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REES France

**A specific quality of
life scale
in secondary upper
limb
lymphoedema after
breast cancer**

Robert LAUNOIS Françoise ALLIOT

launois.reesfrance@wanadoo.fr

Health Related Quality of Life: A Buzz Word ?

The concept has two fundamental components [1]:

- ***Subjectivity:** quality of life supposes an ability to describe the hardship experienced. Only the patient can perform this task.*
- ***Multidimensionality:** life cannot be evaluated in general; its various dimensions have to be investigated.*

[1] Cella DF. «Quality of life : The concept » Journal of Palliative Care 8:3, 1992; 8-13.

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

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

Development Stages of the Quality of Life Scale ULL-27

- ***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 :
27 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 dimension : (15 items)
 - Psychological dimension : (7 items)
 - Social dimension : (5 items)
- **1 global index** (27 items)

Wording of the Questions

- During the last four weeks, have you, despise of your arm or because of it:

(5 items with 5 modalities) :

- Had confidence in the future? (item 20)
- Being afraid of looking at yourself in the mirror? (item 21)
- Felt well in yourself (item 22)

- During the last four weeks did you have difficulties due to your arm

(4 Items with 5 modalities) :

- in your social life: going to a restaurant, to a party or doing the shopping ? (item 24)
- in your intimacy with your spouse or partner? (item 26)

The Questionnaire as it Looks Today

- **Self-questionnaire**

- During the last four weeks, have you experienced difficulties because of your arm in your working relationships and tasks?

Never

☐

Rarely

☐

Sometimes

☐

Often

☐

Always

☐

- **Questionnaire for interview**

1. Never
2. Rarely
3. Sometimes
4. Often
5. Always



The Validation Study: Methods

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 œdema**
(> 300 ml & < 500 ml)
- **Clinical medium volume œdema**
(> 500 & < 800)
- **Clinical large volume œdema**
(> 800)

Benchmarked Criteria

- **Generic quality of life scale (SF36):** *8 dimensions*
PF-RP-BP-GH-VT-SF-RE-MH
- **Global symptoms score (GSS)** (heaviness, swelling, hardness - frequency and severity)
- **Patient's Arm Comfort Scale (VAS)**
- **MD's Global Clinical Impression (GCI)**
- **Difference in volume (DIV)** between the healthy limb and the affected limb

Psychometric Validity:

Three Conditions

- **Reliability:** *Do the answers to the same questions remain the same at two different periods of time on stable patient ? Are the different items in a same dimension measuring the same concept even when they are worded differently?*
- **Construct validity:**
 - WITHIN SCALE ANALYSIS:** *Do the content of the dimensions of the scale is representative of the domain it is intended to cover ?*
 - KNOWN GROUPS DIFFERENCES:** *Do the correlations between the ULL quality of life scores and external criteria such as severity of illness, controlateral and ipsilateral involment in right handed people match the logical relation that should exist across groups of individuals?*
 - CONVERGENT ANALYSIS :** *Do the correlations with other quality of life scales' dimensions fit the expected relationships?*
- **Responsiveness:** *Are changes in scores observed in patients whose states of health is deteriorating or improving ?*

Psychometric Norms

Caractéristiques	Statistical Tests	Validity thresholds
Reliability	Intraclass correlation coefficients (ICC) across stable patients at D0-D28 Cronbach α coefficients	> 0,80 > 0,70
Construct validity : <i>Within scale analysis</i>	Muti-trait,Multi-items analysis Item scale corrélation coefficients at D0	> 0,40
Construct validity <i>Known groups differences</i>	Analysis of variance (kruskal wallis)	P < 0,05
Construct validity <i>Convergence analysis</i>	Spearman correlation coefficients at D0 with homologous dimensions of validated quality of life scales	> 0,40
Responsiveness	Effect size	> 0,40



