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Validation of the French versions of the Speech Handicap Index and the Phonation Handicap Index in patients treated for cancer of the oral cavity or oropharynx

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ABSTRACT

Context: Nowadays, clinical tools are available to evaluate the functional impact of speech disorders in neurological conditions, but few are validated in oncology. Because of their location, cancers of the upper aerodigestive tract directly impact patients' communication skills. Two questionnaires exist in French: the Speech Handicap Index and the Phonation Handicap Index, but none are specifically validated for the head and neck cancer population. Our aim is to evaluate the validity of these two questionnaires in a population of patients treated for oral cavity or oropharyngeal cancer.

Material and method: Eighty-seven patients treated for cancer of oral cavity or oropharynx, and 21 controls filled the questionnaires during a consultation or one-day hospitalization. Validation was studied by the analysis of convergent and discriminant validity, clinical validity, criterion validity, and internal consistency.

Results: The two questionnaires present a coherent structure in two distinct dimensions for the SHI, and in three dimensions for the PHI. Both tools discriminate patients and healthy subjects (p-value <0.001, Mann-Whitney test). The comparison of the SHI and PHI scores with the "social role functioning" dimension of the MOS SF36 chosen as a reference shows similar performances for the two questionnaires ($\rho > 0.42$). Lastly, the internal consistency is good (Cronbach's alpha > 0.71).

Conclusion: In patients treated for oral cavity or oropharyngeal cancer, the SHI and PHI are two valid and reliable tools for the self-assessment of speech disability. A limitation can be found about criterion validity, because a true gold standard does not exist at the moment. However, the reduced number of questions of the PHI, which implies a shorter filling, leads to prefer this tool over the SHI.

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KEYWORDS

Speech; Quality of life; Oncology; Assessment

1 INTRODUCTION

Current “biopsychosocial” models, such as the International Classification of Functioning described by the WHO (World Health Organization) in 2001, allow considering both organic structures and functions of subjects, and also their impact on daily life activities and their consequences on social participation of the subjects [1]. Hence, beyond the symptomatology, it becomes necessary to consider the functional and psychosocial impact of speech disorder in clinical care.

In speech disorder, the functional dimension of communication and the psychosocial impact on subjects are at the forefront [2]. A speech disorder may have serious consequences [3], with repercussions on family, social and professional relations [4, 5, 6]. Several tools exist to assess patients' health-related quality of life, defined as "the individual's subjective perception of his or her physical, emotional and social state after taking into consideration the effects of the disease and its treatment" [7]. Some are general and assess the overall quality of life, both physical and mental, such as the "Medical Outcome Study Short Form 36" (MOS SF36) or "Short Form 36" (SF36) [8]. Others have been developed to target specific pathological contexts, specifically in oncology. These specific tools include complementary modules according to the tumor location, such as the EORTC QLQ C30 with the "Head and neck 35" module translated into French [9, 10]. Some others are built regarding functional areas, like the "University of Washington Quality of Life" with speech [11].

But health-related quality of life depends on speech disability. Many processes, such as daily activities or support of peers which vary a lot from one individual to another, modulate the perceived impact of disability [12]. Thus, a gap can exist between the patients' quality of life and the functional impact of the speech disorder in communication [13].

Two validated self-questionnaires, translated or elaborated in French, exist and allow a self-assessment of the subject's speech disability: the Speech Handicap Index (SHI) [14], and the Phonation Handicap Index (PHI) [15].

The SHI is made up of 30 items structured in two dimensions of 15 questions: speech function or SHI-S (questions about symptoms and restriction of social activities), and psychosocial function or SHI-PS (perception of speech disorders and modification of state of mind). Each item is built on a five-level Likert scale, ranging from "never" (rated 0) to "always" (rated 4). It allows the calculation of subscores for each dimension, and of an additive global score. The higher the scores, the greater the impact in terms of speech disability. This questionnaire was initially validated in Dutch in a population of 104 patients treated for oral or pharyngeal cancer [14], then in French [16] on a population of 112 healthy controls and 118 patients grouped according their pathology: 28 patients with vocal disorder (including dysfunctional dysphonia, laryngeal immobility or partial laryngectomy), 57 patients with neurological pathology (including amyotrophic lateral sclerosis or Parkinson's disease), 32 patients surgically treated for oral cavity or oropharynx cancer, and 1 patient for whom no information is given. Scale structure, reliability, construct validity and known groups validity were studied in different articles about the validation of the SHI [14, 17]. In French validation, internal consistency, test-retest reliability, construct validity and known groups validity were assessed [16].

The PHI includes 15 items structured in three dimensions of five questions: physical signs or PHI-F (including voice, prosody and articulation changes), functional impact or PHI-C (namely repercussions on the most basic daily needs to expression of more complex emotions and communication skills) and psychosocial repercussions or PHI-E (social handicap perceived by the patient). Its construction model is identical to the SHI. Each item is based on a Likert scale with a score of 0 to 4, allowing the calculation of sub-scores for each dimension and an overall additive score. The interpretation is similar to the SHI: the higher the scores, the greater the impact in terms of speech disability. This questionnaire demonstrated good psychometric qualities in terms of validity (clinical validity, and criterion validity: comparison with scores obtained at reference questions were evaluated) and reliability (in terms of internal consistency and test-retest reliability) [15] in a population of 17 healthy controls and 21 patients in a first group (five with ENT cancers, nine with neurodegenerative pathology, six with motor impairment and 1 traumatic brain injured patient), and 48 patients in a second group (22 ENT cancers, two cerebrovascular accidents, 13 neurodegenerative pathologies, seven traumatic brain injured patients and four unspecified).

