

# Validation of the 10-Item Unilateral Vocal Fold Paralysis-Handicap Index quality of life questionnaire

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## Abstract

**Objectives:** To validate and test the reliability of the 10-Item Unilateral Vocal Fold Paralysis-Voice Handicap Index (UVFP-HI-10) quality of life (QoL) questionnaire for patients with UVFP.

**Design:** Prospective describe study based on perceptive surveys.

**Participants:** We recruited 61 patients with UVFP and 53 healthy individuals comprised the control group.

**Main Outcome Measures:** Both the patients and controls completed the UVFP-HI-10 questionnaire. A statistical analysis was performed to assess the internal consistency and validity of the survey. In addition, maximum phonation time (MPT) was used to objectively measure patient QoL.

**Results:** Internal consistency was high ( $\alpha = .914$ ) and the correlation with MPT was significant ( $r_s = -0.722$ ). The estimated marginal mean in the discriminant validity study was around seven times higher in the UVFP group compared to the controls. The UVFP-HI-10 cut-off value was more than 0.9 and the sensitivity and specificity were more than 0.8.

**Conclusions:** The UVFP-HI-10 is a self-administered patient-reported outcome questionnaire with a high reliability and excellent criterion-based validity. This questionnaire can be used to evaluate specific clinical complaints (e.g., vocalisation, swallowing, and breathing) in terms of their impact on QoL in patients with UVFP. Thus, its use is appropriate as a basic assessment tool as part of a specific UVFP treatment protocol.

## KEYWORDS

self-assessment questionnaire, unilateral vocal fold paralysis, validation

## 1 | INTRODUCTION

In recent years, the diagnosis of unilateral vocal fold paralysis (UVFP) has increased because more head and neck, cervical spine, and cardiothoracic surgeries are being performed.<sup>1</sup> In this context, the more lateralised the paralytic fold, the more difficult it is to complete glottic closure. The most common specific complaint in

symptomatic patients with UVFP is dysphonia, caused by a weak and breathy voice, vocal fatigue, dysphagia with aspiration, dyspnoea, ineffective coughing to mobilise secretions, and difficulty performing Valsalva manoeuvres. In severe cases, aspirations carry a high risk of pneumonia.<sup>2</sup>

The management of these patients must be individualised and focused on improving their quality of life (QoL). The international

consensus (ICON) on basic voice assessment for patients with UVFP (2018) recommends the systematic use of the Voice Handicap Index (VHI), Hirano's Grade Breathness Roughness Scale, and aerodynamic studies which should at least include an evaluation of the maximum phonation time (MPT).<sup>3</sup> However, this protocol does not involve the evaluation of the impact of non-vocal symptoms. Thus, the aim of this current study was to develop and validate a self-assessment questionnaire adapted to patients with symptomatic UVFP.

## 2 | MATERIALS AND METHODS

### 2.1 | Study design

This was a descriptive and prospective study of 114 adult patients (61 with UVFP and 53 healthy controls) recruited from January 2020 to December 2022 at a General University Hospital of Valencia, a tertiary hospital, with extensive experience in treating patients with UVFP. This project was approved by the Clinical Research Ethics Committee at the same Hospital. We used the STROBE guideline. All the patients were informed of the purpose of the work and consented to participate in it.

The sample included patients with UVFP of varying severity, as confirmed by flexible laryngoscopy. The exclusion criteria were the presence of bilateral vocal hypomobility, patients who had undergone vocal medialisation, those with a tracheotomy or aetiology compatible with laryngeal fixation. Control patients were healthy individuals without any history of vocal pathologies and who were non-smokers. Demographic data such as age and sex, the vocal paralysis cause, paralysed vocal cord side, and MPT with the phoneme /e/ were collected for the patients with UVFP. In turn, the variables of age, sex, and MPT were obtained in the control group. MPT is obtained by asking the patient to pronounce a vowel, usually 'a' or 'e', all the time he is able to do it, after a deep inspiration. Intensity and frequency of voice should be comfortable for the patient.