Results

PATIENT'S CHARACTERISTICS

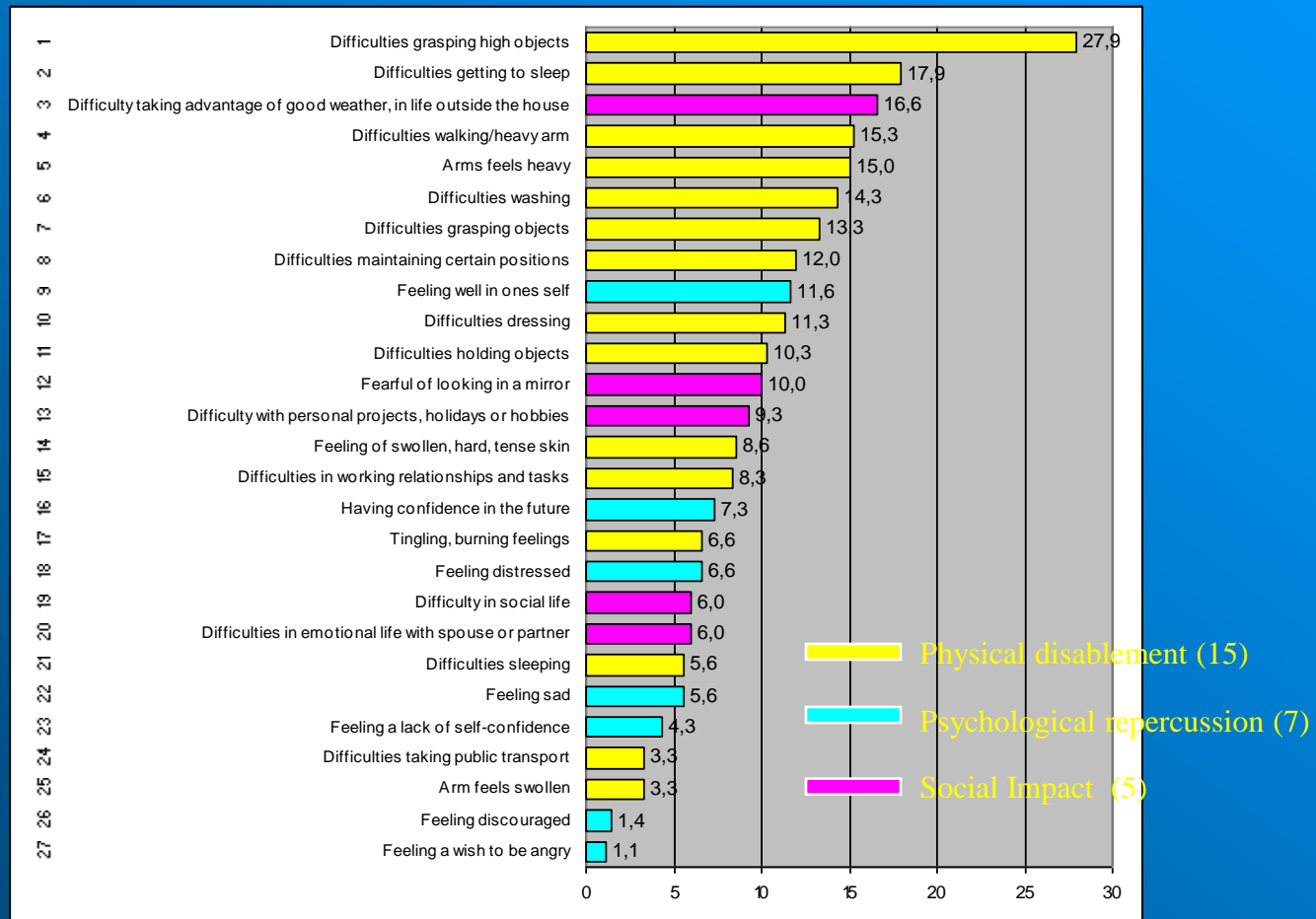
Descriptive Parameters

- 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:** 92.00%
- **Chemotherapy:** 45.00%
- **Hormone therapy:** 24.00%
- **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

