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Ecuadorian Spanish Translation and Validation of the VELO Quality of Life Instrument

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Abstract

Objectives—Adapt the Spanish translation of VPI Effects on Life Outcome (VELO) instrument into Ecuadorian Spanish; test the resulting instrument for reliability and validity.

Methods—A cross-sectional, prospective design, set at a humanitarian mission within a community hospital. Linguistic validation: native Ecuadorian-Spanish speakers modified the Spanish VELO to Ecuadorian Spanish. Cognitive interviews were conducted with children with cleft palate (CP) and their parents (n=50), guiding instrument modifications. An expert panel reviewed changes, resulting in the VELO-Ecuadorian dialect (VELO-Ec).

Instrument Assessment: 88 participants with CP (88 parents, 46 children) and 33 non-cleft controls (33 adult, 11 children) completed the VELO-Ec, Spanish-Pediatric PreVoiceHandicapIndex(pVHI), and Spanish-Intelligibility in Context Scale (ICS). Internal consistency was assessed with Cronbach's alpha; test-retest reliability was assessed by calculating the intraclass correlation coefficient (ICC); standard error of measurement (SEM) was calculated.

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Concurrent validity was assessed with Pearson correlations of VELO-Ec with pVHI and ICS. Discriminant validity assessment used an established ICS cutoff. Construct validity was assessed by grouping patients by parent report of hypernasality and early vs. late cleft repair (> 24 months) using the Wilcoxon Rank-Sum test.

Results—VELO-Ec showed excellent internal consistency (alpha 0.96) and test-retest reliability (ICC=0.85, 95% CI 0.68 – 0.93, SEM 5.71). It had strong concurrent validity, correlating with ICS ($r=0.75$, $p<0.001$) and pVHI ($r=-0.79$, $p<0.001$). Discriminant validity was strong with better VELO-Ec scores among subjects with normal vs. abnormal ICS score (median 95 & 61, $p<0.001$). Strong construct validity was identified: those with parent-reported hypernasality had worse VELO-Ec scores than those without (median 59 & 75, $p<0.001$). Those with repair before or after 24 months had similar VELO-Ec scores ($p=0.882$).

Conclusion—The VELO-Ec is a valid and reliable measure of VPI-related quality of life, useful to clinicians and researchers treating Ecuadorian CP patients, especially in areas with limited resources such as on humanitarian missions.

Keywords

VPI; Velopharyngeal Insufficiency; Quality Life; International; Translation

1. Introduction

Cleft lip and palate are common birth defects in Central and South America [1, 2]. These conditions can have a substantial impact on the affected children. One way that children with a cleft palate (CP) can be affected is by alterations in their speech. Patients with CP are at increased risk of developing velopharyngeal insufficiency (VPI), characterized by hypernasal speech, nasal air emission, and nasal reflux during feeding [3]. Quality of life (QoL) can be profoundly impacted by alterations in resonance and intelligibility related to VPI [4]. It may also impair the ability of people with CP to obtain employment and to marry [5].

Measuring QoL is important in this population. The importance of patient-centered metrics led the WHO to set as a top priority the utilization of outcomes important to patients and parents [6]. These metrics are in contrast to measures that are reported by the Pre-provider, such as ratings of appearance or speech. The WHO recommendation has been reiterated by others calling for standardized patient-reported outcomes instruments, specifically psychological and health-related QOL measures [7]. Despite the importance, availability of these types of metrics globally remains limited. Those that assess speech issues and their impact on QoL in cleft patients, including the newer CLEFT-Q instrument, are not designed to measure VPI or hypernasality specifically [8].

To measure VPI's impact on children's lives, the VPI Effects on Life Outcomes (VELO) instrument was developed and validated [9, 10]. The VELO instrument is a patient-reported outcomes measure consisting of a parent report and a child report; it focuses on the impact symptoms of VPI have on quality of life [4, 9, 10] and has been shown to correlate with speech acceptability [11]. It has been translated and linguistically validated in 8 languages

and has become widely used internationally to assess VPI-related QoL [12–16]. Recently, the VELO was translated into Spanish and linguistically validated using an American population [17], undergoing limited prospective validation. There are distinct differences in dialect and culture between US Spanish and Ecuadorian populations which may render the instructions and items developed in the US linguistically or culturally confusing [18, 19]. Previous instrument translation work has emphasized the importance of recognizing regional and dialectal differences in the translation and validation process [20]. The VELO would fill a void for a much needed metric for children with VPI and/or CP in Ecuador and may provide a foundation for validation in other Spanish-speaking South American dialects.

The current project helps to fill the need for QoL measures in this field to provide an instrument for future international studies while accounting for differences in dialects and cultures [6]. The study aims to validate the VELO instrument linguistically and socio-culturally to the cultural and dialectal differences of Ecuador and to prospectively validate the resulting

2. Methods

2.1 Study Design and Subjects

This cross-sectional study a convenience sample and was conducted in phases. For the first phase (linguistic validation), children and parents of children with cleft palate and a history of speech disorders – including VPI – from native Ecuadorian Spanish-speaking families were recruited. In the second phase (instrument assessment), the translated instrument was administered to patients with CP, their parents, and non-cleft controls. Both phases followed established cross-cultural adaptation guidelines [19].

