Development and Preliminary Validation of a Pain Scale Specific to Patients With Voice Disorders: The Voice-Related Pain Scale (VRPS)

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Summary: Introduction. Although pain is one of the complaints reported by voice patients, still there is no valid and reliable scale to evaluate pain in Patients with Voice Disorders (PWVDs). Therefore, the aim of the present study was to develop and validate the Voice-Related Pain Scale (VRPS).

Methods. The present study was conducted in two stages: (1) development of the VRPS based on semistructured interviews with PWVDs and experts in the field of voice disorders and an in-depth literature review, and (2) Evaluation of the psychometric properties of the VRPS. Determining the validity and reliability of the VRPS was performed using qualitative and quantitative content validity, the qualitative face validity, and the test-retest reliability. Content validity of the VRPS was assessed by Speech and Language Pathologists who are experts in the assessment and treatment of voice patients and laryngologist. The reliability of the scale was determined using test-retest reliability.

Results. Based on the interviews with PWVDs and experts, and a thorough review of the related literature, a self-reported scale with 11 items and three sections was developed. The three items included ear, temporomandibular joint, and shoulder all of which were divided into right and left pairs based on the experts' suggestion. One item was eliminated because it had a content validity ratio less than 0.62. The content validity index (CVIs) for all the remaining items were higher than 0.79 and the scale content validity index was equal to 0.93. The test-retest reliability was satisfactory with weighted kappa ranging from 0.64 to 1 for VRPS items. The final version of the VRPS comprised of 13 items related to the pain location in the human body. Each of these items has three sections: frequency of pain, severity of pain, and time of pain occurrence.

Conclusion. The present study indicated that VRPS is a valid and reliable tool to evaluate pain in PWVDs. The VRPS is a useful tool for clinical and research purposes. However, more studies are needed in this regard for further evaluation of the VRPS.

Key Words: Pain−Voice−Voice disorders−Assessment−Development−Validation.

INTRODUCTION

Patients with Voice Disorders (PWVDs) have many complaints including hoarseness, vocal quality changes, breathiness, vocal fatigue, physical discomfort sensation, and pain.[1−6] Meanwhile, less attention is usually paid to the pain in the evaluating processes of these patients,[3] whereas some of the previous studies have shown that both PWVDs and professional voice users experienced pain as a consequence of their voice problems.[3,7−12] In fact, PWVDs have a higher frequency and severity of pain compared with people with normal voice.[7,10,11] Highly voice usage, improper

vocal habits, talking and speaking with excessive efforts, hyperfunctional behaviors, laryngeal, paralaryngeal, and cervical muscle misuse as well as improper postures can lead to pain sensation in PWVDs and professional voice users.[2,9,13−15] PWVDs can experience pain during phonation (odynophonia), at rest, after voice usage, and during movements,[11,15−18] and some of these patients such as patients with muscle tension dysphonia have reported pain during palpation evaluation.[17] Recent studies have indicated that pain can be sensed by PWVDs and professional users in the following areas of the body: throat, larynx, head, neck, shoulder, back, and ears.[8,12,19]

Pain is defined by the International Association for the Study of Pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage."[20] In addition to being an unpleasant and disturbing symptom,[12] pain can adversely affect the patients' well-being, daily lives, and quality of life.[1,21−23] Moreover, having a healthy and appropriate voice quality depends on human health and well-being[24] and untreated pain can cause secondary problems and increase the patients' disability.[25] Therefore, proper attention to the screening, evaluation, and treatment of pain in PWVDs is very important.[12] Given that pain is reported by voice patients as one of the important complaints and considering the

negative effects of this problem on the patients' quality of life, to deliver an appropriate treatment for pain management in PWVDs, a valid and reliable specific scale for measuring and quantifying pain in these patients is necessary. Therefore, the aim of the present study was to develop and validate the Voice-Related Pain Scale (VRPS).

MATERIALS AND METHODS

Development of the new scale to measure pain in PWVDs is reported in two stages: scale development and psychometric evaluation.

SCALE DEVELOPMENT

Item generation

We selected the scale items based on the following sources: semistructured interviews with PWVDs and experts in the field of voice disorders, and an in-depth literature review.

