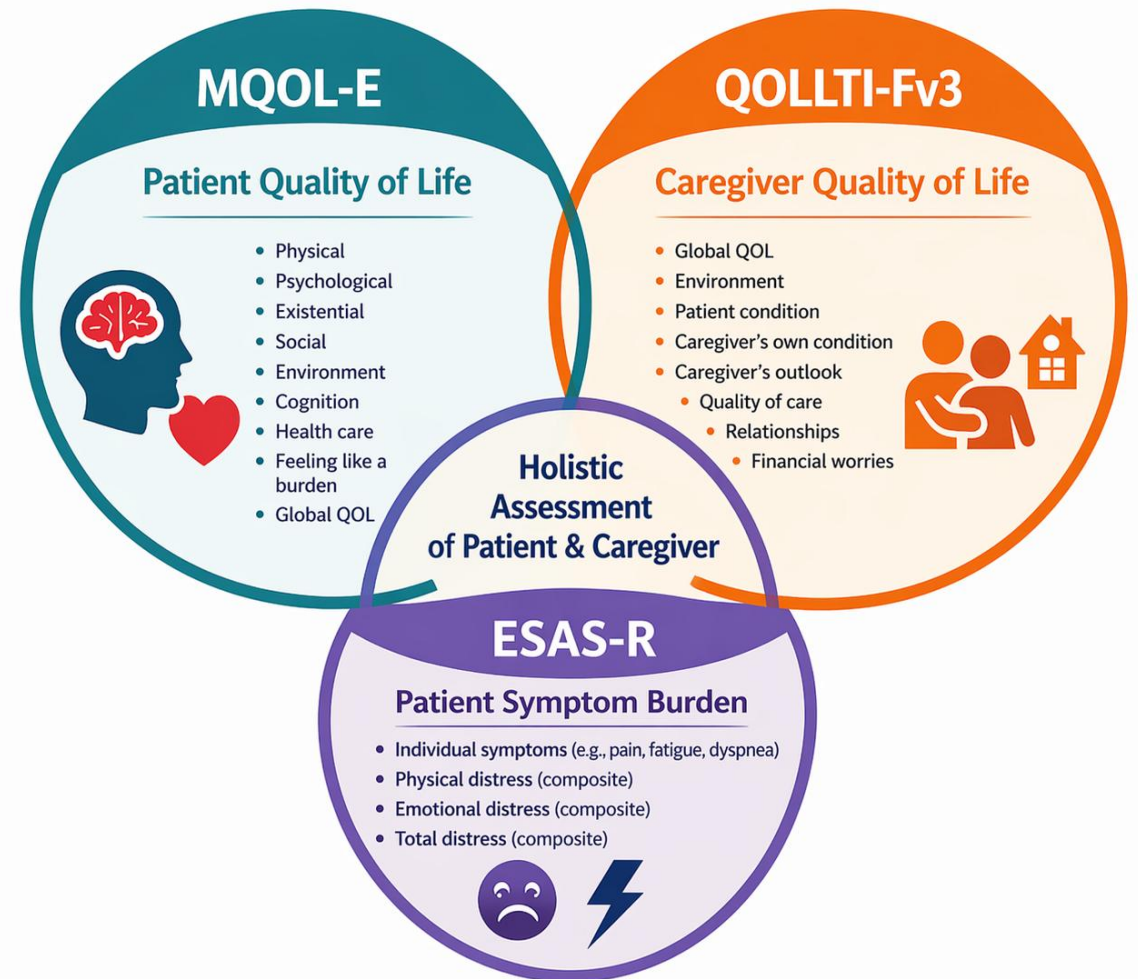
ESAS-R → Symptom burden
(individual symptoms + composite distress scores)

Caregivers

QOLLI-Fv3 → Multidimensional QoL
(e.g., own condition, outlook, relationships, care quality)

Scoring

- All measures: 0–10 scale
- Domain scores derived from item means or sums
- Coded such that higher scores = better outcome



Objective and analytical approach

Contribute to evidence of empirical validity of the VR-12 via:

