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**Quality of Life Scale in Upper
Limb Lymphoedema - A Validation
Study**

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Aims of the study

- to construct a specific evaluative HRQOL scale in upper limb lymphoedema
- to evaluate changes of the patient's HRQOL on treatment in this disorder

Development stages of the specific HRQOL scale

- Phase I : qualitative survey
 - collecting verbatims reports
 - formation of the bank of questions
- Phase II : quantitative survey
 - reduction to produce the initial questionnaire
 - identification of the dimensions
- Phase III : validation study

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Sous l'égide de la Société Française de Lymphologie

Methods

- Design of the study
- The quality of life indicator to be validated
- Reference criteria
- Grades of patient severity
- Validation procedures
- Validation tests

Design of the study

- Inclusion criteria: patients suffering from ULL secondary to breast cancer

Age > 18 years

- Non-inclusion criteria: advanced cancer, ongoing radio or chemo, signs of plexitis, past history of lymphangitis < 2 months
- Number of patients: 300
- Interim analysis (July 1999: n=196)

The quality of life indicator to be validated (28 items)

- Symptom dimension: 8 items
- Physical dimension: 7 items
- Psychol. dimension: 6 items
- Social dimension: 7 items

High score = low quality

Standardisation of dimensions: $(S-m)*100/(M-m)$

Reference criteria

- Oedema volume measurement
- Composite symptom score (heaviness, swelling, hardness - frequency and severity)
- Generic quality of life indicator: SF36: increasing scale with quality
- Visual analogue scale for the patient

Grades of patient severity

- Oedema not measurable
- Low volume clinical oedema
- Moderate volume clinical oedema
- Large volume clinical oedema without trophic disorder
- Large volume clinical oedema with trophic disorder

Validation procedures

Measurement

- of stability of the dimensions
- of precision
- of accuracy
- of suitability measure change

Statistical validation tests

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

Results

- Descriptive parameters
- Past medical history
- Changes in the patient's condition
- Factorial analysis
- Precision of the scale
- Accuracy of the scale
- Sensitivity of the scale

Descriptive parameters

- Interim analysis of 196 patients
- Age: 61.65 ± 1.14 years
- Height: 1.60 ± 0.02 m
- Weight: 69.32 ± 1.86 kg
- Body mass index: 25.74 ± 0.66
- All educational levels
- 50% of women were retired

Past medical history

- Surgical treatment for cancer and lymph node clearance: 100% of women
- Radiotherapy: 91%
- Chemotherapy: 41%
- Hormone therapy: 20%
- Median time between surgery and development of ULL: 17 months
- length of history of ULL at the time of the study: 76.75 ± 10.58 months

Changes in the patient's condition between D0 and D28

State	N	%
Unknown	4	2.0
Worse	19	9.7
Stable	63	32.1
Improved	110	56.2
Total	196	100.0

Range of correlations between each of the 28 items and dimensions

	Symptom Items	Psychol. Items	Physical Items	Social Items
Symptom	0.69 Ğ 0.79	0.08 Ğ 0.49	0.58 Ğ 0.67	0.25 Ğ 0.47
Psychol.	0.28 Ğ 0.40	0.59 Ğ 0.85	0.23 Ğ 0.34	0.33 Ğ 0.54
Physical	0.55 Ğ 0.65	0.06 Ğ 0.42	0.77 Ğ 0.82	0.20 Ğ 0.47
Social	0.26 Ğ 0.49	0.29 Ğ 0.66	0.36 Ğ 0.49	0.63 Ğ 0.82

Short Form Scale

(27 items)

- Very close correlations between « symptom » items and the « physical » dimension
- Very close correlations between the « physical » items and the « symptom » dimension
- 80% simultaneous changes in both dimensions
- Item 08 correlated very closely with all dimensions
- Simplifications adopted
 - fusion of the « symptom » and « physical » dimensions
 - removal of item 08 « dress style »
- New 27 items scale with 3 dimensions: ULL27

Factorial analysis across two populations

(n = 150 ; n = 196)

