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Presentation

HEALTH-RELATED QUALITY OF LIFE IN THE WA HIV COHORT: 2008

Herrmann S, Duracinsky M, Lalanne C, McKinnon E, Acquadro C, Mallal S, Nolan D

Introduction

- Health related quality of life (HRQL) is a major concern in the clinical care of people living with HIV.

- Measuring quality of life (QOL) is one way of assessing the patients experience with long term therapies and other psychosocial dimensions of living with the infection.

- Patient reported outcomes (PRO), measure HRQL – their use is mandatory during the drug approval process.

- PRO instruments currently used were devised for generic health assessment and during the early HAART period.

1. EMEA/CHMP/EWP/139391/2004. Reflection paper on the regulatory guidance for the use of health-related quality of life (HRQL) measures in the evaluation of medicinal products. London, EMEA, 2005.
2. 2. Draft Guidance for Industry – Patient-reported Outcomes Measures: Use in Medical Product Development to support Labeling Claims. Docket 2006D-0044, FDA Federal Register, 2006.

Introduction

- A new Patient-Reported Outcomes questionnaire to measure QOL in people living with HIV/AIDS has been developed.

- The instrument, PROQOL-HIV, has undergone psychometric validation in 791 individuals from 8 countries including 102 people from the WA HIV Cohort Study.

Here we describe:

1. Factors influencing HRQL in the WA HIV Cohort Study
2. Some comparisons with other countries
3. The reliability and validity of the PROQOL-HIV questionnaire

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METHODS

102 patients (792 globally) attending the Royal Perth Hospital Immunology Outpatient Clinic- completed three HRQL instruments:

- (1) the 70-item PROQOL-HIV – to be tested
- (2) the EQ-5D
- (3) the MOS-HIV *
- (4) a symptom questionnaire
- Other information: Self reported missed doses in the preceding two weeks, demographic and biomedical data

The QOL score† from the PROQOL-HIV was expressed on a 0-100 point scale with higher values indicating better QOL.

*France, USA and Australia only, † standardised raw score

METHODS: (1) The PROQOL-HIV Questionnaire

Qualitative input from semi directive interviews revealed 12 dominant themes which informed the 70 item PROQOL-HIV questionnaire to be validated:

- Ability to work
- Social life
- Stigma
- Family
- Sexuality
- Spirituality
- Medication
- Energy/fatigue
- Psychological burden
- Leisure
- Ability to travel
- Resources

METHODS: (2) The MOS-HIV SF 36

- general health perceptions
- physical functioning
- role functioning
- pain
- social functioning
- mental health
- energy
- health distress
- cognitive functioning
- quality of life

A physical health summary score: PHS

A mental health summary score: MHS

METHODS: (3, 4) The EQ-5D & Symptom Questionnaire

The EQ-5D is a standardised instrument for use as a generic measure of health outcome. It assess 5 traits:
- Mobility, self-care, usual activities, pain/discomfort, and anxiety/depression together with a general health state scored on a visual analogue scale.

Symptoms/health conditions were measured using an modified version of the self completed HIV symptom index developed by *Justice et al (2001)*

RESULTS - Psychometric validation

PROQOL sub-scales

1. Physical Health & Symptoms   (PHS)
2. Treatment Impact (TI)
3. Emotional Distress (ED)
4. Health Concerns (HC)
5. Body Image (BC)
6. Intimate relationships (SR)
7. Social Relationships (IR)
8. Stigma (St)

RESULTS: Patient characteristics: Australia N=102

- Mostly caucasian (80%) men (85%)
- Aged between 37 – 53 yrs (mean 45)
- The earliest diagnosis was in 1981 with half of the patients diagnosed before 2000 (n=47) and half since (n=55)
- Transmission commonly msm (53%)
  - Hetero = 27%, IVDU = 20%
- Living alone (39%) vs with a partner (33%) vs with others (28%) and employed (80% vs 18%)
- Most common co-morbidity: depression (24%) followed by HCV (17%), psychiatric disorder (5%), CVD (3%) and HBV (2%)

RESULTS: Patient characteristics: Australia antiretroviral therapy (ART), n = 87

- 87 pts on ART, 76% were 100% adherent
- 52% on protease inhibitors (PI)
- 70% on a once daily regimen
- 85% had an undetectable viral load
- Mean CD4T cell count ranged from 6 – 62% average = 26%

RESULTS: Patients on protease inhibitors n = 42 (52%)

- More likely to be on BD regimen (p= 0.01)
- Take more tablets (p<0.001)
- Report more symptoms (p=0.007)

