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QUALITY OF LIFE SCALE IN UPPER LIMB LYMPHOEDEMA – A VALIDATION STUDY

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BACKGROUND: Lymphoedema of the arms is a serious long term complication of local and regional therapy in women with breast cancer. The aim of the study, sponsored by the french society of lymphology, was to construct and validate a specific quality of life self-completed questionnaire in Upper Limb Lymphoedema (ULL), in order to be able to assess changes in quality of life on treatment.

METHODS: Conventionally, two types of instruments are recognised; generic and specific quality of life scales. The former are designed to be applied to all diseases; the best known are the sickness impact profile (SIP), Nottingham health profile (NHP) and the SF36. Specific scales are centred on fields which are particularly affected by consequences of the disease in order to increase the instrument's sensitivity. In cancer for instance, we have the functional living index in cancer (FLIC) and the upper limb lymphoedema quality of life questionnaire (ULL-QoL). These two specific scales have been constructed from statements made by the patients concerned. In the case of lymphoedema, the questionnaire was developed in three stages.

i) A qualitative survey was conducted to identify patients' complaints and to create a database of items. An interview guide was drawn up from preliminary interviews with patients, nurses and medical doctors in order to reconstruct the history of the disease and to obtain a detailed description of the patient's complaints. 24 semi-structured interviews were conducted. Each interview lasted between one hour and one and half hour. The interviewer was given some degree of freedom in obtaining responses to his questions and the patient could speak openly. Patient's complaints were assembled by thematic analysis. 495 verbatim reports were classified into four dimensions : signs and symptoms (pain and sleep disturbances), functional effects (physical ability, limitation of acts of daily living), emotional upset (anxiety, depression, esthetical problems or prejudices) and effects on social life and relationships. Selection of items were based on six criteria. Ease of understanding, acceptability, sensitivity, exhaustiveness, continuous of depth in questioning. This leads to the development of a preliminary version of the questionnaire (V00) containing 70 items.

ii) this preliminary questionnaire was administered to 154 patients in a subsequent quantitative analysis to select the most relevant items. Principal component analysis was used to identify the dimensions of impairment. Factors with an eigen value less than 1 was disregarded. A varimax rotation was conducted in order to achieve a simple structure. Variables with a loading factor inferior to 0,5, with a communality

inferior to 0,5 or with a cronbach x coefficient less than 0,8 were eliminated.

iii) a validation study is ongoing in 300 patients among specialised oncology services, internal medical wards and lymphology department to assess face validity, content validity, reliability, accuracy and responsiveness of the instrument.

Validation Procedures

The face validity of a questionnaire depends on the quality of its preparation : are the questions precise enough to specify the domains explored. Do they relate to a well defined period of time? Is the aggregation procedure adequate? Content validity requires two conditions to be fulfilled, exhaustivity : is the entire range of possible complaints covered? Representativity : are the questions a good sample of all those which could be asked on the same topic. Reliability : Are the dimension constant among different population? (Factorial stability) Do the answers to the same questions remain the same at two different period of time on stable patient? (Reproducibility) Accuracy : Do the nature and the strength of the correlation between the quality of life scores and independent external criteria such as clinical end points or other quality of life instruments fit the expected relationships at a point of time and longitudinally on time. Responsiveness : changes in scores must be observed in patients whose states of health is deteriorating or improving.

5 grades were identified according to two criteriae, first, the parameter between the limb with oedema and the one without it, second, the volume difference between the two. For instance, a clinical oedema of moderate volume is characterised by a difference > 4 cm and < 6 cm between the two arms or in volume, a difference greater than 500 mm or less than 800 mm between both the limbs.

Reference Criteria

Five instruments have been used in the case report form.

- Differences in volume between the healthy and the affected arm were calculated on D0-D8
- Symptoms scale (heaviness, swelling, hardness) were completed by clinicians on D0 and D28 from patient interviews
- SF 36, the ULL scale and the Visual Analogue Scale were completed by the patient on D0 & D28.
- the purpose of the analysis was to check absolute value and the changes in ULL scale bear close correlation with absolute value and changes in physical indicators and other QOLs.

