



HAL
open science

The (head and neck) carcinologic handicap index: validation of a modular type questionnaire and its ability to prioritise patients' needs

Mathieu Balaguer, Maëlle Champenois, Jérôme Farinas, Julien Pinquier,
Virginie Woisard

► To cite this version:

Mathieu Balaguer, Maëlle Champenois, Jérôme Farinas, Julien Pinquier, Virginie Woisard. The (head and neck) carcinologic handicap index: validation of a modular type questionnaire and its ability to prioritise patients' needs. *European Archives of Oto-Rhino-Laryngology*, In press, 10.1007/s00405-020-06201-6 . hal-02899287

HAL Id: hal-02899287

<https://hal.science/hal-02899287v1>

Submitted on 20 Jul 2020

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

The (head and neck) carcinologic handicap index: validation of a modular type questionnaire and its ability to prioritise patients' needs

Mathieu Balaguer ^(1,2), Maëlle Champenois ⁽³⁾, Jérôme Farinas ⁽²⁾, Julien Pinquier ⁽²⁾, Virginie Woisard ^(1,4)

(1) CHU Larrey, Toulouse, France

(2) IRIT, CNRS, Université Paul Sabatier Toulouse III, Toulouse, France

(3) Faculté de médecine Toulouse Rangueil, Université Paul Sabatier Toulouse III, Toulouse, France

(4) Laboratoire Octogone-Lordat, Toulouse, France

Contact information of the corresponding author:

Mathieu Balaguer

IRIT Institut de Recherche en Informatique de Toulouse
118 Route de Narbonne
31062 TOULOUSE CEDEX 9

mathieu.balaguer@irit.fr

+33 6 88 16 32 84

ORCID : 0000-0003-1311-4501

Abstract

Purpose: To validate the upgraded version of the CHI with two new dimensions ("limitation of neck and/or shoulder movements", "changes in physical appearance"). To assess the relationship between CHI scores and patient self-reported management needs.

Methods: 71 patients treated for cancer with ENT complaints and 36 controls were included. Construct validity, internal consistency, criterion validity (using visual analogue scales by dimension), clinical validity (comparison of patient and control scores) and temporal reliability (scores of a second CHI completed after a few days) were studied. A hierarchical ranking of the dimensions according to perceived difficulties was compared to the CHI scores.

Results: Correlations were moderate to high between items of the same dimension ($0.38 < r < 0.73$), between scores on the two new dimensions and on the VAS ($r > 0.68$), and between scores on the two CHI completions ($r > 0.67$). Cronbach's alphas are greater than 0.72. Patients and controls had significantly different scores in the two new dimensions (Mann-Whitney: $p < 0.001$). Sensitivity, specificity and AUC calculated between CHI scores and hierarchy ranking determined patient priority cut-off scores for eight of the eleven dimensions.

Conclusion: The new CHI dimensions have good psychometric qualities. Threshold scores by dimension allow the perceived management needs to be determined.

Keywords

aerodigestive tract cancer; quality of life; handicap; self-assessment

Declarations

Funding: This study was funded by the Hospitals of Toulouse, and Grant ANR-18-CE45-0008 from The French National Research Agency in 2018 RUGBI project “Improving the measurement of intelligibility of pathological production disorders impaired speech” lead by Jérôme Farinas at IRIT (Institut de Recherche en Informatique de Toulouse).

Conflicts of Interest: All authors declare that they have no conflict of interest.

Ethics approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Consent to participate: Each subject was told in advance of the purpose of this study and was given an information sheet. The subjects' non-opposition was obtained.

Consent for publication: Not applicable

Availability of data and material: The database is available on request to the corresponding author.

Code availability: Not applicable

Authors' contributions: Virginie Woisard and Mathieu Balaguer conceived of the presented idea. Maëlle Champenois carried out the experiment. Mathieu Balaguer and Virginie Woisard helped supervise the project (conceive and plan the experiments). Mathieu Balaguer, Maëlle Champenois and Virginie Woisard contributed to the interpretation of the results. Mathieu Balaguer and Maëlle Champenois wrote the manuscript with the support of Jérôme Farinas and Julien Pinquier. All authors provided critical feedback and helped shape the research, analysis and manuscript.

1 Abstract

2 Purpose: To validate the upgraded version of the CHI with two new dimensions ("limitation
3 of neck and/or shoulder movements", "changes in physical appearance"). To assess the
4 relationship between CHI scores and patient self-reported management needs.
5 Methods: 71 patients treated for cancer with ENT complaints and 36 controls were included.
6 Construct validity, internal consistency, criterion validity (using visual analogue scales by
7 dimension), clinical validity (comparison of patient and control scores) and temporal
8 reliability (scores of a second CHI completed after a few days) were studied. A hierarchical
9 ranking of the dimensions according to perceived difficulties was compared to the CHI
10 scores.
11 Results: Correlations were moderate to high between items of the same dimension
12 ($0.38 < r < 0.73$), between scores on the two new dimensions and on the VAS ($r > 0.68$), and
13 between scores on the two CHI completions ($r > 0.67$). Cronbach's alphas are greater than 0.72.
14 Patients and controls had significantly different scores in the two new dimensions (Mann-
15 Whitney: $p < 0.001$). Sensitivity, specificity and AUC calculated between CHI scores and
16 hierarchy ranking determined patient priority cut-off scores for eight of the eleven
17 dimensions.
18 Conclusion: The new CHI dimensions have good psychometric qualities. Threshold scores by
19 dimension allow the perceived management needs to be determined.
20

