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ORIGINAL ARTICLE

Validation of Spanish version of the human papilloma virus impact profile (HIP)

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ABSTRACT

Objective: To examine the construct validity and reliability of the Spanish version of the HPV Impact Profile scale (HIP) among women in Medellin, Colombia.

Methods: We conducted a nested analysis of data from the pragmatic randomized controlled trial "Evaluation of Strategies for Optimal Clinical Management of Women with Atypical Squamous Cells of Undetermined Significance" (ASCUS-COL; NCT02067468). Women with Atypical Squamous Cells of Undetermined Significance (ASCUS) were randomly assigned to one of three triage strategies (Pap smear, colposcopy, HPV). Participants completed a questionnaire with sociodemographic information and the HIP scale translated into Spanish at baseline, two weeks after receiving triage test results, and one year after the second questionnaire. We conducted exploratory and confirmatory factorial analysis, and then assessed test reliability using Cronbach's alpha. Subsequently, we conducted multigroup confirmatory factor analysis to assess differences according to women's age, and configurational invariance of the factor structure over the three time measures.

Results: The sample consisted of 675 women, with a mean age of 40 years. The exploratory and confirmatory factor analysis for the HIP showed a seven-factor structure with appropriate adjustment indicators ($\chi^2_{df=317} = 1466.783$, $p < .0001$). Only two items (1 and 10) had low factor loads and were removed from the confirmatory analysis. Multigroup analysis according to women's age showed acceptable goodness of fit (RMSEA = 0.037, CFI/TLI:0.998/0.998). The factor structure was similar among the tree measures and the model preserved acceptable goodness of fit (RMSEA = 0.079, CFI:0.86). The Cronbach's alpha for the total score was 0.91, with the lowest score for sexual impact (0.49) and the highest score for worries and concerns (0.90).

Conclusions: The Spanish version of the HIP had adequate reliability and construct validity, and its use could be considered in clinic and research settings.

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Human papillomavirus; validation; psychosocial impact; HIP

Introduction

Human Papilloma virus (HPV), the necessary cause of cervical cancer, is a very common sexually transmitted infection worldwide. A meta-analysis of 194 studies between 1995 and 2009, including 1,016,719 women with normal cytological findings, found that the estimated global HPV prevalence in women was 11.7%[1]. However, there is heterogeneity between regions; for instance, the prevalence was 14.3% in low and middle income countries and was 6.2% in high income countries. The highest prevalence was observed in regions such as Africa (21.3%) and the lowest prevalence observed in the American continent (5.7%). There are also within country differences, that are well illustrated in the United States where 19 studies show HPV prevalence between 2.9% and 80.8%[2]. In females inhabiting five cities of Colombia the prevalence of high risk HPV infection was 49.2%[3].

HPV infection is even higher in the general population; for instance, 42.5% of adults aged 18–59 years had a genital infection with HPV in the United States between 2013 and 2014[4]. This diagnosis or even the uptake of the test can cause a series of psychological and social effects. Depression, guilt, anxiety, and anger are the most frequently reported emotions[5–7]. Some studies have also reported negative feelings toward sexual relationships, fear of rejection, stigmatization, worries about fertility, or fear of cancer[8–10].

Given the high prevalence of the infection and its psychosocial impact, it seems essential to have a validated tool that can measure this impact in one instrument, rather than using a series of scales or questionnaires. The HPV Impact Profile (HIP) was developed and validated in English by Mast et al., among US women to assess the psychosocial impact of abnormal cytology, cervical intraepithelial neoplasia, and genital warts, it had satisfactory reliability and construct validity as well as the capacity to discriminate disease severity[11]. The HIP has been used in studies in China, Canada, UK, India, South Korea, Portugal, and Philippines, most of the studies

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have evaluated the psychosocial impact of genital warts, although some of them have also evaluated the impact of cervical cancer screening[6,12–19]. Pirotta et al. conducted a study among Australian women and used the HIP to evaluate the psychosocial impact of HPV related illnesses and compared the survey with other generic quality of life instruments, and concluded that the HIP measures more sensitively the psychosocial impact than other surveys[20]. In 2010, Wang et al. conducted a study with a translated version of the survey into Chinese mandarin, however, did not report the psychometric properties of the instrument[21]. In 2019, Santos published a validation of the scale in Portuguese and suggested some modifications to the original instrument[22]. To our knowledge, there is no validation of the HIP in Spanish. Therefore, the purpose of this manuscript was to examine the construct validity and reliability of the HIP in Spanish among women in Medellin, Colombia.