Statistics

The internal validity of items in the dimensions making up the scale was evaluated by calculating the Cronbach alpha coefficient and by confirming that the factorial structure was stable. For external validation two types of Spearman correlations were calculated for all patients: i) correlations on D0 and D28 between absolute scores by

grade of severity of the ULL and three other measurements: the clinicians opinion about progression of the disorder, scores in the symptom scales and the sub-scores of the SF36 scale. ii) correlations between the differential scores for the same instruments on D0 and D28. Sensitivity was tested only in patients with progressive disease between D0 and D28 by comparing mean sub-scores for the ULL.

RESULTS:

i) Three groups of patients were identified in the qualitative survey according to the severity of lymphoedema :

- Patient physically or psychologically unaffected but afraid of becoming worse
- Patient physically or psychologically affected
- Patient with progressing problems.

66% of the patients were older than 51 years. 33% were progressing patients. The 495 verbatims were classified under four dimensions. We used the patient's own words to write out a preliminary questionnaire, V00 ensuring a colloquial formulation so as to enable the interviewed patient to answer the questions easily. For instance, when the patient declares, "I think everyone is looking at me, that is the end" or "The assistant in the dressing room is staring at me, it's awful". From those two statements, we came up with the following question, "Do you think that all the people are staring at you?" Two methods of questioning were used for each item. The first, concerns the presence and the intensity of the impairment (never troubled, rarely troubled, sometimes troubled, most often troubled, always affected). The second expresses the importance assigned to it by the patient in the day to day life (no significant, slightly significant, moderately significant, very significant, of great importance). Attributions of degree of seriousness and importance was taken into account through a five level lickert scale to come up with a standardised measuring tool. Each question was allocated a score from 0 to 5.

ii) The first quantitative survey was implemented in 15 centres, 154 patients were recruited. The average age of the patient was 62.2 years. Range is quite broad, the younger patient was 27 years old and the oldest 81. The time required to fill the question did not exceed 30 minutes. Principal component analysis was then performed to identify the dimension of the scale. This process produced the initial version of the questionnaire ULL-28 which contains 28 items, 8 for symptoms, 6 for physical, 7 for psychological and, lastly, 7 for social dimension. The higher the score by dimension, the lower is the quality of life of the patient.

iii) The third study was launched over 300 new patients to check the validity of this scale. In Chennai, we presented the results of an intermediate analysis extracted from the available data on 30 July 1999 over 196 patients. The aim of this study was to check if the same dimensions of the scale can be found again across a new population. The average age of these patients was 61,65 years. All patients had unilateral problems. All the patients had breast cancer, underwent a surgery and had a lymph node clearance. Most of them also had a radiotherapy and only 20 % had hormonal therapy. The median time between surgery and development of lymphoedema was 17 months and the length of history of the illness at the time of the

study was around 76 months i.e. 6 years. The sickness of 19 out of 196 patients i.e. 10% became worse during the follow-up but 56 % of the patients improved under treatment and 32 % remained stable.

Symptom items are highly correlated with the physical dimensions. At the same time, physical items are strongly correlated with the symptom dimension. (table 1)

Table 1 : Range of correlations between each of the 28 items and dimensions

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

Therefore, the distinction between the two do not seem to be any longer appropriate anymore. We established a simplified version of the initial scale which combines symptoms and functional items into a new dimension called physical in which includes 14 items. Item 8 on "dress style" (do you have difficulties in the choice of your dressing due to your arm?) which is highly correlated with all dimensions has been deleted because we anticipated that it would not be stable across studies and populations.

We analysed this short form scale across two different population and the same factorial dimension were identified in both cases. The stability of the factorial structure seems to be clearly established. Our new scale is now defined by 27 items and 3 dimensions.

Physical (14 questions), Psychological (7 questions) and social (6 questions).

- Physical dimension : (14) The questions are the followings :

have you suffered problems :

(1) because of a swollen arm, (2) a heavy arm (3) pins and needles (4) a swollen skin, (5) in going to sleep, (6) washing yourself, (7) picking up objects, (8) sleeping, (9) walking, (10) using public transport, (11) dressing, (12) remaining in certain positions, (13) holding, (14) seizing things from a certain height.

- Psychological dimension (7)

are you prone :

(1) to becoming angry, (2) feeling sad, (3) lacking confidence in yourself, (4) lacking confidence in the future, (5) feeling well in yourself, (6) feeling low, (7) feeling distressed.

1. Social dimension (6)

are you disturbed when you :

(1) go to a restaurant, (2) go out in the sun, (3) go on holiday, (4) look at yourself in a mirror, (5) in your emotional life with your partner, (6) in your professional relationships.