The structure of these two questionnaires is presented in Appendix 1. There is an overlap between the two questionnaires with eight questions in common: three questions of the SHI “speech function” dimension are common to the "physical signs" dimension of the PHI (“*I run out of air when I speak*”, “*The intelligibility of my speech varies throughout the day*”, “*I use a great deal of effort to speak*”), one "psychosocial" item of SHI is common to the "functional impact" dimension of the PHI (“*I speak with friends and neighbors or relatives less often because of my speech*”), and four "psychosocial" items of the SHI are common to the "psychosocial repercussions" dimension of the PHI (“*People seem irritated with my speech*”, “*I find other people don't understand my speaking problem*”, “*My speaking difficulties restrict my personal and social life*”, “*My speech makes me feel handicapped*”).

These two self-report questionnaires have been validated on very different pathological groups, with subjects suffering from functional, neurological or oncological pathology. The latter subgroup represents only 32 subjects in the SHI study population (all were surgically treated), and 22 subjects of the PHI study population. However, oral cavity or oropharyngeal cancers have functional consequences on the ability to articulate because of their location, targeting the organs involved in speech production. With the decrease in cancer mortality, patients now live longer with the functional sequelae of oral or pharyngeal cancers on their speech.

Thus, there is a real need for assessment tools of speech disability in patients with oral or oropharyngeal cancer. The validation of both SHI and PHI are partial in this population because of small corpora, whatever the treatment undertaken (surgery and/or radiotherapy and/or chemotherapy). Moreover, none of these validation processes allow evaluating the criterion validity by comparing them to a reference tool.

Therefore, our objective is to evaluate the validity of these two questionnaires (SHI and PHI) in a population of patients treated for oral cavity or oropharynx cancer, which is the most concerned population in head and neck oncology by speech disorders.

2 MATERIAL AND METHODS

2.1 Presentation of the corpus and the study population

Data was collected as part of the C2SI project (Carcinologic Speech Severity Index), funded by the National Cancer Institute (Grant INCa SHS #2015-135) [18]. The objective of this project was to obtain a measure by automatic speech processing comparatively to perceptual methods of the impact of head and neck cancer treatments on speech production.

Eighty-seven patients treated for oral cavity or oropharyngeal cancer were recruited (51 males and 36 females, mean age 65.8 years, extreme values: 36 - 87 years). Inclusion criteria were: patients in chronic phase (therapeutic protocol completed for at least six months) and in clinical remission, so that the speech disorder was as stable as possible. Patients with a speech disorder potentially related to another pathology were excluded. Thirty-five patients had oral cancer (16: oral floor, eight: tongue, six: retromolar area, five: jaw), and 52 had oropharyngeal tumor (26: tonsils, 13: root of the tongue, nine: oropharynx, four: soft palate). Among the 87 patients, 73 got surgical treatment, associated with radiotherapy or chemotherapy or lymph node resection surgery. The other 14 participants were treated only by radiochemotherapy. The post-treatment delay on inclusion time was 64.2 months on average (range: 6; 239) with a median of 39 months. Data is given in table 1.

Table 1: description of the study population

| | Patients | Controls |
|--|------------|-------------|
| Individual sociodemographic data | | |
| Number of subjects | 87 | 42 |
| Age (years) | | |
| Missing data | 1 | 5 |
| Extreme values | 36; 87 | 30; 79 |
| Shapiro-Wilk test: p-value | 0.63 | 0.03 |
| Mean (standard deviation) / Median [interquartile range] | 65.8 (9.6) | 62 [55; 68] |
| Gender: n (%) | | |
| Missing data | 0 | 3 |
| Male | 51 (59) | 18 (46) |
| Female | 36 (41) | 21 (54) |
| Clinical data | | |
| Location: n (%) | | |
| Missing data | 0 | |
| Oral cavity | 35 (40) | |
| Oropharynx | 52 (60) | |
| TNM classification: "T" (tumor size) : n (%) | | |
| Missing data | 0 | |
| T1 | 11 (13) | |
| T2 | 33 (38) | |
| T3 | 12 (14) | |
| T4 | 31 (35) | |
| TNM classification: "N" (nodes) : n (%) | | |
| Missing data | 17 | |

| | | | |
|--|------------------------------|-------------|--|
| | 0 | 22 (32) | |
| | 1 | 17 (24) | |
| | 2 | 3 (4) | |
| | 2a | 5 (7) | |
| | 2b | 13 (19) | |
| | 2c | 5 (7) | |
| | 3 | 5 (7) | |
| Treatment data | | | |
| Time since the end of treatment | | | |
| | Missing data | 0 | |
| | Extreme values | 6; 239 | |
| | Shapiro-Wilk test: p-value | < 0.001 | |
| | Median [interquartile range] | 39 [21; 91] | |
| Tumor surgery: n (%) | | | |
| | Missing data | 0 | |
| | Yes | 73 (84) | |
| | No | 14 (16) | |
| Node surgery: n (%) | | | |
| | Missing data | 0 | |
| | Yes | 76 (87) | |
| | No | 11 (13) | |
| Radiotherapy: n (%) | | | |
| | Missing data | 0 | |
| | Yes | 82 (94) | |
| | No | 5 (6) | |
| Chemotherapy: n (%) | | | |
| | Missing data | 0 | |
| | Yes | 48 (55) | |
| | No | 39 (45) | |

All patients were recruited in post-treatment consultation between 2015 and 2016 at the Toulouse University Cancer Institute Oncopole. All data collection was made at the same place and day, during a follow-up consultation or one-day hospitalization. The inclusion time and the duration of participation was therefore one day per subject. Informed consent to participate in the C2SI project was obtained from each subject, by filling a specific form.

A group of 21 healthy controls composed of accompanying patients was also included, in order to get a recruitment similar in age, gender and geographic origin. The criteria for non-inclusion were the absence of speech disorders, cognitive and / or visual impairment. Each control also gave written informed consent.

2.2 Data from SHI, PHI and SF36

On the day of their participation in the study, patients and controls filled the French versions of the SHI, the PHI and finally the MOS SF36.

Regarding the PHI, the participants only filled the specific questions: questions common to the SHI and PHI had already been answered during the completion of the SHI. Duplicate questions from the PHI were excluded to reduce the number of items submitted, and the duration of the questionnaires in a context of fatigability of the patients during the consultation.