We conducted semistructured interviews with 30 PWVDs and 15 experts experienced in the assessment and treatment of voice disorders. The experts were clinically and academically active in the field of voice disorders and comprised of 10 speech and language pathologists and five otolaryngologists. The data were collected using face-to-face interviews and e-mails. During the interviews, notes were taken by the interviewer and all interviews were recorded and transcribed verbatim. The main questions of the interviews were as follows influencing factors in the development of MTD, neck and laryngeal anatomical structures, item categorization, appropriate title, evaluation methods, appropriate factors that can be used as criteria to assess muscle tension, and appropriate grading system.

To conduct literature review, papers published up to 2018 in the MEDLINE (PubMed), Science Direct, Scopus, Web of Knowledge, and Cochrane Library databases were searched using these keywords: "voice disorder," "dyspho*," "evaluat*," "diagnos*," "pain," "musculoskeletal pain," "larynx," "muscle*," "assess*," "tool*," "scale," "questionnaire," "psychometric," "valid*," and "reliability."

After conducting semistructured interviews and literature review, the preliminary scale was developed in several sessions in the presence of research team members. In these sessions, sections and items of the scale were refined, organized, and classified into a proper and practical format.

PSYCHOMETRIC EVALUATION

Content validity

The aim of investigating content validity of the developed scales and instruments is to determine whether the scales and items adequately address the construct of the subject under consideration.[26] To determine the content validity of the VRPS, we used both qualitative and quantitative methods. For qualitative content validity, the prepared scale was given to an expert panel consisting of seven speech and language pathologists and three otolaryngologists who are specialists in the field of voice disorders. The experts were requested to evaluate and comment on wording, item allocation, and scaling of the items.[27] Guided by this input, we subsequently revised the questionnaire.

In quantitative content validity evaluation, the above-mentioned 10 experts were requested to determine the content validity ratio (CVR) and the content validity index (CVI), respectively. To calculate the CVR, the experts were requested to assess each item using a three-point Likert scale: 1 = essential, 2 = useful but not essential, and 3 = unessential. Then, according to the Lawshe's table, items with CVR scores of 0.62 or above were selected.[28] To calculate the CVI, based on Polit et al's recommendations, the same panel evaluated the items according to a four-point Likert scale with regard to "relevancy." A CVI score of 0.78 or above was considered satisfactory.[29] The CVI can be calculated for each item's scale (referred to as I-CVI) and for the overall scale (S-CVI).[29]

Face validity

In the present study, we performed qualitative face validity. Face validity was conducted to investigate responders' understanding and comprehension of the VRPS scale (Fitzner 2007). Given that respondents to this scale are patients, we gave the prepared scale to the 10 PWVDs with pain complaint and asked them to comment on the clarity, intelligibility, the layout and style of the scale, difficulty, ambiguity, and/or incomprehensibility of the sections, items, sentences, and words of the scales. Also, they were requested to make suggestions to improve the VRPS. According to PWVDs' suggestions, some changes were made to the scale.

Reliability

To evaluate the reliability of the VRPS, the weighted kappa was determined to assess the test-retest reliability. To this end, 34 PWVDs were requested to complete the VRPS twice with 2 weeks of interval. In both administrations, the questionnaire was completed in-person by the patients and in the same way. None of the patients had received treatment during this period. It should be noted that based on the participants' statements, there were no changes in their conditions and symptoms during this 2-week interval and patients with any changes in this period were excluded from test-retest reliability analysis. Four patients were excluded from this stage of the study due to significant reduction in pain symptoms.

Ethical considerations

The present study was approved by the Ethics Committee at Semnan University of Medical Sciences, Iran (IR. SEMUMS.REC.1397.240). Participation in the present study was on a voluntary basis and the participants were all informed about the aims of the study. Moreover, the participants could withdraw at any phase of the study. It should be noted that the consent form was completed by all the participants who accepted to participate in the study.

Statistical analysis

In the present study, we used a weighted kappa (k*) statistic for test-retest reliability for each single item, since the VRPS items are ordered categorically. The MedCalc software (MedCalc Software, version 15.0, Ostend, Belgium) was used to determine weighted kappa. To interpret the determined weighted kappa, the following benchmarks suggested by Landis and Koch[30] was used <0.00 = poor, 0.00 −0.20 = slight, 0.21−0.40 = fair, 0.41−0.60 = moderate, 0.61−0.80 = substantial, and 0.81−1.0 = almost perfect.