### 2.2 | Preparation of the questionnaire

A new questionnaire adapted to assess the impact of UVFP was developed by otorhinolaryngologists who were experts in this field (Table 1). We based the design of the new questionnaire on the 10-item Voice Handicap Index (VHI-10) questionnaire,<sup>4</sup> but adapted it to ask the patients about their experience of UVFP. Thus, we retained five questions from the VHI-10 (items 1, 3, 4, 5, and 9) and replaced the other five questions to assess the vocal and non-vocal symptoms most specific to UVFP. Hence, one question assessed difficulty with communication by telephone (item 2), another assessed shortness of breath when speaking (item 6), two questions (items 7 and 8), obtained from Dysphagia Handicap Index (DHI)<sup>5</sup> addressed the presence of dysphagia, and one question estimated difficulty with coughing or mobilising bronchial secretions (item 10).

The new questionnaire, the 10-Item Unilateral Vocal Fold Paralysis-Voice Handicap Index (UVFP-HI-10), contains seven questions

#### Key points

- The symptomatic unilateral vocal fold paralysis (UVFP) affects all laryngeal functions with physical (vocal and non-vocal) consequences and with a strong emotional impact on patients.
- Optimal management must be personalised and based on individual patient assessments.
- UVFP-HI-10 is a self-assessment questionnaire capable of evaluating specific clinical impairments that affect the quality of life of patients with UVFP.
- UVFP-HI-10 demonstrated a high reliability and excellent criterion-based validity.
- This questionnaire is suitable as a basic assessment tool for a specific UVFP treatment protocol.

on the functional sphere (items 1, 2, 3, 6, 7, 9, and 10), two questions on the physical aspect of the disease (items 4 and 5), and one question on the emotional domain (item 8). Each question was measured on a Likert-style scale with five possible numerical responses: 0 = never, 1 = almost never, 2 = sometimes, 3 = almost always, and 4 = always (Table 1). Like the VHI-10, the minimum score was 0 points and the maximum was 40 points. Thus, the values of the results were very close to those of the VHI-10, which was useful because most voice professionals are familiar with this assessment scale.

### 2.3 | Validation of the questionnaire

Both the new questionnaire and the VHI-10 (as a comparative model) were administered to patients with UVFP with different pathological profiles. We asked the patients if the questionnaire was easy to

**TABLE 1** The 10-Item Unilateral Vocal Fold Paralysis-Voice Handicap Index (UVFP-VHI-10) questionnaire for the assessment of quality of life in patients with unilateral vocal fold paralysis.

|     |                                                             |
|-----|-------------------------------------------------------------|
| 1.  | My voice makes it difficult for people to hear me.          |
| 2.  | It is difficult for me to communicate by telephone.         |
| 3.  | My voice difficulties restrict my personal and social life. |
| 4.  | My voice problem causes me to lose income.                  |
| 5.  | I feel as though I have to strain to produce voice.         |
| 6.  | I get exhausted or short of breath when I talk.             |
| 7.  | I choke or cough when drinking.                             |
| 8.  | I choke or cough when eating.                               |
| 9.  | My voice makes me feel handicapped.                         |
| 10. | My cough is ineffective.                                    |

understand, if it asked about the complaints caused by UVFP, and if they would change or add any questions; they did not request any modifications.

The total score of the UVFP-HI-10 questionnaire in patients with UVFP was recorded and compared to that from the VHI-10. In both the control group and in patients with UVFP, the MPT was used as the objective measure to determine the degree of glottal efficiency, considering a value of less than 10 s as pathological.<sup>6,7</sup>

## 2.4 | Statistical study

The data were recorded in a table using Excel software (Microsoft Corporation, 2018) and were analysed using SPSS software (version 25, IBM Corp., Armonk, NY), applying several different statistical techniques to achieve our objectives. First, the homogeneity of the two samples was calculated using Pearson Chi-squared tests (men vs. women and healthy vs. sick). The normality of the data was tested using Kolmogorov–Smirnov tests. For non-parametric data, Mann–Whitney *U* tests were used to assess age distribution, item scores, MPT, and overall score in both groups. The mean global score of the UVFP-HI-10 was compared between healthy individuals and patients with UVFP, when adjusted for age, by using a general linear model with covariances.