Convergent validity

- Relative strength and direction of association between VR-12 utility score/attributes and other PROMs

Known-groups validity

- Multiple hypotheses developed and tested
 - Strong hypotheses – 15 for patients and 7 for caregivers
 - 'Exploratory' hypotheses - 6 for patients and 4 for caregivers

Sensitivity to change

- Baseline and 2-month follow-up → complete cases only
- Two external QoL measures as 'anchors' → from MQOL-E and QOLLI-Fv3
- Classified into three categories (worsened, no change, improved) → Norman's 0.5 SD criteria
- Effect size, standardized response mean (SRM) and AUC-ROC assessed

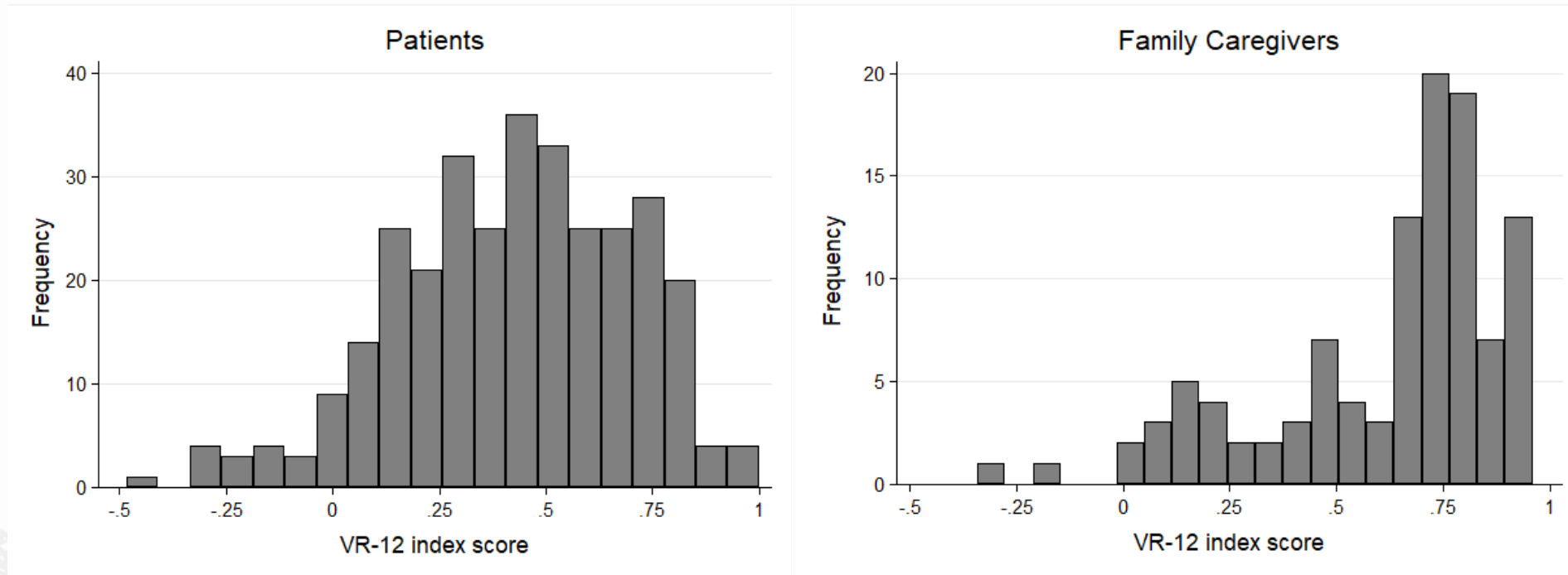


RESULTS

Table. Socio-demographic characteristics

Characteristics/outcome	Patients, n(%) (n=331)	Family caregivers, n(%) (n=111)
Mean age	79.1 ± 9.9	66.9 ± 13.0
Gender - female	205 (62.1)	75 (67.6)
Highest education		
Elementary/incomplete high school	64 (19.6)	5 (4.6)