RESULTS: PROQOL –HIV Score

All patients (n = 102)
50.2, 64.4, 77.6

Naïve patients (n= 13)
48.1, 64.1, 77.6

Treated patients (n=87)
50.9, 65.4, 79.8

Lowest , median and highest score

RESULTS: All Countries

Variable	West Australia N = 102	All countries N = 692	P - value
Gender m/f	85/15% (87/15)	60/40% (419/273)	<0.001
Age (yrs)	45	41	<0.001
Body Mass Index	25	23	<0.001
Diagnosis (<2008)	3 7 16	2 5 9	<0.001
Transmission Msm Hetero IVDU	53% (54) 27% (28) 20% (20)	26% (175) 55% (374) 10% (68)	<0.001 <0.001 NS
Living alone	39% (40)	19% (131)	<0.001
Secondary education	98% (100)	19% (126)	<0.001

Demographics

RESULTS: All Countries

Variable	West Australia N = 102	All countries N = 692	P - value
Depression	24% (24)	10 % (67)	0.037
Psychiatric disorder	5% (5)	6% (41)	NS
Hepatitis C	17% (17)	12% (72)	NS
Hepatitis B	2% (2)	6% (36)	NS
Cardiovascular disease	3% (3)	11% (69)	NS
Alcohol (>2/day)	15% (15)	8% (47)	0.027
Tobacco (>2/day)	40% (41)	28% (163)	0.008

Co-morbidities and Substances

RESULTS: All Countries

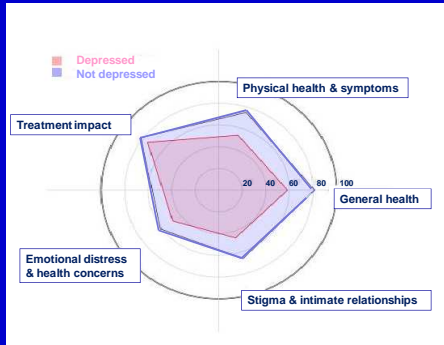| Variable	West Australia N = 102	All countries N = 692	P - value
Treatment/naive	85% (87)	86% (596)	NS
Dosing schedule OD, BD, >BD	70.5% (62) = OD 29.5 (26) = (BD) 0 = >BD	18%= OD 82%= (≥BD)	
ART pill burden	3	5	<0.001
100% Adherence (last 2 weeks)	79% (84)	70% (512)	<0.04
CD4 T Cell copies/ml	579	405	<0.001
Viral load (undetectable)	75% (77)	85% 377	NS
No of symptoms	7	9	0.018

Treatments and Outcomes

RESULTS: Rank order of factors influencing Quality of Life

Variable	All Countries	West Australia
Symptom burden (≥5)	1	2
Depression	2	1
Dosing schedule (≥BD)	**3**	**6**
Pill burden (>2tablets)	**4**	**8**
Psychiatric disorder	5	4
CD4 T-cell count (<200cps/ml)	6	7
Lack of Professional activity	7	3
Gender (female)	**8**	**5**
Living alone	9	7
Cardiovascular disease	10	9
PROQOL std score	**47.4 60.8 61.3**	**50.2 64.4 7.6**

RESULTS: Differences in sub-scales according to country

- Australia, US & France
- Brazil & Thailand
- China & Cambodia
- Senegal

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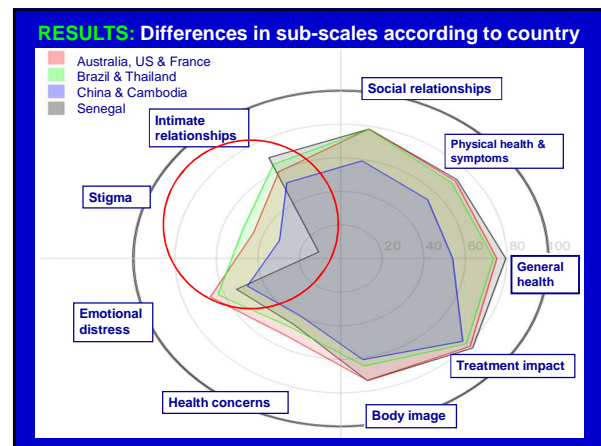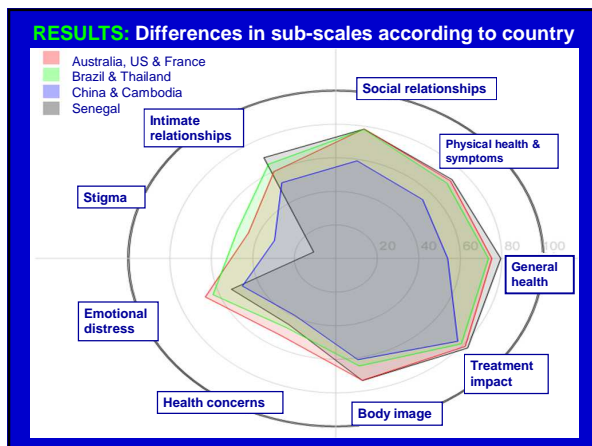
Relationship of depression to **PROQOL** subscales

(Each sub-scale contributes equally)

N = 102 Western Australians

RESULTS: **Depression & Symptoms**

- Participants who reported depression scored on average 13 points lower (95% CI, [-20.8;-6.2])

- For each increase in the number of reported symptoms, there is a loss of about 2 points of HRQL (95% CI, [-2.3;1.1]).