Rho Spearman tests were used to evaluate the associations between item/global scores and age, MPT and the global UVFP-HI-10 score, and the UVFP-HI-10 versus the VHI-10. The internal consistency and reliability of the scales in each questionnaire dimension (functional, physical, and emotional) were assessed using the Cronbach alpha estimator. A receiver operating curve (ROC) was applied to the global UVFP-HI-10 score in the UVFP group to calculate the area under the curve (AUC) and cut-off point. The significance level used in all these analyses was 5% ( $p = .05$ ).

## 3 | RESULTS

A total of 114 patients participated in this study: 59 women and 55 men. There were 61 patients with UVFP (with a mean age of 63 years) and 53 healthy controls (with a mean age of 55 years). The vocal paralysis had most often been secondary to surgery, in our study there had been 21 cases of thyroid surgery, 7 for a vagal glomus, 3 aorta dissections, 1 esophagectomy, 4 cervical spine surgeries, 2 for a jugulotympanic glomus, 1 thymoma and 1 tracheal lesion. One case of lymphoma, 5 cases of lung cancer, and 15 cases were considered idiopathic. The results of the statistical analysis are described below.

### 3.1 | Internal consistency

The global score for the UVFP-HI-10 did not differ according to sex or age. The Cronbach alpha statistic showed significant

correlation with the overall questionnaire score for all the items. The Cronbach alpha value was .914 for the functional dimension (items 1, 2, 3, and 4) and .860 for the physical dimension (items 5, 6, 7, 8, and 10), thereby demonstrating optimal consistency (Tables 2 and 3).

**TABLE 2** The internal consistency functional dimension questions (items 1, 2, 3, and 4).

| Functional dimension                                        |                    | Group |      |         |
|-------------------------------------------------------------|--------------------|-------|------|---------|
|                                                             |                    | Total | UVFP | Healthy |
| My voice makes it difficult for people to hear me.          | No. valid          | 114   | 61   | 53      |
|                                                             | Mean               | 1.68  | 2.57 | 0.64    |
|                                                             | Standard deviation | 1.48  | 1.26 | 0.94    |
|                                                             | Median             | 2.00  | 3.00 | 0.00    |
| It is difficult for me to communicate by telephone.         | No. valid          | 114   | 61   | 53      |
|                                                             | Mean               | 1.46  | 2.43 | 0.34    |
|                                                             | Standard deviation | 1.62  | 1.58 | 0.71    |
|                                                             | Median             | 1.00  | 3.00 | 0.00    |
| My voice difficulties restrict my personal and social life. | No. valid          | 114   | 61   | 53      |
|                                                             | Mean               | 1.34  | 2.38 | 0.15    |
|                                                             | Standard deviation | 1.61  | 1.47 | 0.63    |
|                                                             | Median             | 0.00  | 2.00 | 0.00    |
| I choke or cough when drinking.                             | No. valid          | 114   | 61   | 53      |
|                                                             | Mean               | 1.24  | 1.98 | 0.38    |
|                                                             | Standard deviation | 1.40  | 1.43 | 0.71    |
|                                                             | Median             | 1.00  | 2.00 | 0.00    |
| I choke or cough when eating.                               | No. valid          | 114   | 61   | 53      |
|                                                             | Mean               | 0.68  | 1.03 | 0.28    |
|                                                             | Standard deviation | 1.09  | 1.26 | 0.66    |
|                                                             | Median             | 0.00  | 1.00 | 0.00    |
| My cough is ineffective.                                    | No. valid          | 113   | 60   | 53      |
|                                                             | Mean               | 1.23  | 2.12 | 0.23    |
|                                                             | Standard deviation | 1.50  | 1.52 | 0.54    |
|                                                             | Median             | 0.00  | 2.00 | 0.00    |
| My voice problem causes me to lose income.                  | No. valid          | 93    | 48   | 45      |
|                                                             | Mean               | 0.87  | 1.56 | 0.13    |
|                                                             | Standard deviation | 1.48  | 1.76 | 0.40    |
|                                                             | Median             | 0.00  | 0.00 | 0.00    |
| Cronbach $\alpha$ statistic                                 |                    | .914  | .852 | .752    |

*Note:* The Cronbach alpha statistic showed that all the items were significantly correlated with the total value of the UVFP-VHI-10 test and therefore demonstrated an optimal consistency.  
Abbreviation: UVFP, unilateral vocal fold paralysis.