Methods

Recruitment

The evaluation of psychometric properties of the HIP was conducted within the study "Psychosocial impact of the incorporation of the HPV test in the clinical management of abnormal Pap smears in women in Medellin, Colombia" that was nested in the trial "Evaluation of Strategies for Optimal Clinical Management of Women with Atypical Squamous Cells of Undetermined Significance" (ASCUS-COL, NCT02067468). In summary, ASCUS-COL was a pragmatic randomized controlled trial, in which women with an atypical squamous cells of undetermined significance (ASCUS) pap-smear were recruited through two private and one public health insurance companies. Participants were assigned randomly by blocks to one of three triage strategy groups: immediate colposcopy, conventional cytology at 6 and 12 months, or immediate hrHPV molecular test. A detailed description of the trial design is presented elsewhere[23]. For the purpose of this study, we included women enrolled and allocated to intervention between September 2012 and January 2014. Participants answered a questionnaire three times: (1) at enrollment, (2) at least two weeks after receiving their screening results, and (3) one year after the second questionnaire was applied.

HPV impact profile questionnaire

Feelings related to abnormal cytology and triage tests were measured through the HIP, which measures seven domains with 29 items. Domains include: worries and concerns (domain 1); emotional impact (domain 2); sexual impact (domain 3); self-image (domain 4); partner issues and transmission (domain 5); interactions with doctors (domain 6); and control/life impact (domain 7). This scale was validated in the United States and has been subsequently applied in the Taiwanese population[11,21]. Responses to each item were presented on a scale of 0–10, 0: Not at all, 1–3: A little, 4–6: Somewhat, 7–9: A great deal, 10: Extremely. Subsequently, each item was linearly transformed to a scale of 0 to 100, according to the methodology reported by Wang[21]. For all participants who answered at least 50% of the questions, a total score was calculated by adding all the items. Scores below 40 indicate little or no impact, between 40 and 70 a moderate impact, and above 70 indicate a high psychosocial impact[21].

Translation and cross-cultural adaptation

The HIP was developed in English. The questionnaire was translated into Spanish and back translated to English to verify the accuracy of the translation. Then, conceptual equivalence was confirmed by a panel of psychologists and the researchers. The priority was to ensure equivalence rather than having an exact reproduction, assuring that target audience perceived the meaning of each item in the same way as the original scale. Therefore, any words that caused misunderstandings or inconsistent interpretations were revised. Then, we piloted the questionnaire to five women, with similar socio-demographic characteristics as our target population, with the purpose of identifying words or phrases that caused difficulties in interpretation or understanding. Finally, we conducted a pilot test with 10 women, which informed the implementation of minor changes regarding the order of the questions and language.

Analysis

First, we described the population according to demographic characteristics such as age, marital status, educational level, and socio-economic status. Age and items of the HIP were described by means and standard errors, and categorical variables were described with the corresponding percentage and number of participants.

In the second step, we conducted an Exploratory Factor Analysis (EFA), in order to determine if the identified structures were similar to those found in the study by Mast et al.[11]

In the third step, we conducted a Confirmatory Factor Analysis (CFA) to confirm the factorial structure proposed by Mast et al.[11] using the mean and variance-adjusted weighted least-squares method (WLSMV). Factors that were not significant or had a loading less than 0.3 were removed from the final model. Models with comparative fit index (CFI) >0.9, and Root Mean Square Error of Approximation (RMSEA) ≤ 0.05 were considered to have a good fit, models with RMSEA ≤ 0.08 were considered to have an acceptable fit index[24]. We conducted CFA using a complete case analysis because of the low proportion of missing data. We assessed modification indices between the items and dimensions, allowing for cross-loading. After we obtained a CFA model with acceptable goodness of fit, we compared the mean score of each factor among study groups (pap-smear, colposcopy, and HPV). When the factor scores were normally distributed and homoscedastic, we used ANOVA to test differences among screening groups. When the factor score did not have a normal distribution or had heterogeneity variances, we performed a Kruskal–Wallis test.

In the fourth step, we assessed the HIP reliability, calculating the Cronbach's alpha for each factor using a polychromic correlation matrix. Cronbach's alpha ≥ 0.70 was considered acceptable[25].

In the fifth step, we conducted a multi-group CFA to assess the differences in the model according to participant age. We compared two groups: women aged under 40 years and women 40 years or older.

Finally, we tested configurational invariance of the factor structure obtained in model one comparing three time measures (questionnaire 1, 2, and 3). The aim of this analysis was to test how the factor structure may change over time. We calculated the factors scores for the three-time points. Then, we measured the invariance of the factor structure across time using maximum likelihood (ML) estimation for continuous variables. The analysis was conducted in Mplus 7.0 and R[26].