The French validated version of the SF36 was used [8]. It includes 36 items allowing the evaluation of the following domains: Vitality, Physical functioning, Bodily pain, General health perceptions, Physical role functioning, Emotional role functioning, Social role functioning and Mental health. It allows the calculation of a score for each domain, but also two summary scores (physical and mental), resulting from a different weighting of each domain score. The domain scores and the summary scores range from 0 to 100: the higher the score, the better the quality of life is. In our study, only the score obtained in the dimension "Social Role Functioning" (SF36-SF) was retained, as part of the study of criterion validity, in the absence of a real reference tool for the self-assessment of speech disability. This SF36-SF dimension is made up of two questions: "6. During the **past 4 weeks**, how much of the time has **your physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?" and "10. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?". These two questions are built on a scale model of Likert, the score ranging from one to five.

These three questionnaires (SHI, PHI and SF36) were filled independently by the participants. However, completion help was provided if needed, in case of fatigue, visual, cognitive or other problems.

2.3 Statistical analysis

All statistical analyses were performed using Stata 14.2 software.

Univariate descriptive analyses were initially conducted on item scores and subscores by dimension (SHI, PHI and SF36-SF). For quantitative variables, a Shapiro-Wilk test was performed, associated with a visual analysis of the distribution. The score distributions led us to use nonparametric tests throughout our study. Finally, the missing data were excluded because of their low number: three in patients (questionnaires analyzed: 84/87) and none in controls (questionnaires analyzed: 21/21) for SHI and PHI, and six among the patients for SF36 (questionnaires analyzed: 81/87).

Construct validity was studied by convergent and discriminant validity analysis, defined as “the degree to which scores of the SHI and PHI are consistent with hypotheses (with regard to internal relationships) based on the assumption that the instruments validly measure the construct to be measured” [19]. A correlation matrix of nonparametric Spearman coefficients between the different SHI and PHI scores was used. The structure of the two questionnaires in our population was verified using a confirmatory principal component analysis for each. For clinical validity, the results obtained in extreme groups (patients and healthy controls) were analyzed using a nonparametric row comparison test (Mann-Whitney test).

The comparison between the SF36-SF score (“Social role functioning” domain) and the dimensions of our questionnaires allowed assessing the criterion validity, defined as the “degree to which the scores of the instruments are in adequate reflection of a ‘gold standard’” (here: SF36-SF score) [19]. As the SF36 is a questionnaire giving a score from 0 to 100 whose interpretation is opposite to the self-questionnaire scores (for the SF36, the higher the scores, the lower the perceived impact on the quality of life), subscores of each SHI and PHI domain were transformed to allow the same interpretation. The transformed scores were calculated with the following formula: $[100 - 5X]$ for the PHI and $[100 - (5X / 3)]$ for the SHI, where X is the total of points obtained by the subject in a domain. Then, this can be interpreted in the same way as the scores of the SF-36, namely scores ranging from 0 (major impact in terms of speech disability) to 100 (no impact). The Wilcoxon test assessed the significance of the differences in results in the questionnaires, and the calculation of a Spearman correlation coefficient allowed evaluating the strength of the relationship between the scores.

Internal consistency of the items in each dimension was measured by a Cronbach’s alpha coefficient. It is defined as “the degree of interrelatedness among the items” [19].

In order to verify that our two questionnaires present similar properties, we first compared the SHI-S scores (speech function) with the PHI-F (physical signs) and the PHI-C (functional impact), then the SHI-PS (psychosocial function) with PHI-C (functional impact), and finally with PHI-E (psychosocial repercussions). Spearman’s correlation coefficients were used. Indeed, according to the authors, the S part (speech) of the SHI includes both physical and functional questions (corresponding to dimensions F and C of the PHI), and the PS (psychosocial) part can be found not only in the communication with others but also psychosocial (corresponding to dimensions C and E of the PHI). PHI scores were transformed to allow a comparison (subscores by dimension were tripled so as to have a subscore out of 60 for both the PHI whose dimensions consist of 5 questions, and for the SHI whose dimensions consist of 15 questions). The study was first conducted on the whole questions of each dimension for each questionnaire. We also conducted the same study by excluding redundant questions, that is, present in both SHI and PHI, to have independent data.

3 RESULTS

3.1 Convergent and discriminant validity

Table 2 presents the correlation matrix of Spearman coefficients for PHI questions.