### 3.2 | Concurrent validity

When comparing the UVFP-HI-10 with the VHI-10, the Spearman Rho was 0.860 meaning that there was a strong positive correlation between them both (i.e., both tests scored similarly). When the VHI-10 had a score equal to or less than 20, 91% of the cases also scored less than or equal to 20 on the UVFP-HI-10; when the VHI score exceeded 20, 94% of the cases also had a score greater than 20 on the UVFP-HI-10.

The correlation between the MPT and the global UVFP-HI-10 score was  $-0.722$  for the Rho Spearman test. This absolute value was high (close to 1), indicating an inversely proportional relationship between these two variables (fulfilled concurrent validity) such that

**TABLE 3** The internal consistency of the physical dimension questions.

| Physical dimension                                  |                    | Group |      |         |
|-----------------------------------------------------|--------------------|-------|------|---------|
|                                                     |                    | Total | UVFP | Healthy |
| I get exhausted or short of breath when I speak.    | No. valid          | 114   | 61   | 53      |
|                                                     | Mean               | 1.65  | 2.64 | 0.51    |
|                                                     | Standard deviation | 1.59  | 1.44 | 0.78    |
|                                                     | Median             | 1.00  | 3.00 | 0.00    |
| I feel as though I have to strain to produce voice. | No. valid          | 113   | 60   | 53      |
|                                                     | Mean               | 1.48  | 2.37 | 0.47    |
|                                                     | Standard deviation | 1.55  | 1.53 | 0.75    |
|                                                     | Median             | 1.00  | 2.50 | 0.00    |
| Cronbach $\alpha$ statistic                         |                    | .860  | .758 | .641    |

Note: The Cronbach alpha statistic showed that all the items were significantly correlated with the total value of the UVFP-VHI-10 test for the physical dimension (items 5, 6, 7, 8, and 10), thereby demonstrating optimal consistency.

the lower the MPT, the higher the test score (Figure 1). Some patients had a low score, indicating that they were healthy despite their low MPT score, while others had high scores and were less healthy but nonetheless had high MPT scores.

### 3.3 | Discriminant validity

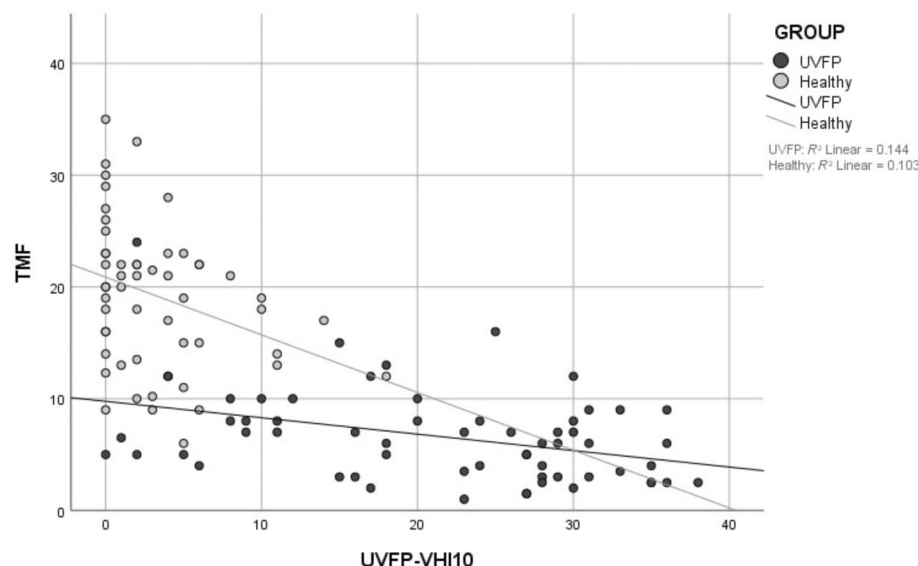
When comparing the global score for both groups, the estimated marginal mean of the UVFP-HI-10 questionnaire was around seven times higher for patients with UVFP when compared to the controls. These data indicate that the new questionnaire can detect UVFP cases (fulfilled discriminant validity; Table 4). Moreover, the AUC obtained exceeded 0.9 and the sensitivity and specificity were more than 0.8, showing that the UVFP-HI-10 had an excellent discriminatory capacity to detect patients with UVFP.