All children were being evaluated by the Global Smile Foundation (GSF) at its established cleft center within Hospital León Becerra, in Guayaquil, Ecuador. GSF volunteers have been providing comprehensive cleft care for over 30 years, with families returning for annual follow-up. The resulting sample contained subjects with untreated VPI and those previously treated for VPI.

The protocol was reviewed and approved by the Ministerio de Salud Pública del Ecuador Dirección de Inteligencia de la Salud Ethics Board. The local ethics Board determined that no written consent was needed for the cognitive interviews, as personally identifying information was not recorded nor were sensitive participant details discussed. Written informed consent was obtained for the second phase (instrument assessment).

2.2 Translation and Linguistic Validation

The Spanish VELO US (VELO-SP) was translated and linguistically validated for Spanish populations in the United States [17]. This process included a series of forward and back translations with attention to reading level, followed by modification through a series of cognitive interviews with native Spanish speakers of the target audience at a tertiary center in the United States.

The conversion of the VELO-SP Ecuadorian Spanish began with independent assessments for potential dialect differences by four native Ecuadorian Spanish speaking study staff members including a certified translator, two medical students with experience in the cleft population, and a craniofacial speech pathologist. Potential changes were discussed by the study's consensus panel to achieve agreement, then reviewed with the first cognitive interview group. The panel consisted of an Ecuadorian Spanish speaking medical student, a craniofacial speech pathologist, and one of the original developers of the VELO with significant instrument adaptation and translation experience from previous translation projects. This panel was used throughout the project.

Since the VELO seeks to measure the impact of VPI on QoL, and VPI is a speech disorder most common in patients with cleft palate, cognitive interviews were conducted with children with both cleft palate and a history of speech disorders, and their parent(s) [19]. Speech disorder status was based on both prior diagnosis by clinic staff and parent report. These interviews included children over age eight (to align with the VELO self-report age) and parents of patients under 18; exclusion criteria included severe developmental disabilities (such as autism) and severe or profound hearing loss, as reported by parents. Subjects reviewed and completed the questionnaire before the interview, marking questions and clarifications. When necessary, study staff assisted participants in reading questionnaires. To avoid bias, parents and children were asked to read the questions individually and not discuss them before the cognitive interviews.

Interviews were led by a moderator using both open-ended and probing questions to review instrument instructions and items, as well as the response format. Participants were asked to explain the concept they believed each item was trying to convey, whether it was exemplified, and to state the item concept in their own words. This ensured that terminology resonated with the target population. Potential changes were discussed group subjects; the proportion in favor of each change was documented.

The project's consensus panel reviewed proposed changes, ensuring conceptual equivalence of the items and instructions. Changes were considered major if the question's language was reworked or changed considerably. Minor changes involved only grammatical edits or redundant language deletion. Cognitive interviews continued iteratively until only minor changes were recommended; four group interviews were conducted. Three items (numbers 4, 14, and 26; see Table 1) lacked group consensus; these were reviewed and modified through individual interviews until only minor or no changes were suggested. Individual interviews also augmented the child/youth sample. The resulting Spanish VELO – Ecuadorian dialect (VELO-Ec) instrument was then assessed prospectively.

2.3 Instrument Assessment

2.3.1 Data Collection—Patients and families were approached between visits during the GSF screening day. Additional subjects were enrolled at the speech and dental clinics. Non-cleft controls consisted of patient siblings or other accompanying relatives. Enrollment and participation were voluntary.

After informed consent, parents of cleft palate patients under age 18 and children with cleft palate age eight and older were asked to fill out the VELO-Ec instruments, as well as other speech and QoL instruments. Patients with parent-reported major developmental co-morbidities were excluded, as were patients with severe-to-profound hearing loss, as reported by their parents; patients with minor hearing loss were included. Parents were asked to allow children to fill out the VELO-Ec alone if possible. Parents with limited literacy were given reading assistance by study staff, and functional assistance was provided for electronic data collection. Because of difficulties with parents understanding the use of tablets for data collection, printed questionnaires were used after the first day of enrollment. Subjects were contacted during follow-up visits to repeat the VELO-Ec, allowing for test-retest reliability. Study data were managed using REDCap electronic data capture tools hosted at the University of Utah [21, 22]. Instruction, assistance, and reassurance was provided to help mothers fill out instruments, as culturally they were often unaccustomed to completing paperwork [23].

2.3.2 Instruments and Metrics—The VELO instrument is comprised of a 26-item version for parents (VELO-P) and a 23-item youth version (VELO-Y), to be completed by patients 8 and older [9]. In this paper, the VELO-P and VELO-Y abbreviations refer to the components of the VELO-Ec instrument. The response format is a 5-point Likert-type scale ranging from never (0) to almost always (4). Total score is calculated with the equation $100 - (\text{Mean} * 25)$. Scores range from 0 to 100; 100 represents the highest QoL. Subscales are scored similarly and include Speech Limitations, Swallowing Problems, Situational Difficulty, Perception by Others, and Emotional Impact; the VELO-P also includes Caregiver Impact.

