

*I.S.L. XVIII INTERNATIONAL
CONGRESS OF LYMPHOLOGY
GENOA (Italy) - September 3-7 2001*

A Specific Quality of Life Scale in Upper Limb Lymphoedema : The ULL-27 Questionnaire

Robert Launois, Françoise Alliot-Launois

REES France : Réseau d 'Evaluation en Economie de la Santé
<http://smbh7.smbh.univ-paris13.fr>

Project Manager & Coordinator :

Françoise Alliot-Launois

Head of the Lymphology Department, Clinique Hartmann, Neuilly sur Seine

Investigation Team

- (1) Hôpital Cognacq Jay, Paris (Service de Lymphologie) - Françoise Alliot, Robert Victor Cluzan, MD, Marina Pascot, MD
- (2) Hôpital Paul Brousse, Villejuif (Service d'Hématologie et Biologie de tumeurs) - Claude Jasmin, Professor
- (3) Centre René Huguenin, St Cloud (Service d'exploitations isotopiques) - Alain Pecking, MD
- (4) Hôpital Saint Eloi, CHU Montpellier (Service de Medecine Interne – Angiologie) - Charles Janbon, Professor, Virginie Soulier-Solto, M D
- (5) Hôpital Saint-Louis, Paris (Pole des maladies du sein) - Marc Espié, MD
- (6) Hôpital Saint-Joseph, Paris (Service de Médecine Interne et vasculaire) - Pascal Priollet, MD
- (7) Hôpital de Toulouse (Service d'Angiologie) - Henri Boccolon, Professor, Marie Elias, MD
- (8) Hôpital de Tours (Service d'Angio-Dermatologie) - Loïc Vaillant, Professor

Sous l'égide de la Société Française de Lymphologie

Why a Specific Quality of Life Questionnaire for Upper Limb Lymphoedema ?

- The existing classifications for upper limb lymphoedema (ULL), based on oedema volume, underestimate disturbance
- Specific concepts of upper limb lymphoedema are not assessed by generic quality of life scales: NHP ,SIP,SF-36

Development Stages of the Specific HRQOL Scale

- ***Phase I : qualitative survey (24 patients)***
 - collecting verbatims reports : 1 166
 - formation of the bank of 70 questions
- ***Phase II : quantitative survey (154 patients)***
 - reduction to produce the initial questionnaire : 28 items
 - identification of the dimensions
- ***Phase III : validation study (304 patients)***

Characteristics of the Instrument

- Self-administered questionnaire
- Rating scales : 5 points likert scales
- Median time to complete the questionnaire : 11 ± 1 mn

Conceptual Domains of the Instrument

- 3 dimensions
 - Physical (15 items)
 - Psychological (7 items)
 - Social (5 items)
- 1 global index (27 items)

The Quality of Life Scale to Be Validated (27 items)

Physical functioning :	Psychological dimension :
1. Difficulties grasping high objects	16. Feeling sad
2. Difficulties maintaining certain positions	17. Feeling discouraged
3. Arm feels heavy	18. Feeling a lack of self-confidence
4. Arm feels swollen	19. Feeling distressed
5. Difficulties dressing	20. Feeling well in ones self
6. Difficulties getting to sleep	21. Feeling a wish to be angry
7. Difficulties sleeping	22. Having confidence in the future
8. Difficulties grasping objects	Social dimension :
9. Difficulties holding objects	23. Difficulty taking advantage of good weather, in life outside the housde
10. Difficulties walking / heavy arm	24. Difficulty with personal projects, holidays or hobbies
11. Difficulties washing	25. Difficulties in emotional life with spouse or partner
12. Difficulties taking public tranport	26. Difficulty in social life
13. Tingling, burning feelings	27. Fearful of looking in a pirror
14. Feelings of swollen, hard, tense skin	
15. Difficulties in working relationships and tasks	

Methods

- Design of the study
- Grades of patient severity
- Benchmark criteriae
- Arithmetic of scores
- Evaluation of psychometric properties
- Statistical tests

Design of the Study

- Non randomized multicentric open study
- Inclusion criteria: patients suffering from ULL secondary to breast cancer, Age > 18 years
- Non-inclusion criteria: advanced cancer, ongoing radiotherapy or chemotherapy, signs of plexitis, past history of lymphangitis < 2 months
- Number of evaluable patients : 301

Grades of Patient Severity

- Oedema not measurable (>150 ml & < 300 ml)
- Clinical low volume oedema (> 300 ml & <500 ml)
- Clinical medium volume oedema (>500 & <800)
- Clinical large volume oedema (> 800)

Benchmark Criteria

- Oedema volume measurement
- Global Symptom Index : GSI (*heaviness, tension, hardness - frequency and severity*)
- Patient's Arm Comfort Scale : ACS
- Global Clinical Impression : GCI
- Generic quality of life indicator : SF36 (8 dimensions) PF-RP-BP-GH-VT-SF-RE-MH

Arithmetic of Scores

- Volume : addition of cone trunks
- GSI (*Global Symptom Index*) : 1 dimension and a global score
- ACS (*Arm Comfort Scale*) : 1 dimension; transitional scale : -, +, =
- GCI (*Global Clinical Impression*) : 1 dimension; transitional scale : -, +, =
- ULL-27 : 3 dimensions and a global score
- SF-36 : 8 dimensions and no global score