Using non-parametric Mann-Whitney  $U$  and Pearson Chi-squared tests, we observed that neither the age nor sex of the patients with UVFP influenced the overall UVFP-HI-10 score.

**TABLE 4** The discriminant validity of the UVFP-VHI-10, a general linear model with covariances.

|                   | Group |       |         | p-value<br>GLM | Cohen's <i>d</i><br>(95%<br>confidence<br>interval) |
|-------------------|-------|-------|---------|----------------|-----------------------------------------------------|
|                   | Total | UVFP  | Healthy |                |                                                     |
| UVFP-VHI-10       |       |       |         |                |                                                     |
| <i>N</i>          | 114   | 61    | 53      | .000           | 1.485                                               |
| Mean              | 12.27 | 21.35 | 3.18    |                | (1.24, 0.173)                                       |
| Standard<br>error | 0.74  | 1.36  | 0.61    |                |                                                     |

Abbreviation: GLM, generalized linear model; UVFP-VHI-10, Unilateral Vocal Fold Paralysis-Voice Handicap Index.



**FIGURE 1** The Spearman Rho correlation between the maximum phonation time (MPT) and the overall score of the UVFP-VHI-10. The negative sign indicates that there was an inversely proportional relationship between these variables: the lower the MPT, the higher the test score.

When analysing the results obtained for each of the statements in the UVFP-HI-10, the highest scores were obtained for the 'I get exhausted or short of breath when I speak' item. The lowest scores were obtained for the 'My voice problem affects my work performance' and 'I choke when eating' items.

## 4 | DISCUSSION

When evaluating and comparing surgical treatments for UVFP, the patient's voice is of great importance.<sup>8</sup> However, it is worth noting that UVFP does not only cause vocal symptoms and emotional.<sup>9</sup> In fact, the decision to treat UVFP surgically depends on the three laryngeal functions: protection of the airway, breathing, and phonation. Importantly, 60%–70% of patients with UVFP report dysphagia, manifested as coughing or choking when eating or drinking.<sup>2,10</sup> Insufficient glottic closure alters the ability of these patients to perform Valsalva manoeuvres and in cases of UVFP, coughing is ineffective to mobilise bronchial secretions.<sup>9</sup>

On the one hand, and from a clinical perspective, dysphagia in UVFP is considered the most important problem because it can cause aspiration pneumonia.<sup>2</sup> On the other hand, post-treatment correction of glottic insufficiency may alleviate phonatory dyspnoea.<sup>11</sup> Thus, it is important to collect data regarding these symptoms during patient evaluations so that the severity of these problems can be assessed and appropriate treatments can be planned but there is a lack of a UVFP specific outcome measures and few studies consider non-vocal symptoms.

In general terms, to assess the impact of dysphonia on patient QoL, it is becoming increasingly important to evaluate the efficacy of vocal treatments.<sup>12</sup> Several questionnaires are useful for these purposes, including the VHI-10, 20-item Voice Problem Self-Assessment Scale, Voice-Related Quality of Life questionnaire, Voice Performance Questionnaire, and Voice Symptom Scale, among others.<sup>12</sup> Nonetheless, these scales were not specifically developed for use with patients with UVFP and nowadays it is recommendable a disease-specific patient self-report measures.