Two instruments were used to show concurrent validity of the VELO-Ec: The Intelligibility in Context Scale (ICS), and the Pediatric Voice Handicap Index (pVHI). On the ICS, parents report how well others can understand their child. The ICS has seven items where parents rate how often their children's speech is understood by different communication partners. Each item is rated on a Likert-type 5-point scale (Never-Always). ICS score is the mean of all items, ranging 1.0 (low intelligibility) to 5.0 (high intelligibility). The ICS has shown high internal reliability, sensitivity, and construct validity.[24] The optimal cut-off for abnormal speech has been established 4.6[25].

The pVHI, a parent-report instrument assessing different aspects of voice and speech problems, has 23 items and uses a 5-point Likert-type scale (Never-Always). The pVHI has three subscales: Functional, Physical, and Emotional.[26] The Spanish adaptation of the pVHI has shown good validity and reliability [27].

2.3.3 Statistical Analysis

2.3.3.1 Instrument Reliability: Test-Retest reliability assessed the reproducibility of the instrument by having participants re-take the instrument at a follow-up appointment, which occurred a median of 27 days (range 1–77 days) after the instrument was originally filled out. Intraclass Correlation Coefficients (ICC) were calculated from the baseline and re-test

VELO scale scores using a two-way mixed-effects model on the mean of the measures with an absolute agreement definition [28]. An ICC > 0.7 was considered adequate [29].

Internal consistency, another measure of reliability, is the degree to which an instrument's items measure the same concept. Cronbach's Alpha was calculated for the VELO instrument and sub-scales; for those taking the instrument more than once, the first instance was used. A Cronbach's alpha > 0.70 was considered acceptable [29].

2.3.3.2 Instrument Validity: Validation can be defined as an accumulation of evidence an instrument's function. We tested the VELO-Ec for concurrent, discriminant, and construct validity. For all analyses, groups of patients were tested for difference using the Wilcoxon Rank-Sum test, with $p < 0.008$ considered statistically significant, after adjusting for multiple tests using Bonferroni's correction. For correlations, an $r > 0.6$ was chosen as our threshold, since the R^2 at this level implies that more than 35% of the variation in the dependent variable is explained by the independent variable, which we considered likely to be clinically meaningful. Bonferroni correction for testing on the correlations yielded a p-value for significant association set at 0.007.

Accuracy of parental response as a proxy for youth response was assessed by testing the difference between parent and youth total and subscale scores with the paired t-test. To test the inter-rater reliability (comparing parents and youth), we calculated the intraclass correlation coefficient (ICC) for the total score of VELO-P and VELO-Y using a mixed effects model. An ICC > 0.6 indicates substantial agreement [30].

Concurrent validity was evaluated by correlating total VELO-P and VELO-Y scores with the Spanish ICS and Spanish pVHI. VELO-P and VELO-Y subscales were also correlated with applicable pVHI subscales. Discriminant validity was assessed by comparing the VELO scores of patients with a cleft with non-cleft controls and by using the ICS screening cutoff (4.6) to identify patients with "normal" intelligibility.

Construct validity refers to how well an instrument measures what it attempts to measure. We used Mann-Whitney U tests to compare median performance on the VELO-Ec within several constructs assessed using parent-reported diagnoses and concerns, including perception of hypernasality and concern about the child's ability to be understood. These concerns were collected using dichotomous questions included in the demographics questionnaire parents completed.

Age at repair may be an important factor in speech-related QoL [31–33]; this is particularly important in developing countries, where repair may be significantly delayed until children are older. While this concept is controversial, we felt it was clinically important and that this analysis would add to the literature. We tested the hypothesis that children with older initial repair would have lower VELO scores. Parent-reported age of repair was used to categorize children as late repair (> 2 years).

All analyses were conducted Stata 15 (College Station, TX).

3. Results

3.1 Linguistic and Cultural Validation

Review of the VELO-SP by four native Ecuadorian Spanish speakers identified several minor changes and sociocultural adaptations. The modified version was evaluated in four semi-structured cognitive interviews, followed by twenty focused individual cognitive interviews with parents and children. In total, 11 parents and 9 youth, age 8 and over, participated. All involved youth had cleft palate – 6 had VPI, and 1 had a different speech disturbance. Participant ages ranged from 9–28 years, with a mean of 18.2 years. Parents had a range of education levels: 7 had some college education, 5 had a high school diploma, one had a middle school education, one had a second-grade education, and one did not know. Confusing instructions and item language were reworked and finalized by the panel. Table 1 highlights these changes.

3.2 Prospective Instrument Assessment

We enrolled 88 parents of children with a cleft to assess the Ecuadorian VELO-P, and 58 children 8 years and older with cleft to assess the VELO-Y. Additionally, 22 adult and 11 youth controls were enrolled. The mean age for children with cleft was 10 years (SD Table 2). 67% were male; most had a unilateral cleft lip/palate (48%) or bilateral cleft lip/palate (41%). Eight subjects (9%) had an unrepaired CP at enrollment, and the mean age of CP repair was 3.3 years (SD 4.3, Table 2).

3.2.1 Reliability—Internal consistency for the VELO-P and VELO-Y was excellent (Cronbach's alpha 0.96). All Subscales showed excellent internal (Table 3), all above the 0.7 threshold.

