

*NLN Lymphedema: The Quest for Understanding
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REES France

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

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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 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 : 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 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

Wording of the Questions

- **During the last four weeks, did you experience difficulties due of your arm:**

(11 items with 5 modalities)

- **in grasping objects: opening a door or putting a tap off? (item 03)**
- **in using public transport? (item 07)**

- **During the last four weeks, did you, because of your arm:**

(7 items with 5 modalities) :

- **felt a lack of self-confidence ? (item 16)**
- **felt sensations of tingling, burning, tightness or itching? (item 17)**

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 Quality of Life Scale As it is At the End of the Validation Study

(27 items)

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



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

Concurrent Criteria

- **Difference in volume between the healthy limb and the affected limb:** *addition of cone trunks*
- **Patient's Arm Comfort Scale (VAS) :** *1 dimension, transitional scale : +, =, -*
- **MD's Global Clinical Impression (GCI) :** *1 dimension, transitional scale : +, =, -*
- **Global Symptom Index (GSI) :** *heaviness, tension, hardness - addition of the 3 products freq * severity ; 1 dimension and a global score*
- **Generic quality of life scale :**
SF36 *(8 dimensions)* **PF-RP-BP-GH-VT-SF-RE-MH**

Psychometric Validity:

Five Conditions

- Precision
- Structural validity
- Clinical validity
- Convergent validity
- Responsiveness



Results

PATIENT'S CHARACTERISTICS

Descriptive Parameters

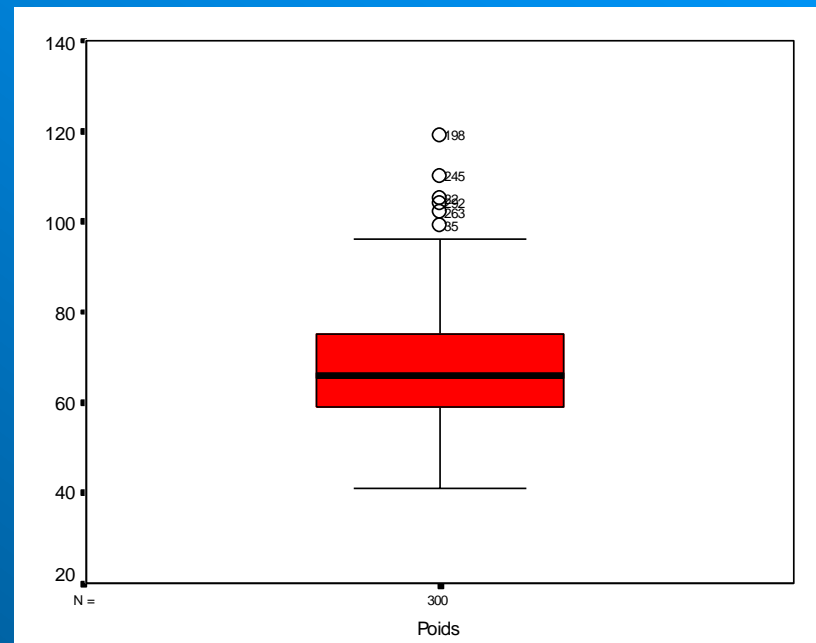
- Final analysis of 301 patients
- Age : 61.61 ± 1.16 years
- Height : 1.61 ± 0.01 m
- Weight : 68.20 ± 0.74 kg
- Body mass index : 26.25 ± 0.27
- All educational levels
- 48.2 % of women were retired