The VHI-10, described by Jacobson,<sup>4</sup> is the most widely used of these at an international level and has the highest number of validations in different languages.<sup>13</sup> As recommended by ICON, the VHI-10 is currently the most used tool to assess UVFP treatments, although it is important to recognise that it is a generic questionnaire used for a variety of voice problems. In turn, the Eating Assessment Tool-10<sup>14</sup> is very commonly used to assess the symptoms of dysphagia in patients with UVFP, even though this questionnaire does not include liquid aspiration—a very frequent complaint in cases of severe UVFP. Thus, different questionnaires must be used to evaluate vocal and non-vocal symptoms in these patients.

There are specific questionnaires for UVFP in the literature, Gliklich et al. developed the first specific questionnaire for patients with UVFP in 1999, the Voice Outcome Survey (VOS)<sup>15</sup> to subjectively assess dysphagia. Despite its specificity, the VOS is not standardised for the evaluation of patients with UVFP. A Patient-reported

Outcome Measure to evaluate the UVFP complaints was published in 2022,<sup>16</sup> it has four subscales, 22 questions, the result requires calculation of the answers over 0–100.

We specifically developed the UVFP-HI-10 to evaluate the impact of the different symptoms of vocal fold immobility. Of note, the completion of this test is simple, both for patients and professionals. It maintains the VHI-10 structure and the score is very similar. The difference between both surveys is the assessment of all UVFP symptoms, covering the functional, physical, and emotional spheres of the disease. The UVFP-HI-10 quantitatively assesses the severity of each patient case, comparing pre- and post-treatment states.

The UVFP-HI-10 was based on the VHI-10, a survey that is very well known among speech specialists. We replaced the questions with poor discriminatory power<sup>13</sup> and added questions that were more specific to the voice-related symptoms in patients with UVFP and non-vocal symptoms, all according to individual patient experiences. We maintained five questions that we considered the most representative of the UVFP: two related to solid and liquid aspiration and another about ineffective coughing. Additionally, we also introduced the item 'I get exhausted or short of breath when I talk' because this is a very frequent symptom in patients with UVFP. Of note, this item attained the highest score on the survey, thereby reflecting the appropriateness of the new questionnaire design.

In order to validate a questionnaire, its reliability or internal consistency must be verified, it must detect and measure clinical changes in diseased individuals, and it must be simple, accepted, and adaptable by the participants, users, and professionals who use it. The UVFP-HI-10 met all of these requirements and is a simple tool whose use we believe will be acceptable and adaptable to patients and professionals alike.

In this current study, we observed discordance between the MPT results, and the UVFP-HI-10 result, with some patients showing a good score despite having a low MPT outcome and vice versa. This result indicates the subjective nature of self-assessment tools, with the results depending, among other causes, on the emotions of the participants and their specific vocal demands. Therefore, our work supports the idea that patient perceptions of their symptoms and QoL are a factor that should be considered in individualised assessments.

## 5 | CONCLUSION

Insufficient glottic closure affects all laryngeal functions. However, the consequences of UVFP extend beyond the physical, vocal, and non-vocal symptoms, because they also have a strong emotional impact on patients. Therefore, optimal management of this disease must be personalised and based on individual patient assessments. Thus, the UVFP-HI-10 is a self-assessment questionnaire capable of evaluating specific clinical impairments (e.g., vocal, swallowing, and breathing) that affect the QoL of patients with UVFP. It is short, easy to answer and scores between 0 and 40, as VHI-10. In this work, we validated this new questionnaire and we showed that it is suitable as a basic assessment tool for a specific UVFP treatment protocol.

## AUTHOR CONTRIBUTIONS

Rosa Hernández-Sandemetrio: Conception or design of the work  
 Natsuki Oishi: Critical revision of the article and data analysis and interpretation  
 Isabel López-Sánchez: Data collection  
 Isabel García-López: Drafting the article  
 Enrique Zapater: Final approval of the version to be published

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## CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

## DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analysed in this study.

## ETHICS STATEMENT

This project was approved by the Clinical Research Ethics Committee at the same Hospital.

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