Ethics

This project was approved by the Bioethics committee of the Nacional School of Public Health, University of Antioquia. Participants signed informed consent prior to participation in the study. Participant health institutions provided permission to conduct the research. M. Merck, Sharp & Dohme, Corp., a subsidiary of Merck & Co. Inc provided authorization for the use of the HPV impact Profile and its translation.

Results

There were 675 women enrolled in the study; 200 women were allocated to the cytology arm, 256 to the colposcopy arm, and 219 to the HPV arm. Out of the 675 women, 468 (69.3%) completed the second questionnaire, 398 (59.0%) the third, and 394 (58.4%) women completed the three questionnaires. Women less likely to complete the three questionnaires belonged to one private health insurer, all other characteristics were similar among those who completed all the questionnaires and participants who completed only the baseline. The mean age was 40 years, approximately 46% of the participants were married or living with a partner, and a high percentage (43.7%) had elementary school or less education. Most of the participants belonged to medium-low or lower socio-economic stratums (Table 1). Differences in sociodemographic characteristics between arms were not found.

Item frequency distribution

Table 2 presents the name and mean of item responses. Items 27, 15, 2 have means close to 5, item 8 has the lowest mean. In the Exploratory Factor Analysis (EFA), we found seven factors that are confirmed by subsequent analysis. The determinant of the matrix was close to zero (0.00000239) indicating there was not an identity matrix; the above was also supported by the Bartlett's Test of Sphericity (p-value $< .05$). Therefore, there was no linearly dependent relationship. The result of Kaiser–Meyer–Olkin Measure of Sampling Adequacy (KMO) was equal to 0.901 indicating that varimax rotation was appropriate in the EFA.

Confirmatory factorial analysis

The structure presented the following factors: Worries and concerns, emotional impact, sexual impact, self-image, partner issues/transmission, interactions with doctors, and control/life impact ($\chi^2_{df=317}$=1466.783, $p < .0001$). Model one (Table 3) with seven factors has acceptable fit (RMSEA = 0.073, CFI = 0.920). However, items 1 (Feel good about myself) and 10 (Feel my body is sexual attractive) had low factor loadings and were removed. We tested modification indices to improve the model fit. Models two to four do not have better fit than model one, which lacks a modification index (Table 3). Figure 1 presents the final factor structure including the modification indices. There was no difference in the mean score of each factor among study groups (Table 4).

Multigroup confirmatory factorial analysis by women's age

The seven-factor model showed acceptable fit for both age groups with RMSEA = 0.068 and CFI = 0.929 for women

Table 1. Sociodemographic characteristics of women with ASCUS Pap-smear in Medellin, Colombia between 2011 and 2016.

	Total ($n = 675$)	Pap-smear ($n = 200$)	Colposcopy ($n = 256$)	HPV ($n = 219$)	p-Value
Age (SD)	40.0 (11.66)	40.7 (12.08)	40.2 (11.40)	39.1 (11.865)	0.379
Range	20–69	21–66	20–68	20–69	
Marital status					
Single	264 (39.1%)	71 (35.5%)	101 (39.5%)	92 (42.0%)	0.767
Married	154 (22.8%)	47 (23.5%)	61 (23.8%)	46 (21.0%)	
Common-law	158 (23.4%)	53 (26.5%)	54 (21.1%)	51 (23.3%)	
Other	99 (14.7%)	29 (14.5%)	40 (15.6%)	30 (13.7%)	
Education					
None or Incomplete elementary	96 (14.2%)	30 (15.0%)	32 (12.5%)	34 (15.5%)	0.356
Completed elementary	199 (29.5%)	70 (35.0%)	74 (28.9%)	55 (25.1%)	
Completed high school	207 (30.7%)	53 (26.5%)	82 (32.0%)	72 (32.9%)	
Technical-technological	121 (17.9%)	31 (15.5%)	52 (20.3%)	38 (17.4%)	
College/graduate	52 (7.7%)	16 (8.0%)	16 (6.3%)	20 (9.1%)	
Health care insurance					
Contributive (private)	361 (53.5%)	106 (53.0%)	141 (55.1%)	114 (52.1%)	0.794
Subsidized (public)	314 (46.5%)	94 (47.0%)	115 (44.9%)	105 (47.9%)	
Socioeconomic level					
Low-low	137 (20.6%)	51 (25.9%)	43 (17.0%)	43 (20.0%)	0.347
Low	314 (47.3%)	86 (43.7%)	126 (49.8%)	102 (47.7%)	
Medium-low	153 (23.0%)	42 (21.3%)	58 (22.9%)	53 (24.8%)	
Medium, medium-high, high	60 (9.0%)	18 (9.1%)	26 (10.3%)	16 (7.5%)	

The table presents all participants enrolled.