Past Medical History

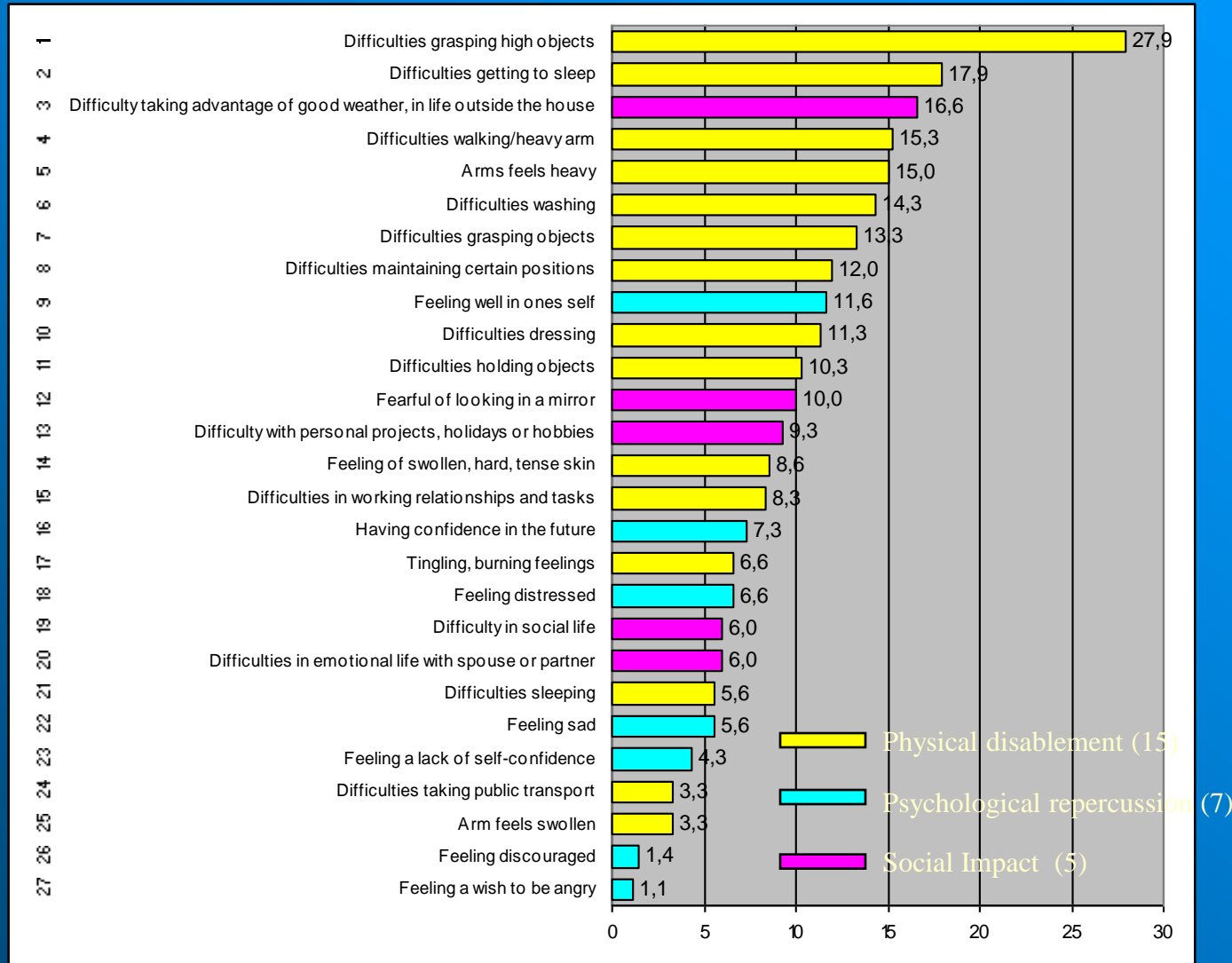
- **Surgical treatment for cancer and lymph node clearance : 98.67 % of women**
- **Radiotherapy : 92 %**
- **Chemotherapy : 45 %**
- **Hormone therapy : 24 %**
- **Median time between surgery and development of ULL : 17 months**
- **Length of history of ULL at the time of the study : 61.45 ± 10.58 months**

Weight Distribution

- Mean = **68.20 kg**
- Standard Error = 0.74
- Range = [41 - 119]
- Médian = 66 kg
- IIQ = [58.58 ; 75.0]



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



ULL-27: AN ACCURATE SCALE

Structural Validity :

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 ($r1 \geq r2$)	93%	100%	100%