Table 2: correlation matrix of PHI scores

| | | PHI - physical signs (PHI-F) | | | | | PHI - functional impact (PHI-C) | | | | | PHI - psychosocial repercussions (PHI-E) | | | | |
|--|---------------|------------------------------|--------|--------|--------|--------|---------------------------------|--------|--------|--------|--------|--|---------|---------|---------|-------|
| | | shis2 | shis3 | shis20 | phif1 | phif2 | ships14 | phic1 | phic2 | phic3 | phic4 | ships12 | ships16 | ships17 | ships27 | phie1 |
| PHI - physical signs (PHI-F) | shis2-phif1 | 1 | | | | | | | | | | | | | | |
| | shis3-phif2 | 0.4354 | 1 | | | | | | | | | | | | | |
| | shis20-phif3 | 0.4913 | 0.4594 | 1 | | | | | | | | | | | | |
| | phif4 | 0.3285 | 0.4124 | 0.3504 | 1 | | | | | | | | | | | |
| | phif5 | 0.2743 | 0.2885 | 0.4369 | 0.5248 | 1 | | | | | | | | | | |
| PHI - functional impact (PHI-C) | ships14-phic1 | 0.4237 | 0.3997 | 0.722 | 0.3953 | 0.479 | 1 | | | | | | | | | |
| | phic2 | 0.3361 | 0.2374 | 0.4382 | 0.1493 | 0.3783 | 0.3512 | 1 | | | | | | | | |
| | phic3 | 0.3428 | 0.27 | 0.6358 | 0.3547 | 0.5727 | 0.5812 | 0.5031 | 1 | | | | | | | |
| | phic4 | 0.3924 | 0.3575 | 0.6965 | 0.4263 | 0.5276 | 0.7293 | 0.2968 | 0.7388 | 1 | | | | | | |
| | phic5 | 0.4617 | 0.3698 | 0.5438 | 0.4315 | 0.418 | 0.5066 | 0.3178 | 0.4999 | 0.6674 | 1 | | | | | |
| PHI - psychosocial repercussions (PHI-E) | ships12-phie1 | 0.3717 | 0.2246 | 0.4843 | 0.1965 | 0.4022 | 0.553 | 0.5043 | 0.4658 | 0.4617 | 0.4229 | 1 | | | | |
| | ships16-phie2 | 0.4406 | 0.1227 | 0.4841 | 0.2401 | 0.3706 | 0.4812 | 0.358 | 0.4545 | 0.5911 | 0.6106 | 0.5946 | 1 | | | |
| | ships17-phie3 | 0.3993 | 0.3818 | 0.7015 | 0.4095 | 0.5406 | 0.7353 | 0.3491 | 0.668 | 0.7138 | 0.5363 | 0.5592 | 0.5087 | 1 | | |
| | ships27-phie4 | 0.4161 | 0.4199 | 0.6759 | 0.4036 | 0.4966 | 0.6119 | 0.2021 | 0.5467 | 0.7579 | 0.5489 | 0.3662 | 0.4611 | 0.7004 | 1 | |
| | phie5 | 0.344 | 0.3503 | 0.6586 | 0.457 | 0.4366 | 0.6933 | 0.2374 | 0.5985 | 0.7267 | 0.5835 | 0.388 | 0.3804 | 0.7003 | 0.797 | 1 |

The names given in the second column are the item codes (see Appendix 1).

The values presented correspond to the Spearman correlation coefficients between each PHI question. Each correlation coefficient is presented on a background of degraded grey, ranging from light grey (lowest coefficient) to dark grey (highest coefficient)

The three-dimensional structure of the PHI is well respected, except for one question whose score seems less well-correlated with the other questions in its own dimension: "I have difficulties to express orally what I need (drink, eat, go to the restroom ...)" (phic2). Two other items seem quite strongly correlated with questions in different dimensions: "I have trouble communicating with unfamiliar people" (phic4) and "I use a great deal of effort to speak" (shis20-phif3). The confirmatory principal component analysis made on PHI items clearly shows three main dimensions. However, the initial three-dimensional structure of five questions does not seem to be verified here. The factor 3 includes two items (shis3-phif2: "The intelligibility of my speech varies throughout the day", and phif4: "My speech rate has changed"), the factor 2 includes three items (shis2-phif1: "I run out of air when I speak", phic2: "I have difficulties to express orally what I need (drink, eat, go to the restroom ...)", and ships12-phie1: "People seem irritated with my speech"). The other items are thus regrouped in factor 1, as shown in table 3.

Table 3: results of the confirmatory principal component analysis of PHI items

| Variable | | Factor1 | Factor2 | Factor3 | Uniqueness |
|---------------|--|---------|---------|---------|------------|
| shis2-phif1 | I run out of air when I speak | 0.2712 | 0.5409 | 0.3506 | 0.5109 |
| shis3-phif2 | The intelligibility of my speech varies throughout the day | 0.2235 | 0.1589 | 0.7801 | 0.3163 |
| shis20-phif3 | I use a great deal of effort to speak | 0.6958 | 0.3991 | 0.2499 | 0.2941 |
| phif4 | My speech rate has changed | 0.3641 | 0.0644 | 0.7002 | 0.3729 |
| phif5 | My voice makes it difficult to express my emotions | 0.5094 | 0.279 | 0.4057 | 0.498 |
| ships14-phic1 | I speak with friends and neighbors or relatives less often because of my speech | 0.7634 | 0.2516 | 0.2168 | 0.307 |
| phic2 | I have difficulties to express orally what I need (drink, eat, go to the restroom ...) | 0.0377 | 0.823 | 0.2275 | 0.2695 |
| phic3 | I am hindered from expressing my thoughts, my opinions | 0.6361 | 0.4012 | 0.1547 | 0.4106 |
| phic4 | I have trouble communicating with unfamiliar people | 0.8865 | 0.1991 | 0.1055 | 0.1634 |
| phic5 | I am asked to repeat because of my speech difficulties | 0.634 | 0.3367 | 0.1939 | 0.4471 |
| ships12-phie1 | People seem irritated with my speech | 0.3701 | 0.7178 | -0.0098 | 0.3477 |
| ships16-phie2 | I find other people don't understand my speaking problem | 0.572 | 0.5313 | -0.2062 | 0.3481 |
| ships17-phie3 | My speaking difficulties restrict my personal and social life | 0.7695 | 0.329 | 0.1913 | 0.2629 |
| ships27-phie4 | My speech makes me feel handicapped | 0.8591 | 0.0405 | 0.2394 | 0.203 |
| phie5 | I suffer from my speech | 0.8609 | 0.0365 | 0.2539 | 0.193 |

The names given in the first column are the item codes (see Appendix 1).

Values in grey are over 0.50.

Table 4 presents the correlation matrix of Spearman coefficients for SHI questions.