21 Main article

23 **1. Introduction**

24
25 Upper aerodigestive tract (UAT) cancers are common forms of cancer. The mortality rate
26 associated with this type of cancer is decreasing thanks to advances in medical research. More
27 and more individuals are living with the treatment-related sequelae of these conditions or are
28 developing late-onset side effects. Quality of life is negatively impacted [1, 2] by altering key
29 functions in the ENT domain.
30 Furthermore, symptom evaluation does not always predict the impact a given symptom will
31 have on how an individual functions. The impact of treatment sequelae on daily life differs
32 from one person to the next [3, 4, 5]. Nowadays, consideration of quality of life measures in
33 clinical practice appears to be of paramount importance in order to individualise, optimise and
34 coordinate the management strategy offered to patients. For example, the priority of some
35 laryngectomized patients is to be able to eat a normal diet, when swallowing abilities are
36 degraded after radiotherapy, more than getting a new voice. Similarly, the identification of
37 deficits related to neck or shoulder restrictions will allow earlier and more effective referral to
38 a physiotherapist.
39 Numerous studies have highlighted the benefits to practitioners when these measures are
40 readily available [6].
41 Many tools have been developed for this purpose, particularly in oncology: the European
42 Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire
43 or University of Washington Quality of Life (UWQOL) Questionnaire [7]. Additional
44 modules, specific to tumour sites, such as the Head and Neck 35 relating to cancers [8], are
45 also available. Other handicap indices specific to a particular function are also used in clinical
46 practice, such as the Speech Handicap Index (SHI) [9] or the Phonation Handicap Index [10]
47 which address the functional impact on speech. The concept of the "Patient Concerns
48 Inventory" (PCI) [11] has also been developed at the same time. This questionnaire is used to

49 identify the concerns that patients want to raise during their follow-up appointment. The
50 benefits of such tools have been demonstrated in current clinical practice [12].
51 The Carcinologic Handicap Index was developed along these lines [13]. It is aimed at
52 assessing the perceived symptoms in the UAT area after cancer treatment, regardless of the
53 initial location of the tumour. To that end, the CHI can be considered as a generic tool in
54 cancerology. The studies carried out with the first version of the CHI showed that the
55 questionnaire has good psychometric features which corroborate its use in clinical practice
56 [13]. However, the practical implementation of this tool highlighted the absence of two
57 dimensions that often pose problems for patients: limitation of neck and/or shoulder
58 movements and the psychosocial impact of changes in physical appearance. To address this,
59 the CHI has been upgraded to include these two new domains. In addition, the PCI approach
60 now begs the question whether the CHI can be used to determine patient priorities in
61 implementing appropriate management strategies.
62 Thus the main purpose of this study was to validate the upgraded version of the Carcinologic
63 Handicap Index following the addition of the two new dimensions. A second objective for
64 ecological purposes focused on highlighting the link between CHI scores and patients' needs
65 in terms of management strategy.

66

67 **2. Material and method**

68

69

2.1 Inclusion and non-inclusion criteria

70 This observational, prospective, cross-sectional questionnaire validation study was carried out
71 between November 2017 and March 2018.

72

73 Current cancer patients or those who previously had cancer (ADT cancer or another site)
74 attending the Oncology Rehabilitation Unit at the Toulouse University Cancer Institute and
75 presenting an ENT problem to justify the consultation, were enrolled in the study.

76 No restrictions were imposed in terms of the tumour site, stage or characteristics of the
77 disease, or the type of treatment administered.

78

79 A "control" population was also recruited at the same time. This control tended to be matched
80 to the patient group as closely as possible in terms of age, gender and socio-professional
81 category in order to compare the answers of these diverse groups to the questionnaire. So, this
82 control cohort was recruited from individuals accompanying patients and from the families of
83 speech therapy students.

84

85 Each patient was told in advance of the purpose of this study and was given an information
86 sheet. The subjects' informed consent was obtained.

87

88

2.2 Data collected

89 The subjects (patients and controls) completed an initial CHI on enrolment. The upgraded
90 version of the CHI was distributed: in addition to the nine initial dimensions (pain,
91 swallowing, feeding, respiration, phonation, hearing, vision, olfaction-gustation,
92 psychosocial), it also included the two new dimensions, "limitation of neck and/or shoulder
93 movements" and "changes in physical appearance" (see Appendix 1).

94 These two new domains were created along the same lines (validity of content) as the original
95 design: an initial drafting phase in discussions with the nursing team to generate relevant
96 questions to ask in each new domain. A second patient testing phase was carried out to check
97 the relevance and assess the clarity and comprehensibility of the questions.