⇒ *Good internal consistency but a moderate discriminant validity*

Clinical Validity :

*Comparison of the ULL27 Dimensional Scores
at D0 Accross 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 Validity:

*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 Index*) - **VAS** (*Arm Comfort Scale*)

- **Psychological Dimension :**

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

- **Social Dimension :**

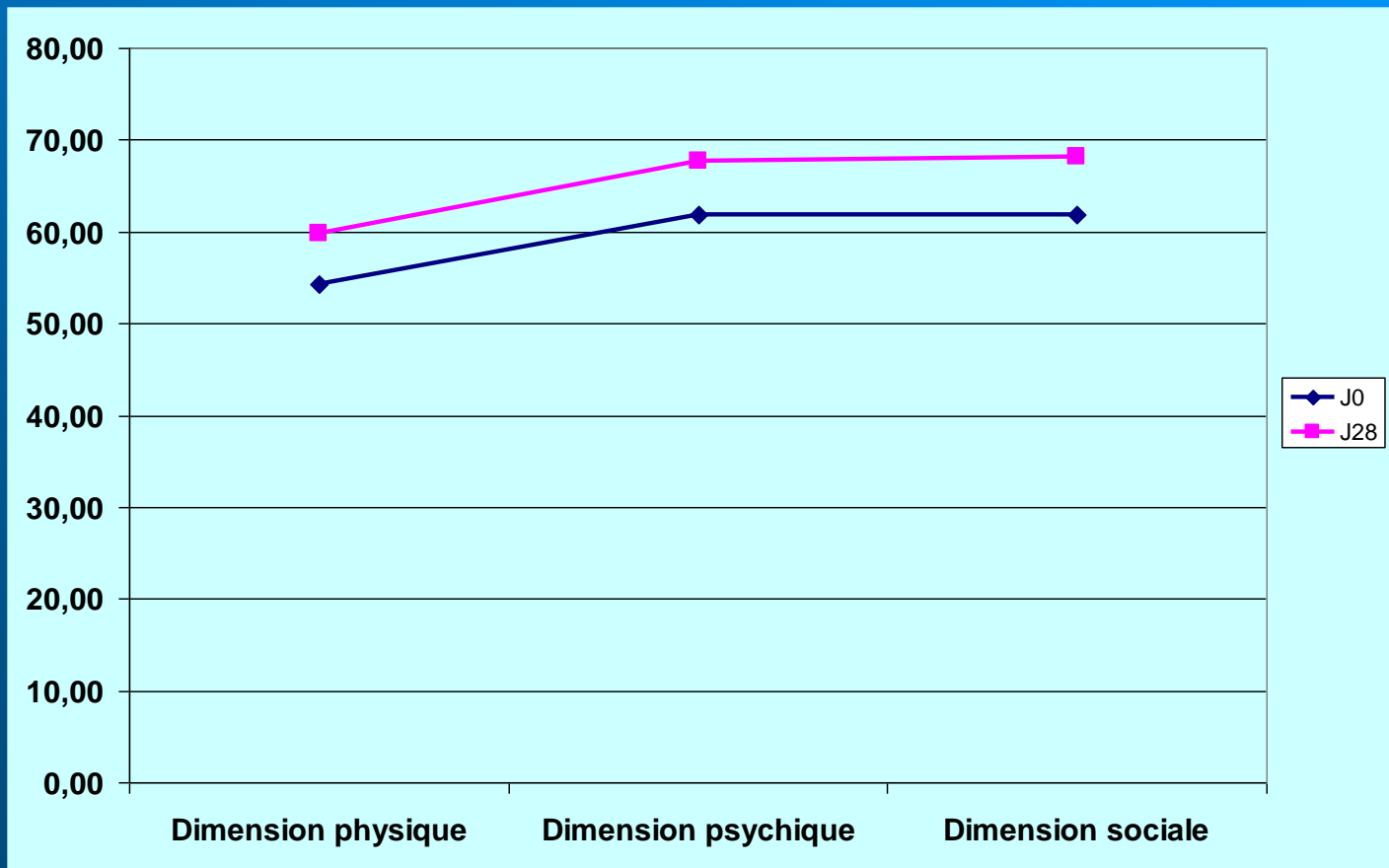
SF (0,579) - **MH** (0,528)