Table 6: Mean, standard deviation, and distribution values for the sub-scores of each PHI and SHI dimension in patients and controls, as well as p-value of the Mann-Whitney test

| | | SUJETS | | | | | | | | | |
|----------|-------------|------------------|---------------------|-------------|-------------------|-------------------|-------------------|--------------|---------|---|--|
| variable | N | Mean | Déviati standard | Minimu m | Percen tile 25 | Percen tile 50 | Percen tile 75 | Maxi- mum | | | |
| shis | 84 | 23.60283 | 12.89868 | 0 | 15 | 22.5 | 33 | 51 | | | |
| ships | 84 | 19.01524 | 14.37753 | 0 | 5.5 | 18 | 32 | 53 | | | |
| phif | 84 | 8.278486 | 4.64468 | 0 | 5 | 8 | 12 | 20 | | | |
| phic | 84 | 6.134779 | 4.535629 | 0 | 2 | 6 | 10 | 16 | | | |
| phie | 84 | 6.702381 | 5.194482 | 0 | 2 | 6 | 12 | 18 | | | |
| | | TEMOINS | | | | | | | | Test de comparaison de rangs sujets / témoins (Mann-Whitney) | |
| variable | Nom- bre | Moyenne | Déviati standard | Minimu m | Percen tile 25 | Percen tile 50 | Percen tile 75 | Maxi- mum | p-value | | |
| shis | 21 | 3.282313 | 4.471878 | 0 | 0 | 1 | 7 | 13 | <0.001 | | |
| ships | 21 | 0.670068 | 1.592469 | 0 | 0 | 0 | 1 | 7 | <0.001 | | |
| phif | 21 | 1.231293 | 1.695568 | 0 | 0 | 0 | 2 | 6 | <0.001 | | |
| phic | 21 | 0.2380952 | 0.7003401 | 0 | 0 | 0 | 0 | 3 | <0.001 | | |
| phie | 21 | 0.2857143 | 0.9023778 | 0 | 0 | 0 | 0 | 4 | <0.001 | | |

SHI and PHI allow a clear discrimination of patients and healthy controls in each dimension of each questionnaire, with significantly different subscores per dimension across all SHI and PHI dimensions ($p < 0.001$, Mann-Whitney test).

3.3 Criterion validity

Comparison of SHI and PHI subscores by dimension with the reference chosen (namely the score on the dimension "Life and relations with others" or SF36-SF) allow the evaluation of the criterion validity.

Table 7 presents the means and standard deviations of the transformed subscores, as well as the p-value of the Wilcoxon test, and the value of the Spearman coefficient.

Table 7: results of the criterion validity study of SHI and PHI sub-scores compared to the SF36-SF sub-score taken as a reference

| | | PATIENTS | | | | |
|----------------|----|----------|-----------------------|-------------------------------|-----------------|--|
| | N | Mean | Standard deviation | p-value (Wilcoxon test) | Spearman rho | |
| SF36-SF | 81 | 62.65432 | 24.32638 | | | |
| SHI | | | | | | |
| SHI-S | 81 | 61.08624 | 21.70556 | 0.4371 | 0.5129 | |
| SHI-PS | 81 | 69.10946 | 23.77752 | 0.0284 | 0.5638 | |
| PHI | | | | | | |
| PHI-F | 81 | 58.74118 | 23.47168 | 0.1487 | 0.4253 | |
| PHI-C | 81 | 69.79497 | 22.38066 | 0.0123 | 0.4891 | |
| PHI-E | 81 | 67.22222 | 25.8602 | 0.0707 | 0.5512 | |

p-values below the threshold of 5% are in bold

No significant difference is found between the chosen reference (SF36-SF "Social Role Functioning") on one side, and SHI-S (speech function), PHI-F (physical signs) and PHI-E (psychosocial repercussions) subscores on the other side. However, there is a significant difference between the SF36-SF score, on the one hand, and the SHI-PS (psychosocial function) and PHI-C (functional impact) subscores on the other hand. We find a moderate correlation [20] between the SF36-SF and the two dimensions of the SHI ($r = 0.51$ with SHI-S, and $r = 0.56$ with SHI-PS) and the PHI-E ($r = 0.55$). This correlation is lower between SF36-SF and PHI-F ($r = 0.43$) and PHI-C ($r = 0.49$).

3.4 Internal consistency

The internal consistency of the two questionnaires SHI and PHI is very good, with values of Cronbach's alphas consistently higher than 0.71 for the PHI, and 0.92 for the SHI. Details of the values can be found in the appendix 2.

3.5 Comparison between SHI and PHI

As the SHI and PHI both present good psychometric qualities, we chose to compare them. The differences between the transformed subscores of each dimension of these questionnaires and strength of their relationship were analyzed, by the calculation of a correlation coefficient.

Table 8 presents the means, standard deviations, p-values (Wilcoxon test) and Spearman's correlation coefficient value for each comparison, on the one hand with all the questions in each questionnaire, and, on the other hand, with excluding the questions in both questionnaires because of the overlap between the SHI and PHI.

Table 8: results of comparison tests of SHI and PHI transformed sub-scores

| | PATIENTS | | | | |
|--|----------|----------|--------------------|------------------|--------------|
| | N | Mean | Standard deviation | test | Spearman rho |
| NON INDEPENDENT DATA (REDUNDANT QUESTIONS) / 60 | | | | | |
| SHI-S (reference) | 84 | 23.60283 | 12.89868 | | |
| PHI-F transformed | 84 | 24.83546 | 13.93404 | 0.0733 | 0.8919 |
| PHI-C transformed | 84 | 18.40434 | 13.60689 | <0.001 | 0.8831 |
| SHI-PS (reference) | 84 | 19.01524 | 14.37753 | | |
| PHI-C transformed | 84 | 18.40434 | 13.60689 | 0.3269 | 0.8959 |
| PHI-E transformed | 84 | 20.10714 | 15.58345 | 0.0609 | 0.9534 |
| INDEPENDENT DATA (UNIQUE QUESTIONS) : / 4 | | | | | |
| SHI-S transformed (reference) | 84 | 1.552574 | 0.8626838 | | |
| PHI-F transformed | 84 | 1.653274 | 1.154703 | 0.1934 | 0.6203 |
| PHI-C transformed | 84 | 1.185268 | 0.8874675 | <0.001 | 0.8459 |
| SHI-PS transformed (reference) | 84 | 1.258681 | 0.1041546 | | |
| PHI-C transformed | 84 | 1.185268 | 0.8874675 | 0.1678 | 0.8502 |
| SHI-PS transformed (reference) | 84 | 1.262208 | 0.9738895 | | |
| PHI-E transformed | 84 | 1.571429 | 1.507297 | 0.0048 | 0.7914 |