Precision : correlation coefficients for dimensions of the ULL scale between D0 and D28, in patients who were clinically stable; were all greater than 0.84 and statistically significant. The Cronbach coefficients are greater than 0,80 for all dimensions. Alpha coefficients above 0,70 are generally regarded to be acceptable for psychometric measurement. These two results confirm that the ULL-27 scale is reliable.

Accuracy : cross-sectional validation was studied by comparing mean scores for the dimensions of ULL and lymphoedema volume at D0 and D28. We observed that the lymphoedema volume is significantly correlated to the quality of life score in the physical dimension ($p = 0.0001$), at the same time, volume is not correlated with the scores of the two others dimensions i.e. psychological and social dimensions of the ULL-27 scale. When we stratified the population according to the severity of illness from grade 1 to grade 5, we observed again that the physical dimension of ULL-27 scale is significantly correlated with severity of illness but it is not the case for the psychological and social dimension. All the dimensions to ULL-27 scale are correlated with the homologous dimensions of the SF36 and with the three symptom scores.

Responsiveness : The sensitivity analysis between D0 and D28 in patients with active disease, demonstrated significant difference between mean scores for all ULL-27 dimensions. Changes in the ULL-27 scores by dimensions in the subjects which were improving or deteriorating to the clinicians' judgement between study visits, bear a close relationship to the corresponding sub-scale change in the SF36. Those two results clearly confirm the sensitivity of the ULL-27 scale to change.

DISCUSSION: Volume of oedema poorly reflects the impact of the illness upon the patient, it neglects completely the social and psychological consequences of the illness. Symptoms in these domains are better indicators of the well being of the patients. Specific quality of life scale reflects appropriately and completely all the possible impact of the lymphoedema in the women daily life.

CONCLUSION : Evaluation of HRQOL i) allows us to better quantify the clinical benefits of the treatment. ii) reintroduces the patient's preferences into the management decision. iii) opens the door to a genuine dialogue between the patient and the practitioner. ULL-27 seems to be a very promising instrument for clinical and therapeutical assessment.

STUDY OF COMPLEX DECONGESTIVE PHYSIOTHERAPY RESULTS IN PATIENTS WITH LYMPHEDEMA AND PERCEPTION OF THESE RESULTS

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AIM OF THE STUDY

Lymphoedema of the limbs is the best known manifestation of lymphatic dysfunction. It has been known for many years and is becoming better understood because of recent progress in physiology and pathophysiology. The causes of lymphoedema include failure of organogenesis with defective components of the lymph tree within a region (the pre-lymphatic spaces, capillaries, pre-collectors, collecting ducts and lymph centres) or destruction of these structures (by surgery, radiation, trauma and inflammatory, infectious or parasitic reactions). Lymphoedema is characterised by the development of protein-rich oedema developing into hyperplastic fibrosis, and fatty infiltration of the subcutaneous tissue, occasionally with episodes of infection. It develops as swelling in fixed tissue, which does not regress with rest at night, it can be depressed and is initially pitting in nature. It may be located in all or part of a segment of the limb or of the entire limb. It may, in periods, become tense and often leads to feelings of heaviness, encumbrance and even pain. Untreated, it may advance to the patient's detriment and reach huge volumes.

The treatment of lymphoedema is based on four principles: (i) avoid overloading the capacity of the lymph system. This is the aim of lifestyle advice. (ii) attempt to restore lymphatic function with manual lymph drainage. (iii) reduce excess volume by applying multi-layer, inelastic bandages, combined with specific mobilisation. (iv) maintain results: this is the purpose of compression dressings, which apply pressure, the type and force of which must be tailored for each patient. This complex decongesting physiotherapy is the primary treatment of lymphoedema and must be carried out using established protocols. It lasts for approximately 3 weeks and patients may need to be treated for several years with repeated courses of complex decongesting physiotherapy, because of the chronic nature of the lymphatic problem.

Complex, decongestive physiotherapy produces undisputed results with reduction in volume varying, depending on the (international) publication from 20 to 70%, although it is difficult to stabilise the volume which it produces. Despite wearing compressive dressings, patients develop recurrences of their oedema which may be of varying severity in the periods between intensive therapy.

METHODS

We have firstly attempted to evaluate the results of therapy after intensive, complex