98 Each of the eleven dimensions included four questions modelled on the Likert 5-point scale.
99 For each question, the subjects had to tick a box that best described the difficulty they
100 perceived (ranging from 0 "never" to 4 "always"). This generated a score for each item (from
101 0 to 4) and a sub-score per domain corresponding to the sum of the scores obtained in relation
102 to the questions asked in that domain (from 0 to 16). The higher the score obtained, the
103 greater the difficulty perceived by the patient.
104 The scores given by the patients and controls in this first CHI were compared to check clinical
105 validity. The patient scores were used to study construct validity by analysing the score
106 correlation matrix for inter- and intra-dimension items, and a confirmatory factor analysis
107 conducted a posteriori.
108 The patients also completed a visual analogue scale (VAS) for each dimension. Criterion
109 validity was investigated by comparing the VAS and CHI scores for each dimension.
110
111 The patients were given a second CHI and stamped envelope on enrolment in the study. The
112 patients were asked to complete this second CHI seven to fifteen days later, which allowed
113 temporal stability (test-retest reliability) to be studied.
114
115 Finally, the patients ranked the 11 CHI dimensions, as instructed below, on the day of
116 enrolment in order to study the link between the CHI results and the patients' needs: "Please
117 rank the following symptoms in order, from most problematic to least problematic, depending
118 on your own feelings at this time". A ranking was then established, with a value of 1 being
119 allocated to the priority dimension (the one placed by the patient at the top of the list) and 11
120 to the dimension considered by the patient to be least important. To compare this ranking
121 against CHI scores, the CHI dimensions were also ranked. A value of 1 was allocated to the
122 dimension with the highest sub-score and 11 to the lowest sub-score.
123 The performance of the CHI in terms of screening priority patient management dimensions
124 was then investigated. Any score greater than or equal to a dimension cut-off value is the
125 score from which the dimension can be considered a priority for the patient.

126
127

2.3 Data analysis

128 Non-parametric statistical tests were used given the non-Gaussian distribution of the data
129 (assessed using Shapiro-Wilk tests).
130 The terminology used complies with COSMIN recommendations [14].
131 Construct validity (study of score correlations per inter- and intra-domain item, criterion
132 validity (sub-scores and VAS) and temporal stability) were thus assessed using Spearman's
133 rank correlation coefficients.
134 Clinical validity in terms of the difference between patient and control scores was
135 investigated using Mann-Whitney's U test. The level of significance was established at 0.005.
136 The results with p values ranging from $0.005 \leq p \leq 0.05$ were deemed to be suggestive
137 whereas results with a p value greater than or equal to 0.05 were considered insignificant [15,
138 16].
139 Internal consistency was measured using Cronbach's alpha coefficients.
140
141 Regarding the secondary objective, a statistical comparison of the scores obtained in the
142 questionnaire and the subjective ranking of the dimensions based on the difficulties perceived
143 by the patients themselves was carried out by analysing intraclass correlation coefficients.
144 The CHI outcome in terms of screening priority patient domains was determined by means of
145 an ROC (Receiver Operating Characteristic) curve analysis to facilitate the practical
146 application of this questionnaire. To this end, a binary variable was created. A value of 1 was
147 allocated if the domain ranked in the top three highest scores on completion of the patient

148 questionnaire, and 0 if it ranked between positions four and eleven. Thus, the area under the
149 curve could be calculated for each domain (with its 95% confidence interval) alongside
150 performance in terms of sensitivity, specificity and proportion of items ranked correctly for
151 each score obtained. This calculation was used to determine the cut-off value from which the
152 domain can be deemed a management priority by the patient: sensitivity and specificity had to
153 be greater than 50% with at least 50% of items ranked correctly.

154

155 Stata 14.2 software was used for all statistical analyses.

156

157 **3. Results**

158

159 *3.1 Population*

160

161 Seventy one (71) patients (46 men and 25 women with an average age of 64.5) were enrolled
162 in the study (Table 1).

163 The length of time since completion of treatment ranged from zero months (currently on
164 follow-up) to 240 months (20 years). The length of time since completion of treatment ranged
165 from zero to 21 months for 50 percent of patients.

166 19.7% of patients were treated for a tumour in the oral cavity, 21.1% for the larynx, 29.6% for
167 a pharyngeal tumour and 7% for an ENT tumour in a different location (thyroid or cervical
168 adenopathy with no primary site). 22.6% of patients had been treated for cancer in another
169 location but presented an ENT problem leading to the consultation.

170 Thirty-six (36) controls (19 women and 17 men with an average age of 59.5) were also
171 enrolled in the study (Table 1).

172

173 *3.2 Construct validity: convergent and discriminant validity for the two new dimensions*

174

175 In terms of convergent validity, the inter-item correlation coefficients in the same domain
176 ranged from 0.35 to 0.61 for "limitation of neck and/or shoulder movements" and from 0.37
177 to 0.74 for "changes in physical appearance".

178 With regard to discriminant validity, for the "limitation of neck and/or shoulder movements"
179 dimension, correlation scores below 0.35 (i.e. the lowest intra-domain correlation for this
180 domain) were recorded for 156 items out of 160 (97.5%). For the "Changes in physical
181 appearance" dimension, correlation scores below 0.374 (lowest intra-domain correlation for
182 this domain) were recorded for 136 items out of 160 (85%) (Table 2).