RESULTS: **Multivariate analysis - Australians**

|	
Number of symptoms	p < 0.001
Depression	p < 0.001
Living alone	p = 0.005
Younger age	p = 0.003
Heterosexual transmission	p = 0.008
On a protease inhibitor	p = 0.046
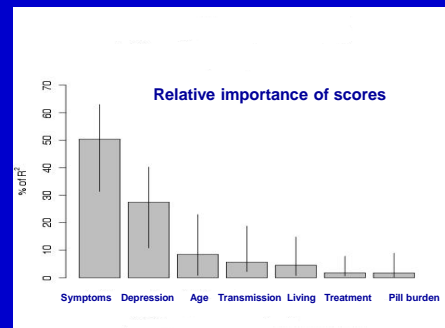
Lower scores were associated with more symptoms, depression, younger age, heterosexual transmission, not living with a partner, PI treatment and higher pill burden
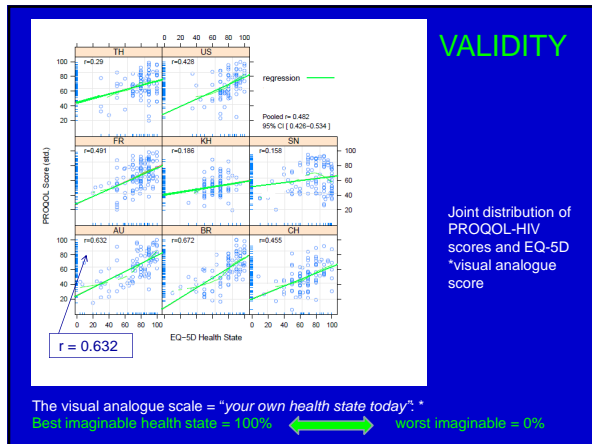
Linear Regression Analysis

Reliability and Validity

Q Is the PROQOL-HIV a 'valid' PRO questionnaire?
Does it measure what it is required to measure?

Q Is the PROQOL-HIV a 'reliable' PRO questionnaire?
Are the observed scores reproducible when the questionnaire is readministered?
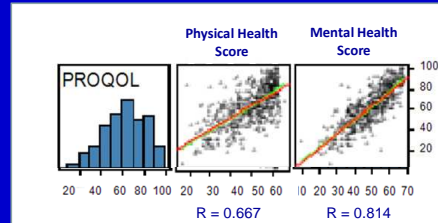
Joint distribution of PROQOL-HIV scores and the composite scores for MOS-HIV PHS and MHS

VALIDITY

Joint distribution of PROQOL-HIV scores and EQ-5D *visual analogue score

r = 0.632

The visual analogue scale = "*your own health state today*": *
Best imaginable health state = 100% ⬌ worst imaginable = 0%

RELIABILITY

Scores reliability was assessed using

❖ Cronbach's alpha = 0.936
  ❖ (95% CI = 0.929 – 0.943)

❖ Intra- class correlation coefficient = 0.859
  ❖ (n= 34, 95% CI = 0.701-0.959)

SUMMARY

In Western Australia in 2008
- The most significant health condition influencing quality of life was depression
- 30% of depressed patients also had hepatitis C
- Depression and the number of reported symptoms were related
- People who acquired HIV heterosexually seem to have worse quality of life
- Patients on PIs reported more symptoms/health conditions

SUMMARY

  ✓ The PROQOL-HIV is a *'valid'* PRO questionnaire
  It measures what it purports to measure

  ✓ The PROQOL-HIV is a *'reliable'* PRO questionnaire
  The scores observed are reproducible when the questionnaire is readministered

COMMENTS

There is an indication to examine:

- The 'social drivers' of depression *in the context of HIV* and coinfections
- The role of stigma and shame and how stigma affects PLWHA

■ There exists a need to

- Consider how societal inequalities for example within gender and ethnicity are exacerbated by HIV and impact on QOL*
- Intervene to reduce substance use and prevent significant associated morbidity

*Kippax et al 2007

CONCLUSION

- The data demonstrate the validity and utility of the PROQOL-HIV to measure QOL in this population.
- The implications of a high frequency of depression is concerning
- Rates of adherence are encouraging and are probably the outcome of active ongoing adherence support
- The information is a useful adjunct to national surveys and can be used to inform HIV services in WA.

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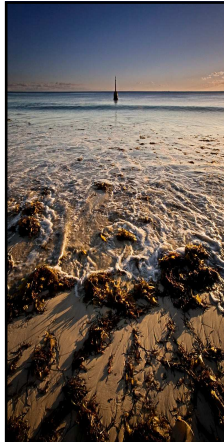Sun Yat-Sen University
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