High school graduate	102 (31.3)	27 (25)
College, trade school, or CEGEP diploma	92 (28.2)	37 (34.3)
University/post-graduate degree	68 (20.9)	39 (36.1)
Marital status		
Married/living as married	105 (31.9)	92 (83.6)
Divorced/separated	62 (18.8)	10 (9.1)
Never married	33 (10)	7 (6.4)
Widowed	129 (39.2)	1 (0.9)
Household income per year (in CAD)		
<\$30,000	136 (48.1)	16 (15.8)
\$30,000 to <\$50,000	81 (28.6)	28 (27.7)
\$50,000 to <\$70,000	33 (11.7)	22 (21.8)
\$70,000 to <\$90,000	13 (4.6)	13 (12.9)
>\$90,000	20 (7.1)	22 (21.8)
Born in Canada	242 (73.3)	86 (77.5)
Lives with the patient	NA	81 (73.0)

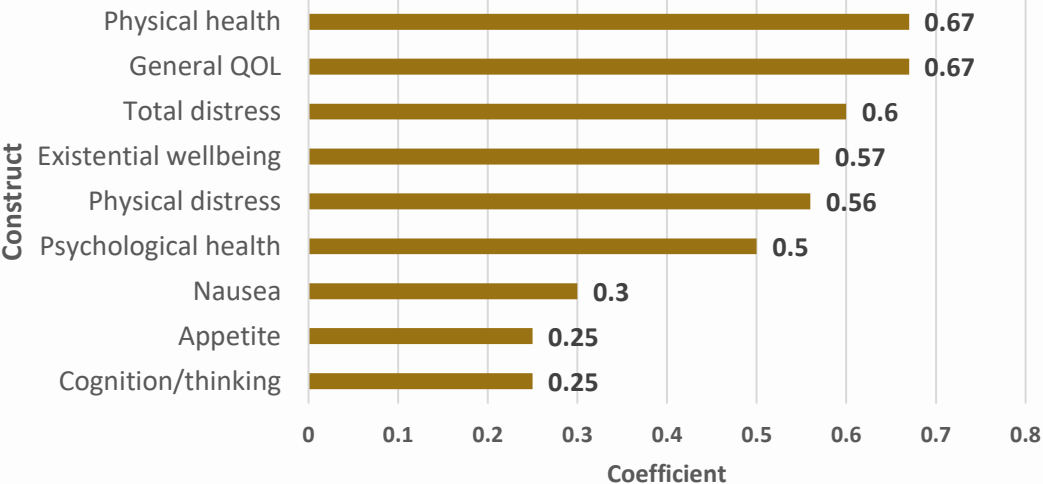
Figure. Frequency distribution of VR-12 utility scores for patients and family caregivers



Group	Mean VR-12 utility (SD)
Patients	0.423 (0.273)
Caregivers	0.621 (0.274)

Convergent validity – VR-12 health utility score

Spearman's correlation (patients)