183 Confirmatory factor analysis revealed strong correlations between the items in each
184 dimension for seven out of eleven dimensions whereas the "Changes in physical appearance"
185 and "Psychosocial" items were strongly correlated and regrouped in the same factor. The
186 same applies to the items in the "Swallowing" and "Feeding" dimensions.

187

188 *3.3 Clinical validity: comparison of patient and control scores*

189

190 A significant difference in scores ($p < 0.001$) was recorded between patients and controls for
191 eight out of the eleven Carcinologic Handicap Index dimensions (Swallowing, Feeding,
192 Phonation, Respiration, Olfaction/Gustation, Psychosocial, Limitation of neck and/or
193 shoulder movements, Changes in physical appearance). A suggestive difference between
194 patients and controls was noted with regard to the Hearing dimension. There was no
195 significant difference between the Pain and Vision dimensions.

196 With specific focus on the two new dimensions, a mean score of 7.23 (standard deviation:
197 4.75) was recorded for patients and a mean score of 1.61 (standard deviation: 2.59) for the

198 controls (Mann-Whitney, $p < 0.001$) for the "Limitation of neck and/or shoulder movements"
199 dimension compared to mean scores of 4.87 (standard deviation: 4.45) for patients and 0.55
200 (standard deviation: 0.91) for the controls (Mann-Whitney, $p < 0.001$) for the "Changes in
201 physical appearance" dimension.

202 *3.4 Criterion validity*

204 Spearman's correlation coefficients between the score obtained in the CHI domain and the
205 VAS score for the corresponding domain were calculated.

207 A strong correlation between CHI and VAS was recorded for both new dimensions ($r = 0.74$,
208 $p < 0.001$ for "Changes in physical appearance" and $r = 0.68$, $p < 0.001$ for "Limitation of neck
209 and/or shoulder movements").

210 *3.5 Reliability of the questionnaire: internal consistency and temporal stability*

212 High Cronbach alphas were recorded for the two new dimensions. Alphas ranging from 0.75
213 to 0.83 and from 0.73 to 0.79 were documented for the "Changes in physical appearance" and
214 "Limitation of neck and/or shoulder movements" dimensions, respectively.

216 With regard to temporal stability, 58% of the questionnaires were returned (41 questionnaires
217 out of the 71 included on D0). Because radiotherapy may impact specific functions (e.g.,
218 mucositis may impair swallowing) after a 15-day delay, one patient who filled in his first CHI
219 less than one month after the end of treatment was excluded from this analysis.

221 On average, patients completed the second questionnaire nine days after the first. The
222 correlation coefficient for the "Changes in physical appearance" dimension was $r = 0.67$
223 ($p < 0.001$) compared to $r = 0.78$ ($p < 0.001$) for the "Limitation of neck and/or shoulder
224 movements" dimension.

225 *3.5 Link between the Carcinologic Handicap Index results and prioritisation of 226 patients' needs (secondary objective)*

228 Calculation of the intraclass correlation coefficient (ICC) per subject between the two
229 rankings (ranking of needs and ranking based on CHI) revealed relatively high ICCs with a
230 peak ranging from 0.6 to 0.8. The confidence interval of this ICC does not include a value of
231 1 in 54% of cases (38/70). There is a significant or suggestive difference between the two
232 rankings.

234 Considering the top three dimensions in both rankings, there is a connection between 2
235 symptoms for 56% of patients.

236 The AUC (area under the curve) with its 95% confidence interval and the chosen cut-off
237 value (with sensitivity, specificity and corresponding items ranked correctly) were calculated
238 for each dimension (Table 3). The threshold parameters were not calculated for an AUC
239 confidence interval of 0.50, thus demonstrating poor screening performance in the dimension.

241 **4. Discussion**

242 *4.1 Validity and reliability of the upgraded CHI version*

243
244
245

246 The two new domains added to the CHI possess good psychometric qualities and can be
247 seamlessly integrated into the overall questionnaire, as shown by the convergent and
248 discriminant validity scores coupled with the internal consistency of the new domains.
249 Two points should be noted regarding the analysis of the two new dimensions.
250 Patients' age and sex may influence their answers to items in the "Changes in physical
251 appearance" dimension. Treatments are often mutilating and contribute to degrading the
252 physical appearance of the face. Indeed, younger and professionally active patients may for
253 example have a different perception of the impact of the aesthetic changes following
254 treatment of their cancer.

255 Regarding the "Limitations of neck and/or shoulder movement" dimension, the first question
256 can be considered ambiguous. Indeed, patients are asked about the change in sensitivity in
257 their neck, shoulders and/or arms. However, it does not directly question the notion of pain in
258 the shoulders, which is frequent in the case of neck dissections [17]. However, perceived pain
259 in these anatomical structures will still be reported by patients in the "Pain" dimension.
260

261 The scores obtained for the inter-domain correlation of the entire questionnaire (see Appendix
262 2) are relatively low, which confirms that the domains focus on different areas. This last
263 conclusion should be weighted on the basis of three observations.

264 The strong correlation between the Swallowing and Feeding dimensions is probably linked to
265 the first two questions, N1 and N2, which concentrate on the symptoms directly related to
266 swallowing difficulties. The Feeding domain can therefore be partly used to assess the impact
267 of swallowing problems on the patient's nutritional status.