Test-retest reliability was obtained on 33 parents and 21 youth and was excellent for the VELO-P and VELO-Y (ICC=0.85 & 0.92). Standard error of measurement (SEM) on the VELO-P, which has a scale of 0–100, was 5.71; SEM for the VELO-Y was 2.56. Subscale reliability was similar, with the exception of the parent Speech Limitations subscale, which was below the established threshold (ICC 0.56).

3.2.2 Validation—Concurrent validity analysis revealed that both VELO-P and VELO-Y total scores correlated with the ICS ($r=0.75$ & 0.76 , $p<0.001$, Figure 1 and Table 4). The VELO-P was also strongly correlated with the pVHI ($r=-0.79$, $p<0.001$, Figure 2); correlation between VELO-Y and the pVHI was just below the hypothesized threshold ($r=-0.51$), though statistically significant ($p<0.001$); all tests met the Bonferroni-adjusted significance level. The VELO-P subscales correlated with the hypothesized ICS and pVHI subscales above the 0.60 threshold. The VELO-Y subscale correlations with the pVHI subscales were below this threshold (Table 4); the correlation between VELO-Y Speech Limitations and the ICS was at the threshold.

Discriminant validity analysis showed normal controls ($n=22$) had better VELO-Y scores (median 94) than children with CP (median 68, $p<0.001$; see Table 5). Patients with CP with normal ICS scores ($n=24$) had better VELO-P scores (median 95) than those with abnormal score ($n=59$, median 61, $p<0.001$).

Construct validity analysis found children whose parents weren't concerned about their child being understood had better VELO-Y scores (median 89) than those with concerns (median 61, $p<0.001$). Parents with concern about hypernasality had worse VELO-P scores (median 59, $n=43$) than parents without such concerns (median 84, $p<0.001$; Table 5). Those with prior secondary speech-improving surgery ($n=58$) reported VELO-P scores (median 75) than those without ($n=25$, median 58, $p<0.001$).

Age of CP repair was available on 57 subjects. Children with CP repair over age 2 ($n=31$) had similar VELO scores (median 74) as those with earlier repair (median 75, $p=0.886$).

Assessment of parent proxy found VELO scores for parents and youth did not differ by paired t-test ($p=0.141$), showing that parents were reliable proxies for youth on this instrument. This was reinforced by the excellent inter-rater reliability (parent and youth), with an ICC of 0.92 (95% CI 0.89 – 0.95).

4. Discussion

This study provides a cultural and linguistic translation of the VELO instrument for use in Ecuador. Expert review and cognitive interviews ensured cultural and linguistic validity, and the reliability and validity of the VELO-Ec were tested against validated speech instruments. The resulting instrument will be valuable as a therapeutic and research tool in Ecuador, and the process provides a strong foundation for adaptation and/or validation for use in other South American countries. Measurement of patient-reported outcomes in this population will help optimize care.

Our results demonstrate excellent test-retest reliability both parent and youth versions of the new instrument (VELO-P and VELO-Y). This is especially valuable for serial measurements, such as pre- and post-intervention evaluations. The VELO-Ec showed better test-retest reliability and similar internal consistency to the Spanish ICS and Spanish pVHI. It will be a beneficial tool for Ecuadorian medical missions and medical centers to measure QoL in patients with VPI and monitor their progress during treatment [23].

The Ecuadorean adaptation of the Spanish VELO was necessary due to dialectical and cultural differences between the population and the US population used for the original Spanish translation [34]. Dialectical differences develop in separate geographical regions and these present variations in vocabulary and word choice [35]. These lexical differences include linguistic borrowings (anglicisms) of English words into Spanish. For example, the VELO-SP instructions use the word “circule” (circle), instead of the Spanish term “encierre” (enclose). This confused Ecuadorean participants, whose Spanish has not been as influenced by English. Other linguistic changes suggested by interview participants included changing the word “cuidadores” (care takers) to “representantes,” “gente” (people) to “personas”, and “direcciones” (instructions) to “instrucciones,” which is the preferred formal language.

The culture of US Spanish-speakers is also quite different from that of South Americans [36]. An example of cultural differences involved an item asking whether the child had difficulty being understood by others while riding in a car. This was a distractingly strange

idea to the cognitive interview participants, used to travelling by foot or bus. The revised question asked about the child's intelligibility by fellow bus passengers.

Other cultural differences arose during the cognitive Researchers observed that mothers, while accustomed to attending medical appointments, were unfamiliar with completing forms and questionnaires [23]. It became clear that fathers typically fill out all family paperwork, and mothers were uncomfortable with the process; they required significant coaching in order to complete the questionnaire. Another issue encountered was the discomfort some parents displayed when trying to use tablet computers to complete the questionnaires; this was especially true of older parents, and paper forms were often easier for these parents to navigate. These cultural insights and the adjustments it engendered to the VELO-Ec instructions and administration enabled mothers to complete the required questionnaires successfully during the instrument assessment process. Further understanding of form-filling behaviors within the culture and how to adapt medical self-assessments to this context would be useful for future projects, and standardization of the coaching process might be useful in populations with low form-literacy.