Data is considered as independent if there is no item overlap between both SHI and PHI questionnaires. In case of overlap, data is considered as non-independent.

p-values below the threshold of 5% are in bold

On analyses with complete data (all questions, including redundant questions), we do not find any significant difference between the two questionnaires, except between the SHI-S (speech function) and PHI-C subscores (functional impact). For each comparison, the correlations are strong ($r > 0.88$). About the independent data analyses (with the exclusion of the identical questions in the two questionnaires), we again do not find any significant difference between the two questionnaires, except between the SHI-S and the PHI-C subscores, but also between the sub-scores SHI-PS (psychosocial function) and PHI-E (psychosocial repercussions). The correlations are strong for each comparison ($r > 0.79$), only the one between SHI-S and PHI-C sub-scores is fairly lower ($r = 0.62$).

4 DISCUSSION

4.1 Convergent and discriminant validity

The study of convergent and discriminant validity shows that the structure of the PHI in three dimensions is questionable, with five items related to the physical signs, 5 items to the functional impact and the last five items about the psychosocial repercussions.

The three questions of PHI less well correlated with the other questions in their own dimension (phic2: *"I have difficulties to express orally what I need (drink, eat, go to the restroom...)"*, phic4: *"I have trouble communicating with unfamiliar people"* and shis20-phif3: *"I use a great deal of effort to speak"*) are linked with the notion of communication of basic needs, such as eating or drinking, or of elaborate needs (about communication with unfamiliar people). Difficulties in communication with unfamiliar people also raise questions about the need for communication according to social circles. This point is crucial in our population of sometimes isolated patients who need help for daily activities. Moreover, the question of the effort to speak (shis20-phif3: *"I use a great deal of effort to speak"*) is ambiguous because the effort can be interpreted either as a physical effort in the articulation of speech or as a cognitive effort in terms of communication and relationship with others. The question ships22 (*"My speech problem causes me to lose income"*) is weakly correlated with the psychosocial dimension. This question has not been studied in the initial validation of the SHI [16] because of lack of correlation, the same results are found in this study. This can be explained by the difficulties in answering about the lack of income, because our study population is 65.8 years old on average, thus mainly composed of retirees. The average age of our population is linked to the fact that head and neck cancer is late-onset cancer, in patients who are retired or close to retirement. Finally, the question shis20-phif3 (*"I use a great deal of effort to speak"*) is correlated quite strongly with the psychosocial dimension with which it is not related: making efforts to speak is part of the speaker/interlocutor dynamic in communication situations.

The confirmatory principle component analysis performed on PHI items shows three dimensions, but not as clearly identified as in the original study [15]. Indeed, the questions specifically related to the symptoms are limited (shis3-phif2: *"The intelligibility of my speech varies throughout the day"* and shis2-phif1: *"I run out of air when I speak"*). The notion of effort is again lowly linked to the symptomatic items. Running out of air during speech can be associated with other health issues, and the expression of emotions is more about vocal production than speech, which may explain its stronger link with the questions related to psychosocial impact. Moreover, these last two questions present a high uniqueness value (percentage of variance of the variable not explained by other factors), which makes their interpretation questionable. Finally, this analysis shows that in our population of patients treated for oral or oropharyngeal cancer, a very tight link exists between functional and psychosocial repercussions.

The initial version of the SHI consists of two dimensions, one about speech function, and the other one about psychosocial function. Our study shows that if the correlation study of item scores makes this structure acceptable, the confirmatory principal component analysis allows a more precise analysis. On a 5-factor structure, the shis22 question (*"My speech problem causes me to lose income"*) always remains a little apart. Questions about specific symptoms (shis3-phif2: *"The intelligibility of my speech varies throughout the day"* and shis21: *"My speech is worse in the evening"*) form a specific group, and shis6, ships29 and ships30 questions dealing with shame and embarrassment are also grouped into a single factor. After having forced the analysis on two dimensions, we find a group of questions about the feeling of the subjects about the perception of their speech by others (shis23: *"I try to change my speech to sound different"*, ships12-phie1: *"People seem irritated with my speech"*, ships16: *"I find other people don't understand my speaking problem"*, shis5: *"People ask me why I'm hard to understand"* and shis13: *"People ask me to repeat myself when speaking face-to-face"*) in which we also find the question about the loss of income. The other factor encompassing 24 questions is broader, including questions about symptomatology, but also to the psychosocial impact of the disorder.

Thus, while it is possible to consider the two-dimensional structure of SHI, and the three-dimensional PHI, in our population, the structure is not so obvious. There is a strong link between functional impact and psychosocial repercussion in oral or oropharyngeal cancer patients.

4.2 Clinical validity and criterion validity

The clinical validity of the SHI and PHI is respected. The two questionnaires allow obtaining significantly different scores in two extreme groups (one with speech problems, the other without).

Regarding the criterion validity, we find a significant difference between the SF36 (SF36-SF) sub-score "Social role function", which be considered as a reference, and the SHI-PS (psychosocial function) and PHI-C sub-scores (functional impact). In addition, the correlations are moderate between the SF36-SF sub-score and the two dimensions of the SHI and the PHI-E (psychosocial repercussions), a little less between the SF36-SF and the PHI-F (physical signs) and PHI-C. However, these correlations are close to those found in other studies [4] between the severity of speech disorder perceptually assessed and the quality of life. There is no proven reference for assessing speech disability by the patient himself in head and neck cancer. The SF36 measures the impact of health status on patient's relationships. Speech is only part of global health: this can explain that the functional dimension of communication is only one element among others that modifies it. It can also explain the lack of significance of the relation between the quality of life related to relationships with others, and the communication of patients. The physical signs of speech disorders and their emotional impact on patients are more closely related to the communication dynamics.