268 The "Psychosocial" dimension is a cross-sectional domain, rapidly impacted by the onset of
269 impaired function. The strongest correlations in this dimension ($r > 0.60$) are apparent in
270 "Phonation" and, above all, in the CHI "Changes in physical appearance" dimension.

271 Psychosocial aspects are therefore known to primarily impact the dimensions involved in
272 interpersonal communication, through speech or physical appearance. Although the other
273 correlations are weaker ($r < 0.50$), they are nevertheless still informative because they allow
274 the therapist to gain an insight into how the individual is feeling overall as a result of the
275 treatment sequelae. However, this questions the impact of a high score in this domain on
276 interpreting the questionnaire. Given the strong correlations observed ($r > 0.60$), the
277 "Psychosocial" dimension appears to influence how patients score the "Phonation" and
278 "Changes in physical appearance" dimensions. An additional analysis was carried out to
279 assess this point by weighting the scores of both these dimensions with a strong
280 "Psychosocial" correlation using simple robust regression analysis (with the target dimension
281 score expressed as the dependent variable and the Psychosocial score as the explanatory
282 variable). Each time the psychosocial score increases by one point, the "Changes in physical
283 appearance" score increases by 0.60 point ($p < 0.001$) and the "Phonation" score by 0.67 point
284 ($p < 0.001$). The scores allocated to other dimensions with higher cohorts could also be
285 analysed in this way to establish whether dimension scores should be qualified according to
286 the "Psychosocial" score to facilitate a more precise interpretation of CHI results.

287 In terms of the other more weakly correlated dimensions, is the psychosocial difficulty due to
288 other deficiencies listed in the CHI? This dimension, which refers to the prioritisation of
289 human needs according to Marslow [18], is probably a reflection of the physiological needs at
290 stake and their impact on other human needs. This mainly concerns the need for security,
291 which also changes because an individual has been diagnosed with cancer, and the impact on
292 appearance and self-esteem. A marked psychosocial impact through these strong correlations
293 with certain dimensions may therefore lead to a change in scoring, regardless of the extent of
294 the deficiency.
295

296 The other psychometric analyses of the validity and reliability of the upgraded version of the
297 CHI confirm the relevance of the questionnaire for an ENT cancer cohort with particular
298 emphasis on the two additional CHI dimensions. Given the clear connection between the
299 questionnaire scores and the way in which patients rate their difficulty in VAS terms, it can be
300 concluded that the two new dimensions clearly portray the difficulty perceived by patients.
301 The CHI was built to address the needs of patients in order to tailor the care strategy. It is
302 deliberately generic, so that it can be administered to all patients with a deficit or complaint
303 regarding upper aerodigestive tract function, whether or not the initial tumor location is in the
304 oro-pharyngeal area. While patients' complaints and needs may differ depending on the tumor
305 location, the treatment method, the age or the sex, the construction of this tool allows to take
306 these factors into account. The sub-scores corresponding to each dimension will highlight the
307 deficits that predominantly affect each patient, according to these factors. Moreover, the
308 validation of the modular aspect of this upgraded version of the CHI allows to adapt the
309 choice of dimensions presented to the patient to a specific complaint depending for example
310 on the initial tumor location. However, the calculation of threshold scores requires further
311 clarification. It is indeed likely that these scores differ according to tumour location with
312 specific functional consequences in the case of oral or breast cancer with an ENT complaint
313 for example. This study should therefore be continued to increase the number of patients
314 treated specifically for UAT and calculating specific threshold scores for this population.
315 However, there is no significant difference between the control and patient populations for
316 certain dimensions such as Pain and Vision. These results are similar to those obtained during
317 the initial CHI validation [12]. Compared to the initial publication, this study shows the
318 "disappearance" of insignificance for the hearing domain, which is linked to the fact that the
319 general population was represented by twice the size of the original sample used in the first
320 validation (36 individuals compared to 18). Apart from the statistical problem of sample size
321 and potential lack of power, these dimensions also focus on current problems, the frequency
322 of which increases with age and which are therefore easily identifiable in our study
323 populations.
324 The results of internal consistency, investigated using Cronbach's alpha coefficients,
325 demonstrate good homogeneity for both domains.

327 ***4.2 Determination of patient needs in adopting a therapeutic strategy***

328
329 The upgraded CHI version prioritises patient needs, not for the entire questionnaire but for the
330 initial symptoms with the highest scores.

331
332 Firstly, any decisions regarding management needs cannot be based on the top score alone
333 since it is not necessarily indicative of the most debilitating symptom as far as the patient is
334 concerned. This means that the practitioner should not focus on the cardinal symptom and
335 highlight this as the cause of all the patient's problems. On the other hand, it is not necessarily
336 practical to take into consideration all symptoms with a score above zero because the domains
337 with the lowest CHI scores are often barely debilitating for patients. Indeed they often rank at
338 the bottom in terms of prioritised needs, or are not even ranked at all.