This project partnered with GSF, a longstanding medical mission serving Ecuadorian patients with a CP. While this history of care provided our study a wide range of patients with VPI, the most frequent age group receiving services were babies and toddlers, limiting the sample size of teen and adult subjects. We addressed these limitations by targeting underrepresented groups for individual cognitive interviews during the linguistic validation phase. Another limitation encountered during the study was the literacy level of patients and their parents. Although Ecuador's literacy rate is high, medical mission patients tend to be rural and with fewer resources. We read the VELO to participants who were insufficiently literate. Additionally, we did not assess the level of hearing loss in participants, leaving us unable to evaluate whether confounding was caused by hearing loss in our population. This may have been a limitation, but we aimed to create an instrument that would be validated across the cleft population in Ecuador. Another potential limitation is inherent to the use of instruments that imperfectly capture VPI to validate the VELO; parents taking the pVHI may confuse vocal disorders with those of resonance, and parent-reported intelligibility captured on the ICS, may not capture vocal acceptability [37], and there may be some variation in QoL that is not captured. These potential limitations emphasize the importance of the VELO-Ec, which measures resonance, speech intelligibility, and speech acceptability. An ideal solution would have been the inclusion of a formal speech evaluation against which to validate the VELO-Ec. The scarce resources available did not allow this during our study, but will be important in follow up studies. A final of the VELO-Ec is that both the parent and youth versions may be too long for use in all patients during busy mission clinics, but use in targeted populations would add value to the care.

VELO-Ec demonstrated its value as a speech-related QoL metric. Validity and reliability testing were largely very positive; it is unclear why VELO-P Speech Limitations subscale test-retest had lower reliability. Strong correlations between VELO-P and both pVHI and ICS demonstrate its concurrent validity. The below-threshold correlation found between VELO-Y and the parent-recorded pVHI subscales may indicate that parent-report for pVHI is not adequately capturing older children's difficulties. The pVHI also captures different

concepts of speech difficulties, which may have led to the limited correlation. Controls had better VELO-Ec scores than children with CP, supporting discriminant validity. VELO-Ec also discriminated between children with CPs with normal and abnormal ICS scores, showing VELO-Ec's ability to detect differences between patients with and without speech disorders.

While age of CP repair was not available on the entire sample, there was not a difference in current VELO score between those with CP repair over and under age two. This study did not include review of participants' medical records and there may be errors in parent-reported medical information. It is possible error rates were different in those with and without late repair, causing bias, but the point estimate difference (1 point on the VELO scale) makes a real difference between the groups unlikely. Future studies further assessing the association of speech outcomes and speech-related QoL with age of primary cleft repair would be useful.

The development of an Ecuadorean VELO version will address the urgent need to assess, treat and improve the QoL of patients with VPI, particularly in medical missions [38]. Research on the differences in patient populations treated through medical missions, including older children with unrepaired palate or VPI, is also lacking. Prospective could utilize VELO-Ecto evaluate the management of cleft lip and palate in adults with VPI, for example.

The VELO-Ec provides a starting-place for validation for similar Andean Spanish populations; in Spanish dialects significantly different from Ecuadorian, the framework used here will prove valuable in creating additional adaptations. Other possible future directions include creating shortened VELO versions, for to serve lower literacy populations.

This project demonstrates the successful adaptation of a rigorously translated instrument into a different dialect and culture. The VELO-Ec provides an important tool in the optimization of care for children and youth with CP and related speech issues in Ecuador and surrounding countries.

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References

1. Gili JA, Poletta FA, Gimenez LG, et al., Descriptive analysis of high birth prevalence rate geographical clusters of congenital anomalies in South America, *Birth Defects Res A Clin Mol Teratol.* 106 (2016) 4 257–266. 10.1002/bdra.23481. [PubMed: 26887535]
2. Menegotto BG, Salzano FM, Epidemiology of oral clefts in a large South American sample, *Cleft Palate Craniofac J.* 28 (1991) 4 373–376; discussion 376–377. 10.1597/1545-1569_1991_028_0373_eoocia_2.3.co_2. [PubMed: 1742306]
3. Kummer AW, Disorders of resonance and airflow secondary to cleft palate and/or velopharyngeal dysfunction, *Semin Speech Lang.* 32 (2011) 2 141–149. <https://www.ncbi.nlm.nih.gov/pubmed/21948640>. [PubMed: 21948640]