- Physical dimension (14) – have you suffered problems
 - because of a **swollen, heavy** arm, **pins and needles**, **swollen skin**, in **going to sleep**, washing yourself, **picking up** objects, sleeping, walking, using transport, dressing, **remaining in certain positions**, holding, seizing things from a certain height.
- Psychol. Dimension (7) – are you
 - prone to becoming **angry**, feeling **sad**, lacking confidence **in yourself**, lacking confidence **in the future**, feeling **well** in yourself, feeling **low**, feeling **distressed**.
- Social dimension (6) – are you disturbed when you
 - go to a **restaurant**, go out in the sun, go on **holiday**, look at yourself in a **mirror**, in your **emotional life** with your partner, in your **professional relationships**.

Precision of the scale

- Cronbach alpha coefficient
 - Physical dimension: 0.93
 - Psychol. dimension: 0.87
 - Social dimension: 0.84
- Reproducibility in stable patients (D0/D28)
 - Physical dimension: 0.85 ($p < 0.001$)
 - Psychol. dimension: 0.84 ($p < 0.001$)
 - Social dimension: 0.78 ($p < 0.001$)

Accuracy

Correlation between lymphoedema volume and dimension scores for the ULL27 at D0 and D28

	Volume D0	Volume D28	P
Physical	0.34	0.26	0.001
Psychol.	0.04	-0.03	NS
Social	0.10	-0.02	NS

Accuracy

Correlation between the three symptoms scores and the dimensions scores for ULL27at D0

	Volume D0	Volume D28	P
Heaviness	0.61	0.29	0.001
Hardness	0.47	0.25	0.001
Swelling	0.45	0.29	0.008

Accuracy

Comparison of dimension scores between severity grades on D0

	Physical	Psychol.	Social
Grade 1	30.87	38.50	28.44
Grade 2	43.56	35.90	33.76
Grade 3	48.72	39.15	39.04
Grade 4	64.70 (n=13)	40.71	43.75
Grade 5	50.58	38.10	39.30
p	0.0001	0.95	0.32

Accuracy

Correlations between the quality of life scores of the ULL27 and SF36 (D0)

Physical 0,59 Role Physical 0,57 Bodely Pain

Psychol. 0,57 Role Emotional 0,75 Mental Health

Social 0,53 Vitality 0,66 Social Funct.

Sensitivity of the scale

Correlation between increments (D28-D0) in ULL and SF36 scores in patients with active disease

Δ Physical - RP - BP:	-0.53	-0.30
Δ Psychol. - RE - MH:	-0.38	-0.43
Δ Social - VT - SF:	n.s.	-0.38

Comparison of ULL dimensions scores between D0 and D28 when real change has taken place

Δ Physical :	$p < 0.0001$
Δ Psychol. :	$p < 0.0001$
Δ Social :	$p < 0.008$

Conclusion

Evaluation of HRQOL

- allows us to better quantify the clinical benefits of treatment
- reintroduces the patients' preferences into the medical management decision
- opens the door to a genuine dialogue between the patient and the practitioner

Clinical examination

	Soft	Firm	Total
Hand	143 (79.4%)	37 (20.6%)	180 (100%)
Forearm	86 (44.3%)	108 (55.7%)	194 (100%)
Upper arm	170 (88.10%)	23 (11.9%)	193 (100%)

Grades of patient severity

Grade of oedema	difference in perimeter of limbs	difference in volume of limbs
Oedema not measurable	$< 2 \text{ cm}$	$\geq 150 \text{ ml}$ or $< 300 \text{ ml}$
Low volume oedema	$\geq 2 \text{ cm}$ or $< 4 \text{ cm}$	$\geq 300 \text{ ml}$ or $< 500 \text{ ml}$
Moderate volume oedema	$\geq 4 \text{ cm}$ or $< 6 \text{ cm}$	$\geq 500 \text{ ml}$ or $< 800 \text{ ml}$
Large volume oedema with trophic disorders	$> 6 \text{ cm}$	$> 800 \text{ ml}$
Large volume oedema with trophic disorders	$< 6 \text{ cm}$	$> 800 \text{ ml}$