339 Hence, the trend in current clinical practice to consider the associated functional impact is
340 perfectly in line with the WHO's International Classification of Functioning. The CHI
341 directly targets activity limitations and participation restrictions in order to tailor care for each
342 patient. Moreover, the CHI should be used early on and at regular intervals during the
343 patient's follow-up. The expressed needs may change according to the recovery progress and
344 the chronic nature of the disease. The CHI is a suitable tool to best adapt the therapeutic
345 strategy of each patient over time.

346 Conversely, this study shows that it is relevant in clinical practice to take into consideration
347 three to five symptoms with the highest CHI scores. The questionnaire prioritises patient
348 needs, not for the entire questionnaire *per se* but for those symptoms with the highest scores.
349 The latter coincide with the patient's feelings and expectations. In clinical practice, good
350 psychometric results were recorded when screening priority areas for the patient, primarily in
351 the following domains: "Swallowing", "Phonation", "Hearing", "Olfaction-Gustation" and
352 "Feeding" (area under the curve >0.74 and ranking performance >75%). The screening
353 performances for the "Pain", "Respiration" and "Limitation of neck and/or shoulder
354 movements" dimensions are still acceptable, albeit to less of an extent. The "Psychosocial
355 impact" and "Changes in physical appearance" domains in turn, are not significant in terms of
356 screening performance. Thus, although the threshold scores seem to be feasible for eight out
357 of the eleven dimensions, use of the CHI should still be supported by patient discussion to
358 establish the impact of the problem and the importance attached to it in terms of
359 "Psychosocial impact", "Changes in physical appearance" and "Vision".

360 **4.3 Perspectives**

361
362 Although the CHI was built to assess the dimensions by asking patients about their general
363 complaints after cancer treatment, environmental, socio-educational and cultural factors may
364 modify the perception of deficits. Therefore, the CHI might need to be revalidated before
365 being used in populations from different socio-cultural backgrounds. The problem
366 encountered by tube-fed patients is another important item for consideration in subsequent
367 developments. Indeed, the wording of the "Swallowing" and "Feeding" questions does not
368 allow tube-fed patients to 'voice' their problems. Given the strong correlation that generally
369 exists between these two areas, it would seem useful to establish whether the rules governing
370 use or interpretation could improve usage or whether both these dimensions should be
371 reconstructed.

372
373 Furthermore, the psychosocial dimension is often scored but it does not always appear to be a
374 priority for the patient (particularly for tube-fed patients, which corroborates our earlier
375 analysis in this area). It is assumed that, faced with "physical" symptoms such as swallowing
376 difficulties, speech problems or even pain, it is more difficult for patients to assess any
377 feelings of isolation or depression. Moreover, this is once again a cross-sectional domain and
378 questions are answered in the affirmative as soon as treatment sequelae impact daily life,
379 albeit not to any considerable extent.

380
381 It is therefore entirely appropriate to consider a modular CHI format where patients are
382 questioned on only one or more specific dimensions. As the perceived needs may differ
383 depending on the age, professional activity, sex, tumor location, treatment and functional
384 recovery, an evaluation of the relevance of some dimensions according to these parameters
385 and the patient's profile could be carried out in a future study.

386 The use of an overall cumulative score does not seem relevant given the heterogeneity of the
387 dimensions tested and the fact that patients' feelings could be linked to the tumour site, for
388 instance, or to the psychosocial dynamics in which individual patients find themselves.

389 **5. Conclusion**

390
391
392 Thanks to its good psychometric properties and appropriate clinical use, the CHI allows
393 practitioners to steer the consultation directly to these symptoms or even to refer the patient to
394 another professional, if required. CHI performance should ideally be compared to a

395 questionnaire such as the Patient Concerns Inventory to check its validity in terms of the
396 merits of CHI as a tool for steering patient/therapist consultations.
397 Finally, we suggest that the upgraded version of the CHI be renamed to align this tool more
398 accurately with the underlying objectives: "Head and Neck Carcinologic Handicap Index
399 (HN-CHI)".