ULL-27: A SENSITIVE MEASURE

Lymphoedema Evolution According to five different End Points

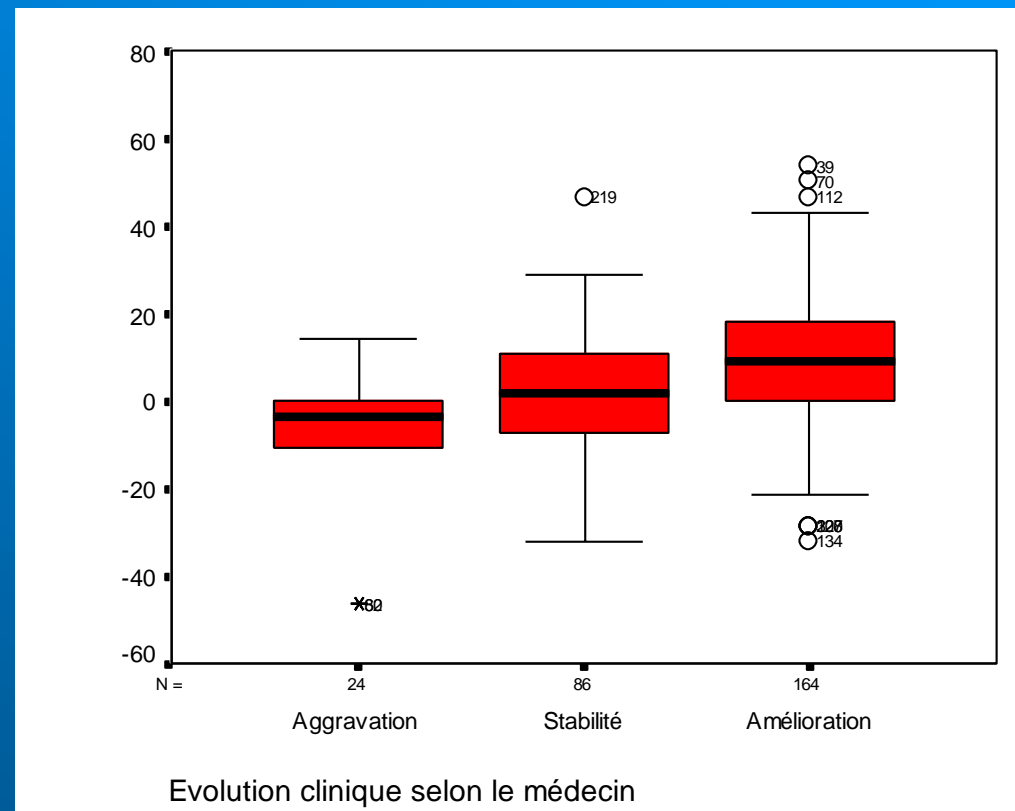
	STABILITY	IMPROVEMENT	WORSENING
Doctor's Opinion: <i>GCI</i>	31 %	61 %	08 %
Patient's Opinion: <i>VAS (± 5)</i>	26 %	60 %	14 %
Global Symptoms Index: <i>GSI (± 5)</i>	25 %	65 %	10 %
Volume (± 10%)	29 %	59 %	12 %
Hand (± 1 cm)	77 %	18 %	5 %

Average ULL-27 Scores by Dimensions at J0 and J28 Across all Clinical Status And Treatements



Responsiveness to change In the ULL-27 Psychological Dimension Compared to the Overall Clinician's judgement

- **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	STANDARDISED RESPONSE MEAN	EFFECT SIZE
LMS-27		
Physical Dimension	0,41	0,58
Psychological Dimension	0,42	0,62
Social Dimension	0,28	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 lymphœdema 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 lymphœdema.**