# Quality of Life Assessment in Dialysis Patients

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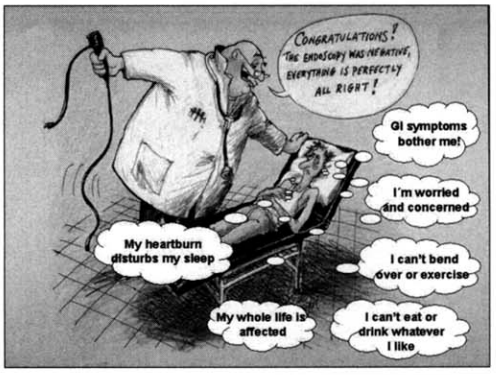


## Part I: Introduction

**Health-related Quality of Life (HRQoL)**

## HEALTH

**"Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity."**

건강이란 "질병이 없거나 허약하지 않은 것만 말하는 것이 아니라 신체적 ·정신적 ·사회적으로 완전히 안녕한 상태에 놓여 있는 것" 이라고 정의하고 있다

**World Health Organization(WHO), 1948**

## WHAT IS HEALTH-RELATED QUALITY OF LIFE (HRQOL)?

Perception of one's well-being based on multidimensional consideration of:

- Physical
- Mental
- Social
- General Health Status

## WHY MEASURE HRQOL IN ADDITION TO TRADITIONAL CLNICAL ENDPOINTS?

In parallel with traditional clinical endpoints (i.e., mortality, disease symptoms), treatment effects may:

- be equivalent physiologically but differ in impact on functioning and well-being
- represent tradeoff between improvement in clinical parameter versus decrement in functioning and well-being

## USES OF HRQOL MEASURES

- Increasingly used outcome measure in clinical trial research
- A primary objective of any health care intervention is the enhancement of quality of life and well-being
- Need to recognize the patient's own perception of changes in their health status
- Individuals with a chronic condition where cure is not attainable, quality of life may be the essential outcome

## HRQOL ASSESSMENT

- health profile questionnaires (generic or specific)
- health profile measures multiple health domains
- each domain is represented by a separate scale
- calculation of data from each scale produces a separate numerical value (score)

## HRQOL CONSTRUCT

Health (WHO Definition)

- refers to the way in which individuals function and their perceived well-being in physical, mental, and social domains of life
- refers to patient's appraisals of their current level of functioning and satisfaction (Cella and Tulsky, 1990)

## HRQOL MEASURES (1)

Generic versus Disease-specific Measures

- Generic:
  measure is relevant to individuals generally rather than specific to one condition
- Disease-specific:
  measure is tailored to a specific disease

## HRQOL MEASURES (2)

Advantages of Generic *vs.* Disease-specific Measures

- Generic:
  - allow comparisons across different patients
  - 예: SF-36
- Disease-specific:
  - believed to be more sensitive to small but clinically important changes
  - 예: KDQOL

## HRQOL MEASURES (3)

Recommendation regarding

Generic *vs.* Disease-specific measures

Conservative strategy:
include generic core together with disease specific supplement

## HRQOL EVALUATION (1)

Evaluation:

- Reliability
- Validity
- Responsiveness

## HRQOL EVALUATION (2)

Evaluation (cont'd)

- Reliability
  the measure yields the same results in repeated applications in an unchanged population
- Validity
  an instrument measures what it is supposed to measure and does not measure what it is not supposed to measure

## HRQOL EVAULATION (3)

Evaluation (cont'd)

- Responsiveness
  - a HRQOL measure should reflect (i.e., be responsive to) the effects of an intervention that changes HRQOL
  - requires:
    - o before and after intervention of known efficacy
    - o defining external criterion for clinically important change

## Part II : QOL of Kidney Disease

**KIDNEY DISEASE QUALITY OF LIFE**
**( KDQOL™ )**

## KDQOL 개발

- The Kidney Disease Quality of Life Working Group이 AMGEN의 연구비로 KDQOL long form (134 items) 개발
- Baxter Renal Outcomes Study를 위하여 KDQOL short form (KDQOL-SF)이 불어, 스페인어, 이탈리아어, 독일어, 일본어 등으로 번역
- 그 이후 KDQOL Working Group은 longitudinal data를 수집하기 위한 활발한 연구 활동을 하고 있음

## 대표적인 KDQOL 연구 (1)

- The Renal Outcomes Study
  - Baxter Healthcare sponsored, randomized, prospective study
  - 30 hospitals and free-standing dialysis units
  - six countries (France, Germany, Italy, Japan, Spain, and the United States)
  - Purpose is to determine if differences in mortality exists between peritoneal dialysis and hemodialysis