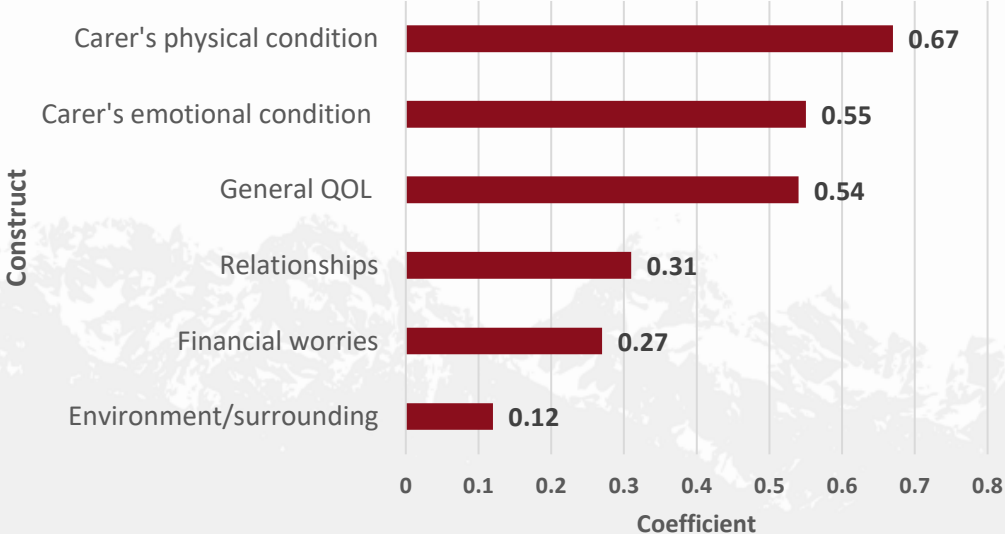


Observed relationships aligned with *a priori* hypotheses

Among patients, strongest associations with:

- Physical health
- Existential wellbeing
- Psychological health

Spearman's correlation (family caregivers)



Among caregivers, strongest correlations with:

- Own physical and emotional condition

Findings support evidence of convergent validity:

- ✓ stronger associations for conceptually related constructs
- ✓ weaker associations for those less closely related

Hypotheses formulation: known-groups validity

Table. Examples of the 22 strong and 10 exploratory hypotheses in the context of older adults and family caregivers

	Construct	Expected relationship with VR-12 utility scores and evidence
Patients	<i>Strong hypotheses</i>	
	Existential wellbeing	Higher spiritual wellbeing and fulfilment associated with <i>improved QoL</i> ; unmet spiritual needs reduce QoL (Coelho-Júnior et al., 2022; Pearce et al., 2012; Sawatzky et al., 2005; Balkin et al., 2024).
	<i>Exploratory hypotheses</i>	
	Cognition/thinking	<i>Mixed evidence</i> : weak or no consistent association with QoL (Baernholdt et al., 2012; Voros et al., 2020).
Caregivers	<i>Strong hypotheses</i>	
	Carer's own physical & emotional state	Level of caregiving burden and family caregiver's decreased mental health status is associated with lower carer QoL (Contreras et al., 2021; de Oliveira et al., 2015; Rossler et al., 2005).
	<i>Exploratory hypotheses</i>	
	Education	<i>Inconsistent evidence</i> : higher education linked to both higher and lower QoL (Lai, 2012; ZamZam et al., 2011).

Known-groups validity - *Patients*

Overall findings

- **13/15 strong** and **5/6 exploratory** hypotheses supported

Examples of hypotheses supported:

- Physical health
- Existential wellbeing
- Pain
- Dyspnea

Examples of hypotheses **not** supported:

- Marital status (*strong*)
- Number of conditions (*strong*)
- Education level (*exploratory*)

Table. Selected results - *patients*

Construct	Categories*	n	VR-12 score	p-value
Physical health (composite, MQOL-E)	Level 1 (lowest)	106	0.223 (0.237)	p<0.001
	Level 2	105	0.418 (0.221)	
	Level 3 (highest)	105	0.630 (0.191)	
Existential wellbeing (composite, MQOL-E)	Level 1 (lowest)	105	0.270 (0.270)	p<0.001
	Level 2	104	0.398 (0.222)	
	Level 3 (highest)	105	0.606 (0.213)	
Pain (single item, ESAS-R)	Level 1 (Most severe)	89	0.276 (0.256)	p<0.001
	Level 2	61	0.387 (0.282)	
	Level 3	49	0.463 (0.243)	
	Level 4	13	0.501 (0.195)	
	Level 5 (None)	100	0.553 (0.241)	
Marital status	Currently not married	213	0.425 (0.27)	p=0.849
	Married/living as married	102	0.419 (0.28)	

*All scores coded so higher values indicate better health/outcomes

Known-groups validity – *Family caregivers*

Overall findings

- **5/7 strong** and **2/4 exploratory** hypotheses supported

Examples of hypotheses supported:

- Carer's outlook
- Own physical & emotional state
- Quality of healthcare

Examples of hypotheses **not** supported:

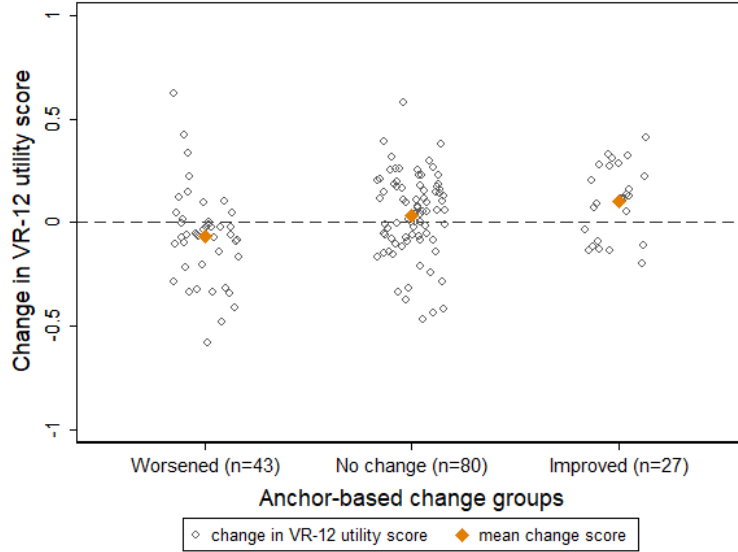
- Marital status (*strong*)
- Environment/surrounding (*exploratory*)

Table. Selected results - *family caregivers*

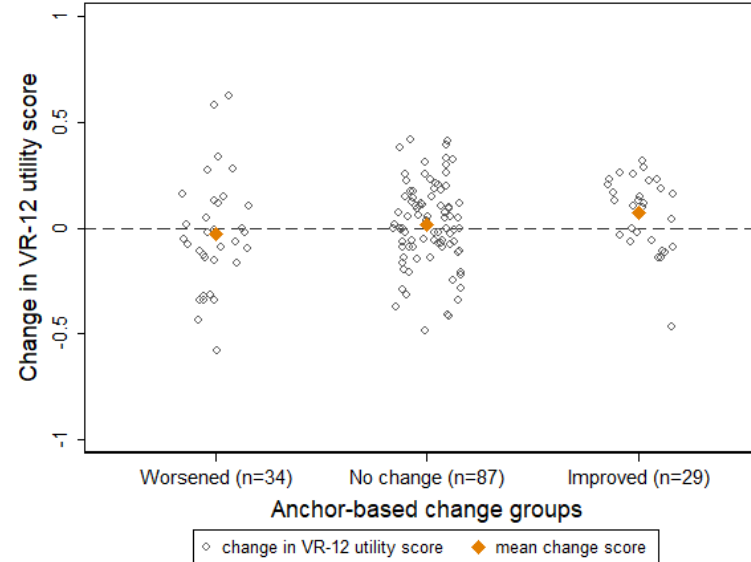
Construct	Categories*	n	VR-12 score	p-value
Carer's outlook/existential wellbeing	Level 1 (lowest)	36	0.476 (0.302)	P<0.001
	Level 2	36	0.687 (0.245)	
	Level 3 (highest)	36	0.713 (0.199)	
Carer's own physical & emotional state	Level 1 (lowest)	36	0.426 (0.308)	p<0.001
	Level 2	36	0.685 (0.173)	
	Level 3 (highest)	36	0.764 (0.190)	
Quality of healthcare provided to patient	Level 1 (lowest)	35	0.513 (0.330)	p=0.006
	Level 2	35	0.658 (0.248)	
	Level 3 (highest)	35	0.706 (0.173)	
Environment/surrounding	Level 1 (lowest)	36	0.552 (0.324)	p=0.101
	Level 2	35	0.689 (0.209)	
	Level 3 (highest)	35	0.637 (0.263)	