4. Skirko JR, Weaver EM, Perkins JA, et al., Change in Quality of Life with Velopharyngeal Insufficiency Surgery, *Otolaryngol Head Neck Surg.* 153 (2015) 5 857–864. 10.1177/0194599815591159. [PubMed: 26124262]
5. Ramstad T, Ottem E, Shaw WC, Psychosocial adjustment in Norwegian adults who had undergone standardised treatment of complete cleft lip and palate. I. Education, employment and marriage, *Scandinavian journal of plastic and reconstructive surgery and hand surgery.* 29 (1995) 3 251–257. <http://www.ncbi.nlm.nih.gov/pubmed/8539569>. [PubMed: 8539569]
6. WHO, Global strategies to reduce the health care burden of craniofacial anomalies: report of WHO meetings on international collaborative research on craniofacial anomalies, *Cleft Palate Craniofac J.* 41 (2004) 3 238–243. 10.1597/03-214.1. [PubMed: 15151440]
7. Mossey PA, Little J, Munger RG, Dixon MJ, Shaw WC, Cleft Lip and Palate, *Lancet* (London, England). 374 (2009) 9703 <https://www.ncbi.nlm.nih.gov/pubmed/19747722>.
8. Wong Riff K WY, Tsangaris E, Forrest CR, et al., CLEFT-Q: Detecting Differences in Outcomes Among 2434 Patients With Varying Cleft Types, *Plastic and reconstructive surgery.* 144 (2019) 1 <https://www.ncbi.nlm.nih.gov/pubmed/31246826>. [PubMed: 31246789]
9. Skirko JR, Weaver EM, Perkins J, Kinter S, Sie KC, Modification and evaluation of a Velopharyngeal Insufficiency Quality-of-Life instrument, *Arch Otolaryngol Head Neck Surg.* 138 (2012) 10 929–935. 10.1001/2013.jamaoto.122. [PubMed: 23069823]
10. Skirko JR, Weaver EM, Perkins JA, Kinter S, Eblen L, Sie KC, Validity and responsiveness of VELO: a velopharyngeal insufficiency quality of life measure, *Otolaryngol Head Neck Surg.* 149 (2013) 2 304–311. 10.1177/0194599813486081. [PubMed: 23585146]
11. Bruneel L, Bettens K, Van Lierde K, The relationship between health-related quality of life and speech in patients with cleft palate, *Int J Pediatr Otorhinolaryngol.* 120 (2019) 112–117. <https://www.ncbi.nlm.nih.gov/pubmed/30776568>. [PubMed: 30776568]
12. Impieri D, Tønseth KA, Hide Ø, Feragen KJB, Høgevold HE, Filip C, Change in quality of life after treatment of mild velopharyngeal insufficiency with autologous fat transplantation, *JPRAS Open.* 13 (2017) 126–135. <http://www.sciencedirect.com/science/article/pii/S2352587817300347>.
13. Huang H, Chen N, Yin H, et al., Validation of the Chinese Velopharyngeal Insufficiency Effects on Life Outcomes Instrument, *Laryngoscope.* 129 (2019) 11 E395–e401. 10.1002/lary.27792. [PubMed: 30671957]
14. Bruneel L, Alighieri C, DeSmet S, Bettens K, De Bodt M, Van Lierde K, Health-related quality of life in patients with cleft palate: Reproducibility, responsiveness and construct validity of the Dutch version of the VELO questionnaire, *Int J Pediatr Otorhinolaryngol.* 119 (2019) 141–146. <http://www.ncbi.nlm.nih.gov/pubmed/30708181>. [PubMed: 30708181]
15. Denadai R, Raposo-Amaral CE, Sabbag A, et al., Measuring Patient-Reported Health-Related Quality of Life in Velopharyngeal Insufficiency: Reliability and Validity of the Brazilian Portuguese Version of the VELO Instrument, *Cleft Palate Craniofac J.* 56 (2019) 9 1195–1205. 10.1177/1055665619846763. [PubMed: 31079479]
16. Lindeborg MM, Shakya P, Pradhan B, et al., Nepali Linguistic Validation of the Velopharyngeal Insufficiency Effects on Life Outcomes Instrument: VELO-Nepali, *Cleft Palate Craniofac J.* (2020) 1055665620905173 <http://www.ncbi.nlm.nih.gov/pubmed/32054301>.
17. Santillana R, Skirko J, Roth C, Tollefson TT, Spanish Linguistic Validation for the Velopharyngeal Insufficiency Effects on Life Outcomes, *JAMA Facial Plast Surg.* 20 (2018) 4 331–332. 10.1001/jamafacial.2018.0005. [PubMed: 29522150]
18. Pena ED, Lost in translation: methodological in cross-cultural research, *Child Dev.* 78 (2007) 4 1255–1264. 10.1111/j.1467-8624.2007.01064.x. [PubMed: 17650137]
19. Guillemin F, Bombardier C, Beaton D, Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines, *J Clin Epidemiol.* 46 (1993) 12 1417–1432. 10.1016/0895-4356(93)90142-n. [PubMed: 8263569]
20. Levin K, Willis GB, Forsyth BH, et al., Using Cognitive Interviews to Evaluate the Spanish-Language Translation of Dietary Questionnaire, *Survey Research Methods.* 3 (2009) <https://ojs.ub.uni-konstanz.de/srm/article/view/88>.
21. Harris PA, Taylor R, Thielke R, Payne J, Gonzale N, Conde JG, Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational

- research informatics support, *J Biomed Inform.* 42 (2009) 2 377–381. 10.1016/j.jbi.2008.08.010. [PubMed: 18929686]
22. Harris PA, Taylor R, Minor BL, et al., The REDCap consortium: Building an international community of software platform partners, *J Biomed Inform* 95 (2019) 103208 10.1016/j.jbi.2019.103208. [PubMed: 31078660]
 23. Alwang J, Larochelle C, Barrera V, Farm Decision Making and Gender: Results from a Randomized Experiment in Ecuador, *World Development.* 92 (2017) C 117–129.
 24. McLeod S, Harrison LJ, McCormack J, The intelligibility in Context Scale: validity and reliability of a subjective rating measure, *J Speech Lang Hear Res.* 55 (2012) 2 648–656. 10.1044/1092-4388(2011/10-0130). [PubMed: 22215036]
 25. McLeod S, Crowe K, Shahaeian A, Intelligibility in Context Scale: Normative and Validation Data for English-Speaking Preschoolers, *Lang Speech Hear Serv Sch.* 46 (2015) 3 266–276. 10.1044/2015_lshss-14-0120. [PubMed: 25934948]
 26. Zur KB, Cotton S, Kelchner L, Baker S, Weinrich B, Lee L, Pediatric Voice Handicap Index (pVHI): a new tool for evaluating pediatric dysphonia, *Int J Pediatr Otorhinolaryngol.* 71 (2007) 1 77–82. 10.1016/j.ijporl.2006.09.004. [PubMed: 17046072]
 27. Nunez-Batalla F, Corte-Santos P, Senaris-Gonzalez B, Llorente-Pendas JL, Gorriz-Gil C, Suarez-Nieto C, Adaptation and validation to the Spanish of the Voice Handicap Index (VHI-30) and its shortened version (VHI-10), *Acta Otorrinolaringol Esp.* 58 (2007) 9 386–392. <http://dx.doi.org/>. [PubMed: 17999902]
 28. McGraw KO, Wong SP, Forming inferences about some intraclass correlation coefficients, *Psychological Methods.* 1 (1996) 1 30–46. 10.1037/1082-989X.1.1.30.
 29. Terwee CB, Bot SD, de Boer MR, et al., Quality criteria were proposed for measurement properties of health status questionnaires, *J Clin Epidemiol.* 60 (2007) 1 34–42. http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=17161752. [PubMed: 17161752]
 30. Landis JR, Koch GG, The measurement of observer agreement for categorical data, *Biometrics.* 33 (1977) 1 159–174. http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=843571. [PubMed: 843571]
 31. Pasick CM, Shay PL, Stransky CA, Solot CB, Cohen MA, Jackson OA, Long term speech outcomes following late cleft palate repair using the modified Furlow technique, *Int J Pediatr Otorhinolaryngol.* 78 (2014) 12 2275–2280. 10.1016/j.ijporl.2014.10.033. [PubMed: 25468463]
 32. Schonmeyr B, Wendby L, Sharma M, Jacobson L, Restrepo C, Campbell A, Speech and Speech-Related Quality of Life After Late Palate Repair: A Patient's Perspective, *The Journal of craniofacial surgery.* 26 (2015) 5 1513–1516. 10.1097/scs.0000000000001811. [PubMed: 26114520]
 33. Willadsen E, Influence of timing of hard palate repair in a two-stage procedure on early speech development in Danish children with cleft palate, *Cleft Palate Craniofac J.* 49 (2012) 5 574–595. 10.1597/09-120. [PubMed: 21309652]
 34. Shi LF, Canizales LA, Dialectal effects on a clinical Spanish word recognition test, *Am J Audiol.* 22 (2013) 1 74–83. 10.1044/1059-0889(2012/12-0036). [PubMed: 23064417]
 35. Chambers JK, Trudgill P, *Dialectology*, 2ed, Cambridge Textbooks in Linguistics, Cambridge, 2004.
 36. Yennurajalingam S, Parsons HA, Duarte ER, et al., Decisional control preferences of Hispanic patients with advanced cancer from the United States and Latin America, *J Pain Symptom Manage.* 46 (2013) 3 3376–385. 10.1016/j.jpainsymman.2012.08.015.
 37. Chapman KL, Baylis A, Trost-Cardamone J, et al., The Americleft Speech Project: A Training and Reliability Study, *The Cleft palate-craniofacial journal: official publication of the American Cleft Palate-Craniofacial Association.* 53 (2016) 1 <https://www.ncbi.nlm.nih.gov/pubmed/25531738>.
 38. Gunther S, Valerio I, Harshbarger R, Kumar AR, Improving Care of Cleft-Related Velopharyngeal Incompetence on Humanitarian Missions Using a Multidisciplinary Team Approach, *The Journal of craniofacial surgery.* 30 (2019) 2 e175–e178. 10.1097/scs.0000000000005117. [PubMed: 30730509]

Highlights

- Velopharyngeal insufficiency (VPI) negatively impacts quality of life
- VPI Effects on Life Outcomes (VELO) measures VPI specific quality of life
- The VELO was translated & adapted to Ecuadorian Spanish, creating the VELO-Ec
- The VELO-Ec has excellent reliability & validity

Figure 1:
Association of VELO-P with pVHI

Figure 2:
Association of VELO-P with ICS

Table 1:

Example changes from cognitive interviews with native Ecuadorian Spanish speakers

Scale, Items	Difficult for patients/parents (English / US Spanish)	Ecuadorian Solutions / Comments
Instructions	Circle / Circule	Encierre / Different meaning
Instructions	caregiver / Cuidadores	Representantes / Formal was preferred
Instructions	Directions / Direcciones	Instrucciones / Different meaning
Speech, 4	Low / Debil	Bajo / Was best understood
Speech, 6,7,11,12,13	Speak / Hablar	Habla / Was best understood
Perception, 20	Less smart / Menos inteligente	No capto bien / Sounded less offensive
Speech, 1	Air comes out of your nose / Aire sale de su nariz	Sale aire de su nariz / Word order was preferred
Situation, 11	Strangers / Extraños	Personas desconocidas / Kids understood best
Situation, 14	In a car / En un carro	En un autobus / Change the example used
Swallowing, 10	Liquids come out of their nose / Líquidos salen de su nariz	Salen líquidos de su nariz / Word order was preferred