## 대표적인 KDQOL 연구 (2)

- The Hospital Pharmacy Cooperative Study
  - Amgen sponsored, Randomized (Tx *vs.* Control), Prospective, Single-Blind Study
  - Conducted by pharmacist and physician co-investigators at over 30 hospital-based dialysis units across the United States

## 대표적인 KDQOL 연구 (3)

- The Dialysis Outcomes and Practice Study
  - Amgen sponsored, National, 5-year longitudinal study of treatment and outcomes for hemodialysis patients
  - PI: The University of Michigan
  - Random sample of 30 patients per dialysis facility in the US (160 facilities, 1800 patients)
  - KDQOL-SF surveys are completed at baseline and annually thereafter

## Part III: QOL of Kidney Disease

**Korean version of the**
**KIDNEY DISEASE QUALITY OF LIFE**
**( KDQOL™ )**

## Korean Version of the KDQOL

*Primary goal of translation effort is a translated version of the KDQOL that is linguistically and conceptually equivalent to the U.S. English version .*

## Translation Steps (1)

1 Contact

2 Forward Translation

3 Backward Translation

4 Field Testing

## Translation Steps (2)

1 Contact
- obtain approval for translation

2 Forward Translation
- translate instructions, items, and response choices independently by at least two trained bilingual translators
- the translators should compare their translations and reconcile discrepancies
- the resulting translation should then be cognitively in a small sample (about 10) of dialysis patients

## Translation Steps (3)

3 Backward Translation
- the final forward translation should be back-translated into U.S. English by two other translators; both of these translators should be native English speakers
- these two translators should compare their backward translators and come to agreement about discrepancies
- a memo summarizing the back-translation will then be written and submitted to the KDQOL Working Group for review

## Translation Steps (4)

4 Field Testing
- at a minimum, the KDQOL-SF should be administered to a sample of 75 people with kidney disease
- Scale equivalence should be assessed by performing standard reliability and validity testing and comparing these results to those obtained for the U.S. English sample
- a final report should be written including the information in the forward and backward translation memos as well as results of the field test

## KDQOL-SF Multi-Item Scales

- Symptom/Problem list
- Effects of kidney disease
- Burden of kidney disease
- Work status
- Cognitive function
- Quality of social interaction
- Sexual function
- Sleep
- Social support
- Dialysis staff encouragement
- Overall health
- Patient satisfaction
- Physical functioning
- Role-Physical
- Role-Mental
- Pain
- General health
- Emotional well-being
- Social function
- Energy / Fatigue

## Pilot Study After Forward Translation

- 목적
  - To validate a Korean translation of the Kidney Disease Quality of Life (KDQOL) instrument
- 대상
  - 분당 차병원과 강남 가톨릭성모병원에 내원한 투석환자 15명
- 도구 (설문지)
  - 한국어로 번역된 KDQOL-SF

## Pilot Study : Descriptive Statistics

| Scale (Number of Items) | n | Mean ± SD |
|---|---|---|
| Symptoms/Problems (12) | 15 | 65.45 ± 21.02 |
| Effects of kidney disease (8) | 15 | 59.85 ± 22.23 |
| Burden of kidney disease (4) | 15 | 31.67 ± 22.09 |
| Work status (2) | 15 | 30.00 ± 31.62 |
| Cognitive function (3) | 15 | 81.11 ± 18.76 |
| Quality of social interaction (3) | 15 | 63.11 ± 26.41 |
| Sexual function (2) | 9 | 52.78 ± 32.24 |
| Sleep (4) | 15 | 67.39 ± 21.81 |
| Social support (2) | 15 | 61.11 ± 16.27 |
| Dialysis staff encouragement (2) | 15 | 79.17 ± 14.69 |
| Overall health (1) | 15 | 46.00 ± 17.65 |
| Patient satisfaction (1) | 15 | 57.78 ± 18.76 |

## Pilot Study : Reliability

| Scale (Number of Items) | n | Cronbach's alpha |
|---|---|---|
| Symptoms/Problems (12) | 15 | 0.87 |
| Effects of kidney disease (8) | 15 | 0.82 |
| Burden of kidney disease (4) | 15 | 0.77 |
| Work status (2) | 15 | - 0.14 |
| Cognitive function (3) | 15 | 0.60 |
| Quality of social interaction (3) | 15 | 0.78 |
| Sexual function (2) | 9 | 0.97 |
| Sleep (4) | 15 | 0.74 |
| Social support (2) | 15 | 0.39 |
| Dialysis staff encouragement (2) | 15 | 0.83 |
| Overall health (1) | 15 | - |
| Patient satisfaction (1) | 15 | - |

## Pilot Study: Conclusions / Discussions

- The results of the cognitive testing support for the reliability of the Korean-translated KDQOL in its present form
- Further refinement for re-wording of the response choice (e.g., 'Most of the time' 'A good bit of the time'), and for providing conceptually equivalent meaning of 'Walking one block' is needed