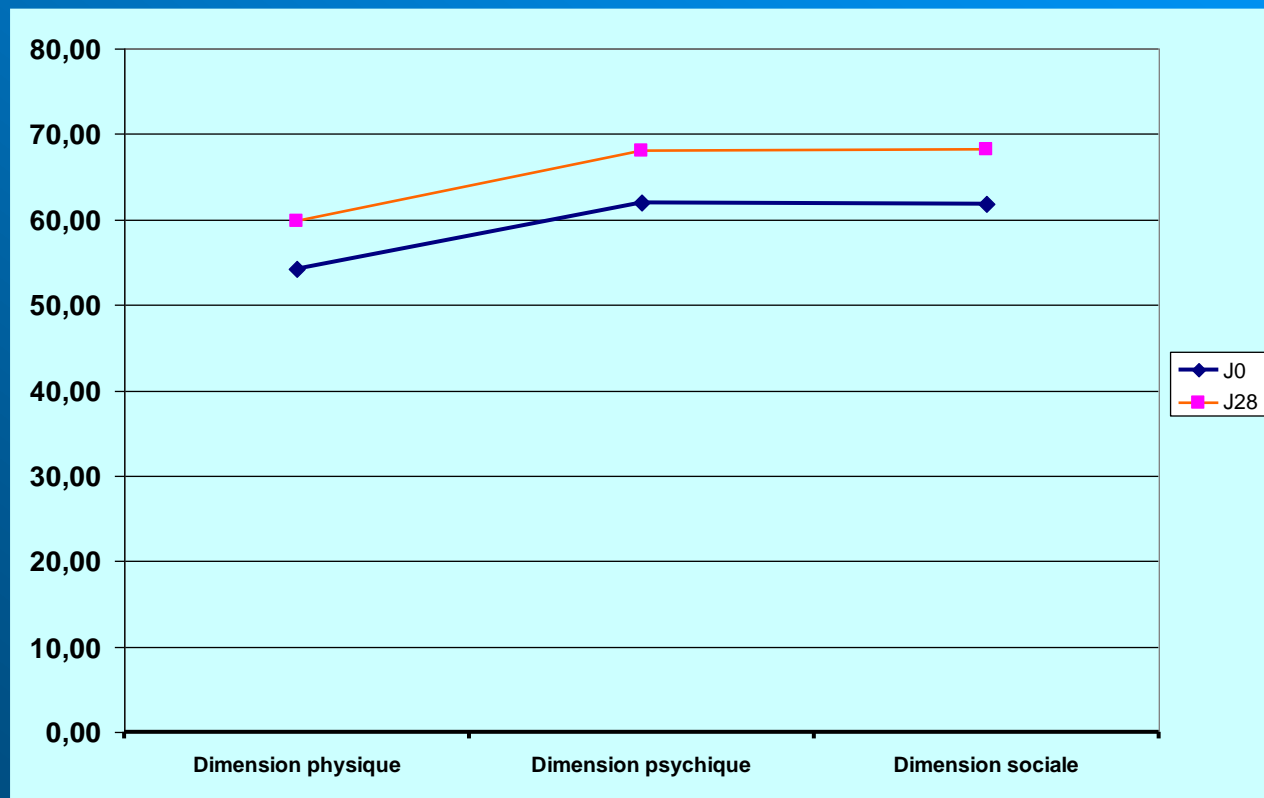
Proportion of Patients with the highest level of complain by Item at J0 (n= 301)



Lymphedema Evolution According to The Conventiannal End Points

	STABILITY	IMPROVEMENT	WORSENING
Doctor's Opinion: GCI	31 %	61 %	08 %
Patient's Opinion: VAS (± 5)	26 %	60 %	14 %
Global Symptoms Index : GSI (± 5)	25 %	65 %	10 %
Volume ($\pm 10\%$)	29 %	59 %	12 %
Hand (± 1 cm)	77 %	18 %	5 %

Lymphedema Evolution According to The ULL-27 Quality of life Scores by Dimensions



(Across all Clinical Status And Treatements)

ULL-27: A PRECISE AND ACCURATE SCALE

Precision

- 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

Within Scale Analysis :

Multi-traits/Multi-items Matrix

	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%

⇒ *Excellent internal consistency and a fair discriminant validity*

Known Groups Differences:

Comparison of the ULL27 Dimensional Scores at D0 Across Severity Stages

	PHYSICAL	PSYCHOL.	SOCIAL
Stage1-n=30	65,27	62,05	71,50
Stage2-n=47	57,17	61,72	63,80
Stage3-n=69	51,74	61,64	63,53
Stage4-n=90	50,54	61,62	55,99
P (ANOVA)	0,008	0,99	0,02

* *n* minimum

⇒ *Good correlations between quality of life scores and clinical stages verify the clinical validity of the instrument*

Convergent Analysis:

Correlations between the ULL-27 Subscales and the other Scales at D0

Are statistically significant and > 0.50 between

- **Physical Dimension:**

SF36 subscales: PF (0,515) **BP** (0,649) **VT** (0,555)

GSI (*Global Symptoms Score*) (0.557) - **VAS** (*Arm Comfort Scale*) (0.531)

- **Psychological Dimension:**

SF36 : VT (0,529) **MH** (0,732)

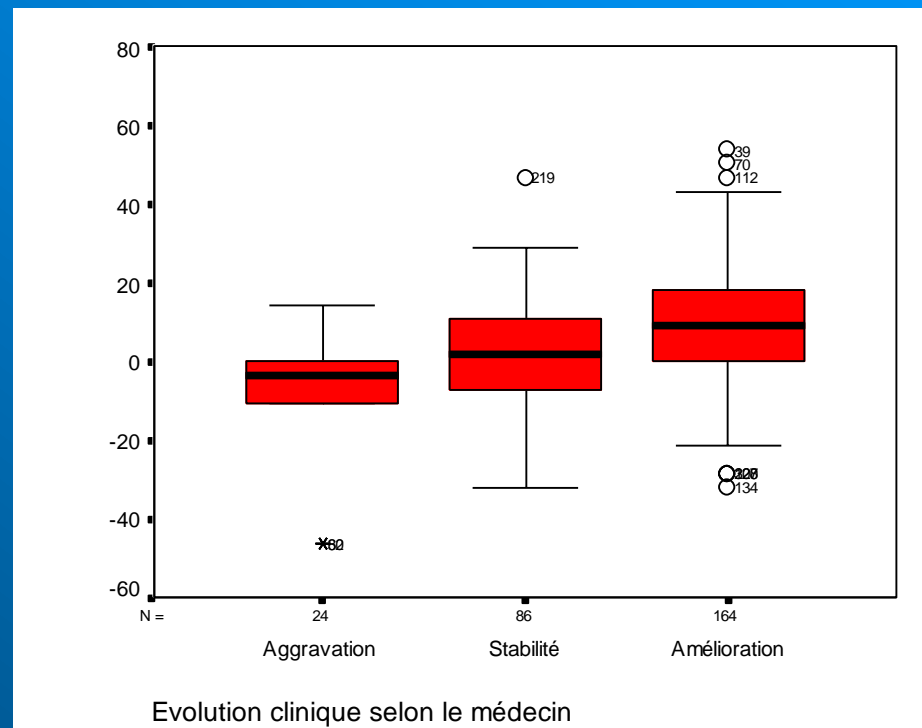
- **Social Dimension:**

SF (0,579) - **MH** (0,528)

ULL-27: A SENSITIVE MEASURE

Responsiveness to Change In the ULL-27 Psychological Dimension Compared to the Overall Clinician's Jugement

- **Worsening (n=24/24)**
 - $m = -5.8$ (-46.4 ; +14.3)
 - $Me = -3.6$ (-10.7 ; +7.1)
- **Stability (n=86/92)**
 - $m = 2.7$ (-32.1 ; +46.4)
 - $Me = 1.8$ (-7.1 ; +13.8)
- **Improvement (n=164/181)**
 - $m = 9.5$ (-32.1 ; +53.6)
 - $Me = 8.9$ (0 ; 17.9)



Responsiveness to Change :

Effect size

Dimensions	EFFECT SIZE
LMS-27	
Physical Dimension	0,58
Psychological Dimension	0,62
Social Dimension	0,38

⇒ *The force of the signal is higher than the magnitude of the noise*



Conclusion

- Volume of œdema 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 lymphedema in the women daily life.
- The ULL27 scale is a validated instrument that adds to our ability to measure outcomes of relevance in upper limb lymphedema.



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For Your
Attention*

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