6. Bibliographical references

- [1] Mlynarek A., Rieger J., Harris J., et al. Methods of functional outcomes assessment following treatment of oral and oropharyngeal cancer: review of the literature. *J Otolaryngol Head Neck Surg.* 2008; 37(1) : 2–10.
- [2] Reich M. Cancer and Body Image : Identity, Representation. *Inf Psych.* 2009; 85(3): 247–254. <https://doi.org/10.3917/inpsy.8503.0247>
- [3] Borggreven P. A., Verdonck-De Leeuw I. M., Muller M. J., et al. Quality of life and functional status in patients with cancer of the oral cavity and oropharynx: Pretreatment values of a prospective study. *Eur Arch Otorhinolaryngol.* 2007; 264(6) : 651–657. <https://doi.org/10.1007/s00405-007-0249-5>
- [4] DeNittis A. S., Machtay M., Rosenthal D. I., et al. Advanced oropharyngeal carcinoma treated with surgery and radiotherapy: Oncologic outcome and functional assessment. *Am J Otolaryngol.* 2001; 22(5): 329–335. <https://doi.org/10.1053/ajot.2001.26492>
- [5] Stelzle F., Knipfer, C. Schuster M., et al. Factors influencing relative speech intelligibility in patients with oral squamous cell carcinoma: A prospective study using automatic, computer-based speech analysis. *Int J Oral Maxillofac Surg.* 2013 ; 42(11) : 1377–1384. <https://doi.org/10.1016/j.ijom.2013.05.021>
- [6] Murphy B. A., Ridner S., Wells N., Dietrich M. Quality of life research in head and neck cancer: A review of the current state of the science. *Crit Rev Oncol Hematol.* 2007; 62(3): 251–267. <https://doi.org/10.1016/j.critrevonc.2006.07.005>
- [7] Thomas L., Jones T. M., Tandon S., Carding P., Lowe D., Rogers S. Speech and voice outcomes in oropharyngeal cancer and evaluation of the University of Washington Quality of Life speech domain. *Clin Otolaryngol.* 2009; 34(1): 34–42. <https://doi.org/10.1111/j.1749-4486.2008.01830.x>
- [8] Bjordal B. K., Hammerlid E., Ahlner-elmqvist M., et al. Quality of Life in Head and Neck Cancer Patients : Validation of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - H&N35. *J Clin Oncol.* 2016 ; 17(3): 1008–1019.
- [9] Rinkel R. N., Leeuw I. M. V., Van-Reij E. J., Aaronson N. K., Leemans R. Speech Handicap Index in patients with oral and pharyngeal cancer: better understanding of patients' complaints. *Head Neck.* 2008; 30: 868–874. <https://doi.org/10.1002/HED>
- [10] Balaguer M., Farinas J., Fichaux-Bourin P., Puech M., Pinquier J., Woisard, V. 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. *Folia Phoniatr Logop.* 2019 ; 15: 1–14. <https://doi.org/10.1159/000503448>
- [11] Rogers S. N., El-Sheikha J., & Lowe D. The development of a Patients Concerns Inventory (PCI) to help reveal patients concerns in the head and neck clinic. *Oral Oncol.* 2009; 45(7): 555–561. <https://doi.org/10.1016/j.oraloncology.2008.09.004>
- [12] Rogers S. N., Lowe D., Lowies C., et al. Improving quality of life through the routine use of the patient concerns inventory for head and neck cancer patients: A cluster preference randomized controlled trial. *BMC Cancer.* 2018; 18(1), 1–10. <https://doi.org/10.1186/s12885-018-4355-0>
- [13] Balaguer M., Percodani J., Woisard V. The Carcinologic Handicap Index (CHI): A disability self-assessment questionnaire for head and neck cancer patients. *Eur Ann Otorhinolaryngol Head Neck Dis.* 2017; 134(6): 399-403. <https://doi.org/10.1016/j.anorl.2017.06.010>
- [14] Mokkink L. B., Terwee C. B., Patrick D. L., et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *J Clin Epidemiol.* 2010 ;63(7),

- 737–745. <https://doi.org/10.1016/j.jclinepi.2010.02.006>
- [15] Ioannidis, J. P. A. The proposal to lower P value thresholds to .005. 2018; 319(14), 1429–1430. <https://doi.org/10.1001/jama.2018.1536>
- [16] Laccourreye, O., Lisan, Q., Bonfils, P., et al. Use of P-values and the terms “significant”, “non-significant” and “suggestive” in Abstracts in the European Annals of Otorhinolaryngology, Head & Neck Diseases. *Eur Ann of Otorhinolaryngol Head Neck Dis.* 2019; 136(6), 469–473. <https://doi.org/10.1016/j.anorl.2019.10.008>
- [17] Manning, M., Stell, P. M. The shoulder after radical neck dissection. *Clinical Otolaryngology.* 14 ; 5: 381–384. doi:10.1111/j.1365-2273.1989.tb00389.x
- [18] Maslow A. H. A theory of human motivation. *Psychological Review.* 1943 ; 50(4), 370–396.

Variable		Patients		Controls	
		Frequency	Percentage	Frequency	Percentage
Gender	Male	46	64.79%	17	
	Female	25	35.12%	19	
Age	In years: mean (sd)	64.54 (10.15)		59.53 (10.23)	
	In years: median [P25; P75]	65 [60; 72]		58 [55; 60.5]	
Tumour site	Oral cavity	14	19.72%		
	Larynx	15	21.13%		
	Pharynx	21	29.58%		
	Other ENT sites ¹	5	7.04%		
	Other site (non-ENT) ²	16	22.54%		
Surgery	No	20	28.17%		
	Yes	48	67.61%		
	Not involved	3	4.23%		
Radiotherapy	No	12	16.90%		
	Yes	56	78.87%		
	Not involved	3	4.23%		
Chemotherapy	No	33	46.48%		
	Yes	35	49.30%		
	Not involved	3	4.23%		
Other treatment (clinical trial, immunotherapy, IRA therapy, laser, hormone therapy)	No	59	83.10%		
	Yes	9	12.68%		
	Not involved	3	4.23%		
Length of time since end of treatment	In months: median [P25; P75]	21 [6 ; 84]			

Table 1: description of subjects enrolled in the study

¹ Cervical adenopathy with no primary, thyroid

² Breast, acute leukaemia, CUP (Carcinoma with Unknown Primary tumour) syndrome, retro-orbital melanoma, prostate, lungs, ovary, paraganglioma, brain stem