4.3 Reliability

The study of internal consistency shows a good homogeneity of items in each dimension.

Because of the one-day participation of the patient, we did not ask them to fill the SHI and PHI again after seven to 14 days. This could have allowed us to assess the temporal reliability of the two questionnaires in our population of patients treated for cancer of oral cavity or oropharynx. The study of this test-retest reliability was conducted as part of the initial validation of the PHI [15], with good reliability on the population composed of only a small number of head and neck cancer subjects. Temporal reliability was not alayed in the validation of the French version of SHI [16].

4.4 Comparison between the SHI and the PHI

We can therefore ask ourselves the question of comparing these two questionnaires.

We find a significant difference between the subscores SHI-S (speech function) and PHI-C (functional impact). Most questions are about physical signs rather than communication disability in the physical signs dimension of the SHI (10/ 15 for physical signs), which may explain the lack of significance, on the one hand, and the weaker correlation between the SHI-S and PHI-C compared to PHI-F (physical signs) on the other hand. There is also a significant difference between the SHI-PS (psychosocial function) and the PHI-E (psychosocial repercussions) subscores after the exclusion of redundant questions. Only one question of PHI-E is not found in the SHI-PS, this element can explain the lack of statistical significance while the correlation remains strong between the dimensions of these two questionnaires. The correlations found in the analysis with redundant questions are high because of the number of common questions (3/ 5 between SHI-S and PHI-F, 1/ 5 between SHI-PS and PHI-C, 4/ 5 between SHI- PS and PHI-E). However, these correlations remain strong ($r > 0.84$) even after the exclusion of redundant questions, which shows the equivalence of these two questionnaires.

Thus, SHI and PHI are two valid, reliable and strongly correlated tools among a population of patients treated for cancer of the oral cavity and oropharynx because both questionnaires respect convergent and discriminant validity, clinical validity, criterion validity and internal consistency. However, the PHI has a smaller number of questions than the SHI (15 versus 30), making the filling shorter in an often easily tired population.

The results of our study, and especially the link found between functional and psychosocial repercussions of speech disorders, lead us to question the impact of speech disorders in the oncological population. This impact must be considered from a functional point of view, on the levels of communication altered by speech disorders: from the communication of basic needs to the more precise elaboration of arguments or ideas. But it would also be necessary to consider the communication dynamics according to communication partners, i.e. the communication needs as for the social circles (family, friends, acquaintances, unknown people). Communication needs are not identical depending on the speaker's affiliation to different social circles. The functional impact of speech disorders will also depend on the entanglement between levels of communication and the communication partner belonging to a given social circle. We can also ask to what extent the satisfaction of the patient about his speech modifies the perception of his speech disability. Finally, in terms of care, we should study how, from a patient's speech evaluation, we can predict the functional impact of speech disorders on communication.

5 CONCLUSION

In patients treated for oral or oropharyngeal cancer, SHI and PHI self-questionnaires are two valid and reliable tools for self-assessment of speech disability. However, criterion is a limit to this analysis, as a reference tool does not currently exist. Moreover, the temporal reliability could not be evaluated in this study. The reduced number of PHI questions making the handover shorter for an often easily tired population lead to prefer this tool to the SHI in clinical care. In terms of oral and oropharyngeal patient care, it seems now essential to question us about the assessment of the functional impact of speech disorders. Based on a speech quality assessment performed in current clinical practice by physicians or speech therapists, it remains to explore what inferences can be made about the communication dimensions impacted for the patient, given his communication needs, the construction of his social circles and his own perception of his speech disorder.

Author version

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STATEMENT OF ETHICS

Subjects have given their informed consent before being included in the study.

The research protocol has been reviewed by ethics committee (CPP: Comité de Protection des Personnes, from University Hospital Centre of Toulouse). CPP analyses ethical aspects of research protocols directly or indirectly involving humans. CPP approved C2SI protocol on 17-may-2016. A processing declaration whose purpose is "recording of the speech of patients treated for ENT cancer" was registered with the Commission Nationale de l'Informatique et des Libertés (CNIL) on 24-July-2015 under number 1876994v0.

DISCLOSURE STATEMENT

Authors do not declare any conflict of interest.

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AUTHOR CONTRIBUTION

Mathieu Balaguer took part in collecting data and performed analysis for the work. Michèle Puech took part in the acquisition of the data, and in the clinical analysis, such as Pascale Fichaux-Bourin. Jérôme Farinas and Julien Pinquier made substantial contributions to the analysis and the interpretation of the data. Virginie Woisard contributed to the conception of the work, and the clinical analyses.

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Appendix 1: details of questions from the SHI and PHI