RESULTS

Scale development

According to the literature review and semistructured interviews with experts and PWVDs, four issues were extracted that were relevant to the pain assessment in PWVDs and should be present in the scale. These issues were pain location, frequency of pain, severity of pain, and time of pain occurrence. According to the suggestion by the research team, pain locations were considered as items in the scale and other issues (frequency of pain, severity of pain, and time of pain occurrence) formed the three sections of each item. This means that each respondent must comment on the frequency of pain, severity of pain, and time of pain occurrence for each part of the body which exists in the scale. Finally, the primary items pool of the scale comprised

of 11 items related to the pain location with each item having three sections: frequency of pain, severity of pain, and time of pain occurrence. Time of pain occurrence section included the following four items: during speaking, after speaking, during swallowing, and all the time. After developing the initial scale, in several sessions, the scale was examined by the members of the research team and they determined its different sections, style, and scoring system for different sections.

Psychometric evaluation

Content validity

In the qualitative content validity stage, the expert panel members commented on the initial version of the scale. At this stage, based on the experts' suggestions, the following changes were applied to the scale: the masticatory muscle was changed to the temporomandibular joint; the ear, temporomandibular joint, and shoulder were divided into right and left pairs; a new item called "Pain after long time speaking" was added to the "time of pain occurrence"; and the item of "pain during swallowing" from the "time of pain occurrence" section was changed to the "pain during swallowing (eating liquids or food)." Also, some changes were made to the words, sentences, and instruction section of the scale in order to make it more clear and obvious.

The results of the CVR and CVI calculation are presented in Tables 1 and 2, respectively. The CVRs all items, except

TABLE 1.
Calculating CVR for the Voice-Related Pain Scale (VRPS)

Number	Items/Sections	Unessential	Useful But Not Essential	Essential	CVR	Interpretation
	Location of pain					
1	Head	4	3	3	0.4	Eliminated
2	Right ear			10	1	Remained
3	Left ear			10	1	Remained
4	Right TMJ		1	9	0.8	Remained
5	Left TMJ		1	9	0.8	Remained
6	Submental area			10	1	Remained
7	Anterior neck			10	1	Remained
8	Posterior neck		1	9	0.8	Remained
9	Throat		1	9	0.8	Remained
10	Larynx		1	9	0.8	Remained
11	Chest	1		9	0.8	Remained
12	Right shoulder		1	9	0.8	Remained
13	Left shoulder		1	9	0.8	Remained
14	Upper back	1		9	0.8	Remained
	Frequency of pain					
	Severity of pain					
	Time of pain occurrence					
14	During speaking			10	1	Remained
15	After speaking			10	1	Remained
16	During swallowing		1	9	0.8	Remained
17	After long time speaking			10	1	Remained
18	All the time			10	1	Remained

Note: Number of experts (N = 10), the items with the CVR lower than 0.62 eliminated.
Abbreviation: CVR, content validity ratio.

TABLE 2.
Calculating CVI for the Voice-Related Pain Scale (VRPS)

Number	Items/Sections	Not Relevant	Somewhat Relevant	Acceptable Relevant	Very Relevant	I-CVI	Interpretation
	Location of pain						
1	Right ear		1	1	8	0.9	Remained
2	Left ear		1	1	8	0.9	Remained
3	Right TMJ		1	1	8	0.9	Remained
4	Left TMJ		1	1	8	0.9	Remained
5	Submental area		1	1	8	0.9	Remained
6	Anterior neck			2	8	1	Remained
7	Posterior neck		1	1	8	0.9	Remained
8	Throat			1	9	1	Remained
9	Larynx				10	1	Remained
10	Chest	1	1	1	7	0.8	Remained
11	Right shoulder		1	1	8	0.9	Remained
12	Left shoulder		1	1	8	0.9	Remained
13	Upper back	1	1		8	0.8	Remained
	Frequency of pain						
	Severity of pain						
	Time of pain occurrence						
14	During speaking			1	9	1	Remained
15	After speaking			1	9	1	Remained
16	During swallowing		1		9	0.9	Remained
17	After long time speaking			1	9	1	Remained
18	All the time			1	9	1	Remained
S-CVI average						0.93	Appropriate

Note: Number of experts (N = 10), the items with the CVI lower than 0.78 eliminated.
Abbreviations: CVI, content validity index; I-CVI, item-content validity index; S-CVI, scale content validity index.

for the "head" item, were higher than 0.62, so the "head" item was eliminated from the scale. The CVIs were calculated for both each item (I-CVI) and overall scale (S-CVI). The I-CVIs of all items were above 0.79 and the S-CVI of the scale was calculated to be 0.93. Therefore, no item needed to be revised or eliminated in this stage.