Dimension	Limitation of neck and/or shoulder movements (Lowest intra-domain correlation: r=0.351)			Changes in physical appearance (Lowest intra-domain correlation: r=0.374)		
	Highest coefficient	Lowest coefficient	Number of inter-domain correlation r>0.351	Highest coefficient	Lowest coefficient	Number of inter-domain correlation r>0.374
Pain	0.24	0.04	0	0.37	0.03	0
Swallowing	0.40	0.01	1	0.32	0.11	0
Feeding	0.29	0.00	0	0.42	0.05	2
Respiration	0.36	0.04	1	0.42	0.08	1
Phonation	0.29	0.03	0	0.50	0.12	3
Hearing	0.21	0.03	0	0.14	0.00	0
Vision	0.22	0.01	0	0.42	0.06	1
Olfaction-Gustation	0.28	0.02	0	0.44	0.05	1
Changes in physical appearance	0.30	0.05	0	/	/	/
Limitation of neck and/or shoulder movements	/	/	/	0.30	0.05	0
Psychosocial impact	0.41	0.07	2	0.80	0.38	16

Table 2 Detailed absolute values of inter-domain correlation scores for items in the following dimensions, namely, "Limitation of neck and/or shoulder movements" and "Changes in physical appearance"

Domain	AUC (Area Under the Curve)	95% CI of the AUC	Determination of the cut-off value			
			Cut-off value chosen (dimension score)	Sensitivity	Specificity	Ranked correctly
Pain	0.73	[0.58; 0.87]	7	64.7%	73.6%	71.4%
Swallowing	0.84	[0.73; 0.94]	4	93.6%	56.5%	81.4%
Feeding	0.78	[0.67; 0.89]	7	80.8%	72.7%	75.7%
Respiration	0.74	[0.54; 0.94]	4	87.5%	50.0%	54.3%
Phonation	0.85	[0.74; 0.95]	6	90.9%	65.4%	81.4%
Hearing	0.88	[0.79; 0.96]	8	83.3%	81.0%	81.4%
Vision	0.55	[0.35; 0.75]	ND	ND	ND	ND
Olfaction-Gustation	0.86	[0.69; 1.00]	7	77.8%	85.3%	84.3%
Changes in physical appearance	0.68	[0.49; 0.88]	ND	ND	ND	ND
Limitation of neck and/or shoulder movements	0.70	[0.57; 0.83]	7	70.8%	52.2%	58.6%
Psychosocial impact	0.48	[0.21; 0.75]	ND	ND	ND	ND

Table 3 Psychometric performances of various CHI dimensions in screening priority management areas for patients (ND: Not Determined)

Appendix 1: Head and Neck Carcinologic Handicap Index

Please tick the box that best describes your current situation where:

N = never; AN = almost never; S = sometimes; AA = almost always; A = always

		N	AN	S	AA	A
PA1	Do you take medication for pain?					
PA2	Do you wake up at night because of pain?					
PA3	Are you hindered in your activities by pain?					
PA4	Do you have pain attacks?					
SW1	Do you have discomfort swallowing?					
SW2	Do you ever choke whilst eating or drinking?					
SW3	Do you have liquid or solid reflux after eating?					
SW4	Do you have problems chewing?					
FE1	Do you need to change the texture of food to swallow it?					
FE2	Do you take longer to eat due to difficulty in swallowing?					
FE3	Do you need to enrich your food?					
FE4	Have you lost weight?					
RE1	Do you have difficulty breathing at rest?					
RE2	Do your breathing problems restrict your physical activity?					
RE3	Do you feel congested?					
RE4	Do you need to be semi-seated to sleep?					
PH1	Do you have difficulty speaking?					
PH2	Do people have difficulty understanding you?					
PH3	Do you speak less with your family, friends, neighbours?					
PH4	Do you have difficulty articulating?					
HE1	Do you ask people to repeat themselves when talking to you?					
HE2	Do you have problems following conversations in a noisy environment?					
HE3	Do you have problems understanding over the phone?					
HE4	Do you have noises in your ears?					
VI1	Do you have difficulty seeing in the shade?					
VI2	Do you see less well at a distance or close up?					
VI3	Are you bothered by dazzle or floaters in your eyes?					
VI4	Has your visual field shrunk?					
OG1	Do you have difficulty smelling?					
OG2	Are you afraid of having an accident because of your difficulty smelling?					
OG3	Do you have difficulty tasting food?					
OG4	Do you feel frustrated by your difficulty smelling and tasting?					
CP1	Are you bothered by changes in your physical appearance?					
CP2	Are you bothered by the way other people look at you since your illness?					
CP3	Is your social life limited by changes in your physical appearance?					
CP4	Has your personal life changed because of your illness?					
LI1	Have you noticed any change in sensitivity in your neck, shoulders and/or arms?					
LI2	Do you have difficulty turning your head?					
LI3	Do you have weight-bearing difficulties?					
LI4	Are you limited in raising your arms?					
PS1	Is your personal and social life limited by problems related to your illness?					
PS2	Has your illness affected your relationship with other people?					
PS3	Are you bothered by problems related to your illness?					
PS4	Do you feel handicapped by your illness?					