| | | | | SHI (Rinkel, 2008 translated by Degroote, 2011) and PHI (Fichaux-Bourin, 2009) | French translation |
|---------|-----------------------|--|--|--|--|
| shis1 | Speech function | | | My speech makes it difficult for people to understand me | On me comprend difficilement à cause de ma parole |
| shis5 | | | | People ask me why I'm hard to understand | On me demande pourquoi je suis difficile à comprendre |
| shis6 | | | | I feel annoyed when people ask me to repeat | Je suis ennuyé(e) quand les gens me demandent de répéter |
| shis9 | | | | My articulation is unclear | Mon articulation n'est pas nette |
| shis10 | | | | People have difficulty understanding me in a noisy room | On me comprend difficilement quand je parle dans une pièce bruyante |
| shis13 | | | | People ask me to repeat myself when speaking face-to-face | Les gens me demande de répéter quand on parle en face à face |
| shis15 | | | | I feel as though I have to strain to speak | J'ai l'impression que je dois forcer pour parler |
| shis18 | | | | The intelligibility is unpredictable | L'intelligibilité de ma parole est imprévisible |
| shis21 | | | | My speech is worse in the evening | Ma parole est plus mauvaise le soir |
| shis23 | | | | I try to change my speech to sound different | J'essaie de changer ma voix pour qu'elle sonne différemment |
| shis26 | | | | My family has difficulty understanding me when I call them throughout the house | Les membres de la famille ont du mal à me comprendre quand je les appelle dans la maison |
| shis28 | | | | I have difficulties to continue a conversation because of my speech | J'ai des difficultés à poursuivre une conversation à cause de ma parole |
| shis2 | | Speech-specific physical signs about voice, prosody and articulation changes | phif1 | | I run out of air when I speak |
| shis3 | phif2 | | | The intelligibility of my speech varies throughout the day | L'intelligibilité de ma parole varie au cours de la journée |
| shis20 | phif3 | | | I use a great deal of effort to speak | Je fais beaucoup d'efforts pour parler |
| | phif4 | | | My speech rate has changed | La vitesse à laquelle je parle a changé |
| | phif5 | | | My voice makes it difficult to express my emotions | Ma voix rend difficile l'expression de mes émotions |
| ships14 | Psychosocial function | phic1 | Functional impact considering the repercussions from the most elementary formulations to the expression of emotions and the communication in group | I speak with friends and neighbors or relatives less often because of my speech | Je parle moins souvent avec mes voisins, mes amis, ma famille à cause de ma parole |
| | | phic2 | | I have difficulties to express orally what I need (drink, eat, go to the restroom ...) | J'ai des difficultés à formuler oralement ce dont j'ai besoin (boire, manger, toilette...) |
| | | phic3 | | I am hindered from expressing my thoughts, my opinions | Je suis gêné(e) pour exprimer mes pensées, mes opinions |
| | | phic4 | | I have trouble communicating with unfamiliar people | J'ai du mal à communiquer avec des personnes peu familières |
| | | phic5 | | I am asked to repeat because of my speech difficulties | On me demande de répéter à cause de mon problème pour parler |
| ships12 | Psychosocial function | phie1 | Psychosocial repercussions reflecting the social handicap felt by the patient | People seem irritated with my speech | Les gens semblent irrités à cause de ma parole |
| ships16 | | phie2 | | I find other people don't understand my speaking problem | Je trouve que les gens ne comprennent pas mon problème pour parler |
| ships17 | | phie3 | | My speaking difficulties restrict my personal and social life | Mes difficultés à parler limitent ma vie personnelle et sociale |
| ships27 | | phie4 | | My speech makes me feel handicapped | Je me sens handicapé(e) à cause de ma parole |
| | | phie5 | | I suffer from my speech | Je souffre de ma façon de parler |
| ships4 | Psychosocial function | | | My speech made me feel incompetent | Je me sens incompetent(e) à cause de ma parole |
| ships7 | | | | I avoid using the phone | J'évite de téléphoner |
| ships8 | | | | I'm tense when talking to others because of my speech | Je suis tendu(e) quand je parle avec d'autres personnes à cause de ma parole |
| ships11 | | | | I tend to avoid groups of people because of my speech | J'ai tendance à éviter les groupes à cause de ma parole |
| ships19 | | | | I feel left out of conversations because of my speech | Je me sens écarté(e) des conversations à cause de ma parole |
| ships22 | | | | My speech problem causes me to lose income | Mes problèmes de parole entraînent des pertes de revenus |
| ships24 | | | | My speech problem upsets me | Mes problèmes de parole me contrarient |
| ships25 | | | | I am less outgoing because of my speech problem | Je suis moins sociable cause de mon problème de parole |
| ships29 | | | | I feel embarrassed when people ask me to repeat | Je suis embarrassé(e) quand les gens me demandent de répéter |
| ships30 | | | | I'm ashamed of my speech problems | J'ai honte de mon problème de parole |

Appendix 2: details of calculation of Cronbach's alphas for both questionnaires on the 84 subjects

PHI :

| PHYSICAL | | FUNCTIONAL | | PSYCHOSOCIAL | |
|--------------|---------------|---------------|---------------|---------------|---------------|
| Item | alpha | Item | alpha | Item | alpha |
| shis2-phif1 | 0.7438 | ships14-phic1 | 0.7956 | ships12-phie1 | 0.86 |
| shis3-phif2 | 0.7353 | phic2 | 0.8636 | ships16-phie2 | 0.853 |
| shis20-phif3 | 0.7118 | phic3 | 0.7834 | ships17-phie3 | 0.7908 |
| phif4 | 0.729 | phic4 | 0.7591 | ships27-phie4 | 0.801 |
| phif5 | 0.7285 | phic5 | 0.807 | phie5 | 0.8087 |
| Test scale | 0.7719 | Test scale | 0.8386 | Test scale | 0.8558 |

SHI :

| SPEECH | | PSYCHOSOCIAL | |
|--------------|---------------|---------------|---------------|
| Item | alpha | Item | alpha |
| shis1 | 0.9248 | ships4 | 0.9419 |
| shis2-phif1 | 0.9306 | ships7 | 0.9383 |
| shis3-phif2 | 0.9304 | ships8 | 0.9385 |
| shis5 | 0.9317 | ships11 | 0.938 |
| shis6 | 0.9305 | ships12-phie1 | 0.945 |
| shis9 | 0.9245 | ships14-phic1 | 0.9402 |
| shis10 | 0.9237 | ships16-phie2 | 0.9438 |
| shis13 | 0.9264 | ships17-phie3 | 0.9382 |
| shis15 | 0.9257 | ships19 | 0.9427 |
| shis18 | 0.9252 | ships22 | 0.9481 |
| shis20-phif3 | 0.9224 | ships24 | 0.9392 |
| shis21 | 0.9313 | ships25 | 0.9417 |
| shis23 | 0.9321 | ships27-phie4 | 0.9384 |
| shis26 | 0.9256 | ships29 | 0.9437 |
| shis28 | 0.9232 | ships30 | 0.9427 |
| Test scale | 0.9318 | Test scale | 0.9451 |

The names given in the first column are the item codes (see Appendix 1).