Table 2:

VELO-Ec Instrument Assessment Population Description

Parameter	Cleft Subjects n=88	Controls n=22
Child's Age in years	10.2 +/- 5.3	8.5 +/- 3.7
Child's Sex; n (%) Male	58 (67%)	14 (64%)
Cleft Type		
Cleft Soft Palate	5 (6%)	N/A
Cleft Soft & Hard Palate	4 (5%)	
Unilateral Cleft Lip & Palate	41 (48%)	
Bilateral Cleft Lip & Palate	35 (41%)	
Unrepaired Cleft Palate	8 (9%)	
Age of Cleft Palate Repair in years	3.3 +/- 4.3	
Quality of Life		
VELO Parent Total- n=88 cleft, 22 control	66 +/- 25	84 +/- 24
VELO Youth Total- n=58 cleft, 11 control	72 +/- 24	87 +/- 14
pVHI	23 +/- 21	13 +/- 18
ICS- n=83 cleft, 22 control	3.8 +/- 1	4.4 +/- 1

Abbreviations: VELO – VPI Effects on Life Outcomes; pVHI – Pediatric Voice Handicap Index; ICS – Intelligibility in Context Scale

Table 3:

Reliability of VELO-Ec

Instrument and Subscale	ICC [†]	95% CI	SEM	Cronbach's Alpha
VELO-P Total	0.85	0.68 – 0.92	5.71	0.96
Speech Limitations	0.56	0.12 – 0.78	15.04	0.87
Swallowing Problems	0.87	0.73 – 0.94	6.39	0.85
Situational Difficulty	0.83	0.64 – 0.92	8.25	0.92
Perception by Others	0.81	0.61 – 0.91	10.32	0.85
Emotional Impact	0.74	0.48 – 0.88	9.02	0.78
Caregiver Impact	0.91	0.82 – 0.96	4.44	0.74
VELO-Y Total	0.92	0.80 – 0.97	2.56	0.96
Speech Limitations	0.83	0.58 – 0.94	6.04	0.82
Swallowing Problems	0.89	0.72 – 0.96	4.48	0.78
Situational Difficulty	0.84	0.59 – 0.94	6.57	0.92
Perception by Others	0.85	0.62 – 0.94	6.93	0.86
Emotional Impact	0.84	0.58 – 0.94	5.45	0.92

[†]For Test-Retest Reliability

Abbreviations: ICC – Intraclass Correlation Coefficient; SEM – Standard Error of Measurement; VELO-P+ – VPI Effects on Life Outcomes Parent Report; VELO-Y – VPI Effects on Life Outcomes Youth Report

Table 4:

VELO-Ec Concurrent Validity Tests

VELO Measure	Correlated with	VELO-P		VELO-Y	
		r	p-value [†]	r	p-value
<u>Concurrent Validity</u>					
VELO Total	ICS	0.75	<0.001	0.76	<0.001
VELO Total	pVHI	-0.79	<0.001	-0.51	<0.001
VELO Speech Subscale	ICS	0.68	<0.001	0.60	<0.001
VELO Speech Subscale	pVHI	-0.77	<0.001	-0.46	<0.001
VELO Situational Diff. Subscale	pVHI - Functional	-0.76	<0.001	-0.56	<0.001
VELO Perception Subscale	pVHI - Physical	-0.67	<0.001	-0.37	0.001
VELO Emotional Subscale	pVHI - Emotional	-0.66	<0.001	-0.49	<0.001

Abbreviations: med (IQR) – Median (Interquartile Range); VELO-P – VPI Effects on Life Outcomes Parent Report; VELO-Y – VPI Effects on Life Outcomes Youth Report; pVHI – Pediatric Voice Handicap Index; ICS – Intelligibility in Context Scale

[†] Significance level has been adjusted to 0.007 using Bonferroni's correction for multiple tests

Table 5:

VELO-Ec Discriminant Validity and Construct Validity Tests

Category	Med (IQR) [†]	Comparison Group	Med (IQR)	VELO-P p-value ^{††}	VELO-Y p-value
<u>Discriminant Validity</u>					
Patients with Cleft	68 (47–88)	Normal Controls	94 (78–99)		<0.001
Abnormal ICS [‡]	61 (42–74)	Normal ICS	95 (89–97)		<0.001
<u>Construct Validity</u>					
Parent Concern [§]	61 (45–78)	No Parent Concern	89 (70–97)		<0.001
Speech Surgery [§]	75 (54–88)	No Speech Surgery	58 (42–87)	<0.001	
Hypernasality [§]	59 (41–75)	No Hypernasality	84 (61–96)	<0.001	
Late Cleft Repair [§]	74 (58–91)	Early Cleft Repair	75 (60–92)		0.882

[†]VELO score[‡]ICS score < 4.6[§]Based on parent report^{††}Significance level has been set at 0.008 using Bonferroni's correction for multiple tests

Abbreviations: med (IQR) – Median (Interquartile Range); VELO-P – Velopharyngeal Effects on Life Outcomes Parent Report; VELO-Y – Velopharyngeal Effects on Life Outcomes Youth Report; ICS – Intelligibility in Context Scale