Face validity
At the face validity stage, the opinions of the PWVDs were incorporated in the VRPS. Also, according to the patients' suggestion, we added a schematic picture of human body to guide respondents. This schematic picture of human body shows the pain locations.

After these changes, the VRPS contains an instruction section with a schematic picture for better guidance of the respondents, and the main section. The main section of the VRPS contains 13 items related to the pain location in human body. Each of these items has three sections: frequency of pain, severity of pain, and time of pain occurrence (See Appendix A and B). Appendix A shows an original version of the VRPS in Persian language and appendix B shows the primary translation of the scale into English. The primary English translation is only to familiarize the readers with the VRPS and there is definitely a need for translation

and cross-cultural adaptation to use this scale in other languages.

Reliability
A total of 30 PWVDs participated in the test-retest reliability analysis and completed the VRPS twice with 2 weeks of interval. The results indicated that the weighted kappa ranged from 0.645 to 1 for the items of the VRPS. The reliability calculation for each item of the scale is presented in Table 3.

DISCUSSION
Pain is known as one of the common complaints in PWVDs.[12] Since pain can adversely affect patients' quality of life, its evaluation and treatment in PWVDs should be considered properly. Valid and reliable assessment tools are very important for proper evaluation of pain in these patients. Given that there is not a comprehensive, valid, and reliable scale to evaluate pain in PWVDs, the purpose of the present study was to develop and validate a new scale to evaluate pain in PWVDs. In the present study, the content validity (qualitative and quantitative), the face validity, and test-retest reliability of the developed scale (VRPS) were confirmed.

TABLE 3.
Weighted Kappa for Each Item of the Voice Related Pain Scale (VRPS)

Items	Weighted Kappa	Standard Error
Frequency of pain		
Right ear	0.818	0.146
Left ear	1	0.00
Right TMJ	0.651	0.171
Left TMJ	1	0.00
Submental area	1	0.00
Anterior neck	1	0.00
Posterior neck	1	0.00
Throat	0.923	0.072
Larynx	1	0.00
Chest	1	0.00
Right shoulder	1	0.00
Left shoulder	1	0.00
Upper back	1	0.00
Severity of pain		
Right ear	0.82	0.143
Left ear	1	0.00
Right TMJ	0.655	0.317
Left TMJ	0.862	0.118
Submental area	1	0.00
Anterior neck	0.888	0.1
Posterior neck	1	0.00
Throat	0.706	0.104
Larynx	1	0.00
Chest	0.948	0.178
Right shoulder	1	0.00
Left shoulder	0.645	0.141
Upper back	1	0.00
Time of pain occurrence		
Right ear	1	0.00
Left ear	1	0.00
Right TMJ	1	0.00
Left TMJ	1	0.00
Submental area	1	0.00
Anterior neck	1	0.00
Posterior neck	1	0.00
Throat	1	0.00
Larynx	1	0.00
Chest	0.737	0.183
Right shoulder	1	0.00
Left shoulder	1	0.00
Upper back	1	0.00

Abbreviation: TMJ, temporomandibular joint.

The final version of the VRPS comprised of the instruction and main section of the scale. The main section of the scale contains 13 items related to the pain location in the human body. Each of these items has three sections: frequency of pain, severity of pain, and time of pain occurrence. Scoring the frequency of pain section is done based on a five-point Likert-type scale. These five-point include never, seldom, sometimes, often, and always. Scoring the severity of pain section is done based on the numerical rating scale and include 11 numbers: zero is equal to no pain, and 10 equals the worst possible pain. The time of pain occurrence included these times: during speaking, after speaking, during swallowing (eating liquids or foods), after long time speaking, and all the time. Also, the VRPS has a schematic human body picture for guiding the respondents regarding the location of pain that is presented in the instruction section of the scale.

The results of the test-retest analysis with 2-week interval showed that all weighed kappa of the VRPS's items were above 0.6. So, these results of test-retest reliability were at least substantial for all items of the VRPS based on the suggestion by Landis and Kotch.[30] They suggested the following benchmarks for the weighed kappa: <0.00 = poor, 0.00 −0.20 = slight, 0.21−0.40 = fair, 0.41−0.60 = moderate, 0.61−0.80 = substantial and 0.81−1.0 = almost perfect.