*All scores coded so higher values indicate better health/outcomes

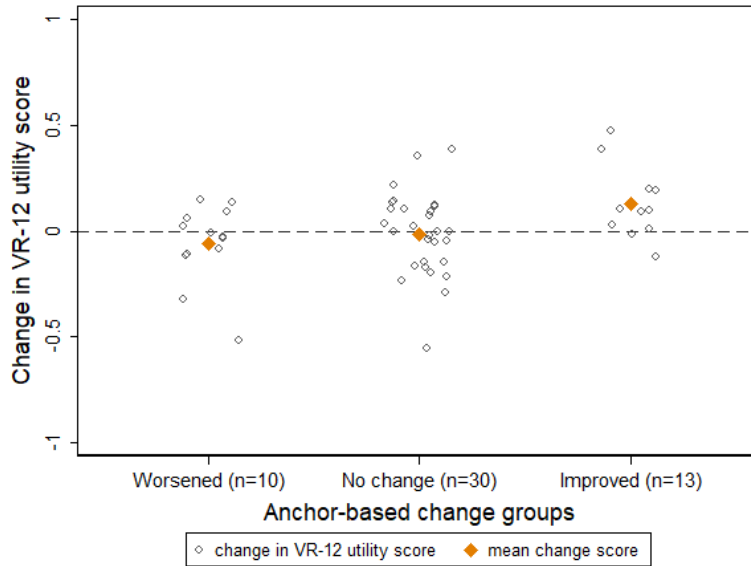
Total quality of life anchor



Global quality of life anchor



Patients



Caregivers

Sensitivity to change

- No global 'rating of change' item in the QPSS study

Anchors:

- **Total quality of life:** Composite of all MQOL-E and QOLLI-Fv3 domains, respectively
- **Global quality of life:** Single QoL item

Effect size (ES) and standardized response mean (SRM)

Patients:

- Total QoL → significant change; small to moderate effects

- Global QoL → non-significant change

Caregivers:

- Total QoL → significant change; moderate effect size

- Global QoL → significant change for improved group

Anchor	Change group	n	Mean Δ VR-12 (SD)	ES	SRM
Patients					
Total quality of life	Worsened	43	-0.068* (0.23)	-0.25	-0.30
	No change	80	0.036 (0.20)	0.13	0.18
	Improved	27	0.103* (0.17)	0.37	0.6
Global quality of life	Worsened	34	-0.030 (0.26)	-0.11	-0.11
	No change	87	0.019 (0.20)	0.07	0.1
	Improved	29	0.071 (0.17)	0.26	0.41
Family caregivers					
Total quality of life	Worsened	10	-0.134* (0.20)	-0.50	-0.68
	No change	31	0.001 (0.17)	0.01	0.01
	Improved	12	0.135* (0.19)	0.5	0.72
Global quality of life	Worsened	13	-0.058 (0.19)	-0.22	-0.31
	No change	29	-0.013 (0.20)	-0.05	-0.07
	Improved	11	0.132* (0.17)	0.49	0.76

Area under receiver operating curve (AUC-ROC)

Patients:

Total & Global QoL → low-to-modest discriminative ability

Caregivers:

Total & Global QoL → modest discriminative ability; better than for patient population

Anchor	AUC	95% CI
Patients (improved vs. not improved)		
Total QoL (MQOL-E, composite)	0.64	0.52–0.76
Global QoL (MQOL-E, single item)	0.60	0.49-0.71
Family caregivers (improved vs. not improved)		
Total QoL (QOLLLTI-Fv3, composite)	0.72	0.55-0.87
Global QoL (QOLLLTI-Fv3, single item)	0.72	0.56-0.88

Discussion

- Findings contribute to the evidence base supporting the construct validity and sensitivity-to-change of VR-12 health utilities
- Multiple complementary approaches:
 - Associations generally consistent with theoretical expectations
 - Discrimination across groups known to differ
 - Sensitive to change over time

Strengths:

- Hypothesis-driven validation (*a priori*)
- First validity study of the VR-12 instrument among caregivers in Canada



Caution

Single trial → caution when generalizing

No global rating of change → reliance on external anchors

Need to compare VR-12 with other generic measures



Implications

Validity supports use of VR-12 for both **patients and their family caregivers**

Relevant for Canadian HTA and policy

Thank you!



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