Standardization of the dimensions SF-36, ULL 27, ACS (Observed value - min) / (max - min) x 100

Statistical Validation Tests

- Cronbach Alpha coefficient - Spearman correlation coefficient
- Stability of the factorial structure in various populations
- Correlations between ULL scale and other indicators on D0, D28 and by grade
- Correlation between increments in the ULL scale and other indicators between D0 and D28

Psychometric Norms

Properties	Statistical method	Limit of validity
Internal validity	Intraclass correlation coefficient (ICC) on stable patients between D-15 and D0	> 0.80
	Cronbach's α coefficient	> 0.70
External validity	Correlation at baseline between clinical criteria, symptoms and QoL scores (Spearman correlation coefficient)	P < 0.05
Responsiveness to change	Responsiveness between D180 and D0 for improved patients Effect size	> 0.40

Results

- Descriptive parameters
- Past medical history
- Internal validity
- External validity
- Responsiveness to change

Descriptive Parameters

- Final analysis of 301 patients
- Age : 61.61 ± 1.16 years
- Height : 1.61 ± 0.01 m
- Weight : 68.20 ± 0.74 kg
- Body mass index : 26.25 ± 0.27
- All educational levels
- 48.2 % of women were retired

Past Medical History

- Surgical treatment for cancer and lymph node clearance : 98.67 % of women
- Radiotherapy : 92 %
- Chemotherapy : 45 %
- Hormone therapy : 24 %
- Median time between surgery and development of ULL : 17 months
- Length of history of ULL at the time of the study : 61.45 ± 10.58 months

Internal Validity ⁽¹⁾

- Reproducibility in stable patients (D0/D28)
 - Physical dimension : 0.86 (p<0.001)
 - Psychol. dimension : 0.80 (p<0.001)
 - Social dimension : 0.70 (p<0.001)
- Cronbach alpha coefficient
 - Physical dimension : 0.93
 - Psychol. dimension : 0.86
 - Social dimension : 0.82

Internal Validity ⁽²⁾ :

Multi-trait/Multi-items Matrix

STAGES	PHYSICAL DIMENSION (15 items)	PSYCH. DIMENSION (7 items)	SOCIAL DIMENSION (5 items)
Internal consistency of items	0.48 - 0.71	0.42 - 0.77	0.55 - 0.71
Success rate ($r \geq 0.40$)	100%	100%	100%
Discriminatory ability of items	0.23 - 0.48	0.13 - 0.60	0.27 - 0.52
Success rate ($r_1 \geq r_2$)	93%	100%	100%

External Validity ⁽¹⁾ :

Comparison of the ULL27 Dimensional Scores at D0 Accross Severity Stages

STAGES	PHYSICAL	PSYCHOL.	SOCIAL
Stage 1-n=30	65.27	62.05	71.50
Stage 2-n=47	57.17	61.72	63.83
Stage 3-n=69	51.74	61.64	63.53
Stage 4-n=90	50.54	61.62	55.99
p (Anova)	0.008	0.99	0.02

External Validity ⁽²⁾ :

Correlations between the ULL27 Subscales and the other Scales at D0

Are statistically significant and > 0.40 between

- **Physical Dimension** : ACS (*Arm Comfort Scale*) - GSI (*Global Symptoms Index*) -all SF36 subscales (except GH)
- **Psychological Dimension**: SF36 (except PF and GH)
- **Social Dimension** : VT - SF - MH (except PF RP RE BP and GH)

Responsiveness to Change ⁽¹⁾ :

Correlations

- Changes in the *ULL27 Physical dimension* between D0 and D28 for improving patients are significantly correlated with changes in the **GSI** (*Global Symptoms Scale*), the **ACS** (*Arm Comfort Scale*) and the SF36 subscales : PF, BP
- Changes in the *ULL27 Psychological dimension* are correlated with the **ACS** (*Arm Comfort Scale*) and the SF36 subscales : PF - BP - VT – MH
- Changes in the *ULL27 Social dimension* are correlated with the SF36 subscales : VT - MH

Responsiveness to Change ⁽²⁾ :

Mean test comparisons between D28 and D0

- ULL-27 Scale : significant statistical differences for the 3 dimensions
- Volume Index ; **GSI** (*Global Symptoms Scale*) and **ACS** (*Arm Comfort Scale*) : significant statistical differences
- SF-36 Scale : not significant differences for PF - RP - GH dimensions

Conclusion

- Volume of oedema poorly reflects the impact of the illness upon the patient, it neglects completely the social and psychological consequences of the illness.
- Specific quality of life scale reflects appropriately and completely all the possible impacts of the lymphoedema in the women daily life.
- The ULL27 scale seems to be a consistent instrument that adds to our ability to measure outcomes of relevance in upper limb lymphoedema.

An Overall View of the Results

Properties	Results
Internal validity	All Cronbach's $\alpha > 0.70$ ICC and CCC coefficients > 0.80 irrespective to the clinical definition of stability
External validity	<ul style="list-style-type: none">- Correlation > 0.18 between QoL scores and clinical criteria- Correlation coefficients : high statistical significance ($P < 0.0001$)
Responsiveness to change	<ul style="list-style-type: none">- Good responsiveness to clinical improvement in all dimensions, and global index ($p = 0.0001$)- ES > 0.40