Regarding the location of pain, the VRPS included 13 locations: right ear, left ear, right temporomandibular joint, left temporomandibular joint, submental, anterior neck, posterior neck, throat, larynx, chest, right shoulder, left shoulder, and upper back. These locations of pain were selected based on the patients' and experts' views and in-depth literature review. Some previous studies have pointed out these locations.[7,11,31] Ramos et al reported a higher pain severity in the larynx and a greater pain frequency in the larynx, submandibular area, and anterior neck in dysphonic patients compared to the nondysphonic subjects.[7] In another study, Silverio et al[11] reported more pain frequency in dysphonic women than in nondysphonic women in their larynx, submandibular area, shoulders, anterior and posterior neck, and upper back. In addition, dysphonic women had higher pain severity in their larynx, pharynx, and posterior neck.

The voice users are another group of people who experience voice-related pain.[10] Some previous studies investigated voice-related pain in voice users, including actors, teachers, telemarketers, translators, and receptionists reporting that pain can be experienced in the head, neck, larynx, shoulders, and back location of these professional voice users.[9,12] For example, Vaiano et al[8] investigated pain in professional voice users, including teachers, actors, popular singers, classical choral singers, telemarketers, and speech-language pathologists and reported pain in the neck, back, shoulder, head, and throat of this population. In addition, pain during speaking in the neck, shoulders, throat, head, back, and ears were reported in professional voice users compared to those in the control group in another study by Van Lierde et al.[12] In some previous studies, too, wind instrumentalists reported pain after playing their instruments in their neck, cervical musculature, back, and shoulders.[32−34]

To date, there is no comprehensive and specific assessment tool for evaluating pain in PWVDS. Therefore, it is not possible to compare VRPS with other scales. However, there are only two scales, each with only one item for pain assessment in PWVDs. The Vocal Tract Discomfort scale has an item about the sensation of pain in the vocal tract.

The Vocal Tract Discomfort scale investigated the frequency and severity of pain. Also, the Laryngeal Palpatory Scale, developed recently by Jafari et al[35] for palpatory evaluation in patients with muscle tension dysphonia, has one item for evaluating pain in the anterior/posterior neck during rest/speaking.

One of the sections of the VRPS developed in the study was the time of pain occurrence. This section included pain occurrence during speaking, after speaking, during swallowing (drinking liquids or eating foods), after long time speaking, and all the time. These times of pain sensation were emerged from both interviews with PWVDs and experts in the field of voice disorders, and literature review. The contemporary voice literature mentioned that PWVDs might experience pain during voice usage (odynophonia)[2,12,18,36] and after voice usage.[12,37,38] Professional voice users also reported pain in different studies. For example, Vaiano et al[8] reported that popular singers experience pain during speaking. In another study, Van Lierde et al reported that the professional voice users experienced more pain during speaking in comparison with the nonvocal professionals.[12] However, pain during palpation evaluation has been reported in most patients with hyper-functional dysphonia[17,39]; the VRPS did not include this time of pain occurrence. The reason why we did not evaluate pain during palpation on the VRPS is that this scale is a self-reported scale, whereas assessment during palpation requires evaluation by the therapist. Therefore, a special tool is needed to assess pain during palpation.

The present study had some limitations that should be considered in future studies. Given that there was no appropriate specific instrument to assess pain in PWVDs, concurrent validity of VRPS could not be examined. In the present study, the responsiveness to change of the VRPS was not evaluated. So, future studies can establish the responsiveness of the VRPS to changes in pain of PWVDs according to interventions. Also, evaluation of construct validity of the scale should be considered in future studies. We developed the VRPS to address the need for a scale that is specific for measuring pain in PWVDs. Given that professional voice users are a large group of PWVDs and may have some specific conditions, designing a special tool for pain assessment in professional voice users seems to be necessary.

Finally, it seems that the VRPS can contribute to the promotion of assessment and treatment of pain in PWVDs in clinical setting or research purposes. Therefore, it is recommended that this scale be translated into different languages for use in different countries.

CONCLUSION

The present study showed that VRPS is a valid and reliable tool to evaluate pain in patients with voice disorders. It seems that VRPS is a useful tool for both clinical and research purposes. Given that VRPS is a new scale, more studies are needed in this regard to further evaluate the VRPS.

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