Table 2. Mean and standard deviation of HIP items.

	Factor/item	Survey 1 Mean (SD)	Survey 2 Mean (SD)	Survey 3 Mean (SD)
Worries and concerns				
7	Feel something is seriously wrong with her	3.50 (2.872)	2.28 (2955)	1.36 (2489)
12	Concerned about having genital warts	4.47 (4032)	2.53 (3505)	1.61 (2864)
13	Worried there are no treatments for genital warts	3.44 (3860)	1.96 (3204)	1.39 (2680)
15	Worried about having abnormal Pap test results	5.69 (3571)	3.54 (3625)	2.12 (3158)
16	Worried that there is no cure for what causes an abnormal Pap test	4.22 (3815)	2.75 (3517)	1.61 (2879)
17	Worried about fertility	1.76 (3175)	1.21 (2772)	0.68 (2022)
18	Concerned about getting cervical cancer in the future	5.86 (3870)	4.53 (3671)	3.27 (3285)
19	Worried that there are no treatments for cervical cancer	4.43 (3957)	3.13 (3585)	2.43 (3090)
20	Worried about having pain during future gynecological exams	3.53 (3620)	3.23 (3675)	2.17 (3106)
Emotional impact				
2	Feel anxious	5.51 (3057)	3.68 (3316)	1.98 (2846)
3	Feel recent gynecology test results were unexpected	7.13 (3078)	4.05 (3832)	3.15 (3470)
5	Feel depressed	3.72 (3197)	2.42 (3069)	1.27 (2407)
8	Feel angry	1.57 (2694)	1.19 (2492)	0.67 (1940)
14	Optimist about future gynecological health	2.45 (2489)	2.17 (2407)	1.73 (2166)
Sexual impact				
24	Reduction in sexual activity	3.36 (3595)	2.55 (3546)	1.34 (2811)
25	Satisfaction with sex life	3.28 (3052)	2.70 (2799)	2.25 (2497)
Self-image				
1	Feel good about herself	4.92 (3053)	2.90 (3108)	2.07 (2571)
10	Feel her body is sexual attractive	3.49 (2718)	2.82 (2513)	2.61 (2240)
11	Feel ashamed	2.05 (2969)	1.31 (2672)	0.88 (2164)
23	Feel upset by recent gynecology exam and results	2.24 (3144)	1.41 (2775)	0.88 (2166)
Partner issues/transmission				
9	Feel confident partner will accept her	2.82 (3048)	1.94 (2623)	1.74 (2282)
21	Worried about transmitting an infection to her sexual partner	3.51 (3766)	2.11 (3349)	1.05 (2458)
22	Worried about the partner transmitting her a sexual infection	5.16 (3806)	4.12 (3671)	3.23 (3430)
Interaction with doctors				
27	Feel relaxed after recent gynecological exam	5.75 (3431)	3.02 (3508)	2.13 (2735)
28	Feel embarrassed because gynecological exam	2.13 (3102)	2.12 (3191)	1.98 (3097)
29	Feel unconformable with gynecological exam	2.05 (2925)	2.68 (3395)	2.56 (3310)
Control/life impact				
4	Feel in control over her health	4.25 (2889)	3.51 (2945)	2.22 (2191)
6	Feel can concentrate on everyday matters	3.48 (2863)	2.31 (2574)	1.49 (1957)
26	Sleeping problems	3.15 (3443)	1.95 (3022)	0.90 (2060)

Table 3. Confirmatory Factor Analysis models and goodness of fit.

Models	Chi-square value	Chi-square DF	Chi-square *p*-value	CFI	RMSEA estimate (95% CI)
CFA					
Model 1. General model	1466.780	317	<.000	0.920	0.073 (0.069–0.077)
Model 2. (modification index emotional with P7)	1413.165	316	<.000	0.923	0.072 (0.068–0.076)
Model 3. (modification index control with P7)	1374.260	315	<.000	0.926	0.071 (0.067–0.077)
Model 4. (modification index emotional with P27)	1364.850	314	<.000	0.927	0.070 (0.067–0.075)
Model 5. (modification index imagen with P7)	1340.355	313	<.000	0.928	0.070 (0.066–0.077)
Multi-group CFA					
Model 6. <40-years-old	782.627	303	<.000	0.929	0.068 (0.062–0.074)
Model 7. >40-years-old	817.570	303	<.000	0.920	0.072 (0.066–0.077)
Model 8. Total multi-group	1675.135	700	<.000	0.927	0.064 (0.060–0.072)
Time invariant test					
Model 9. Configurational time invariance model	1562.96	186	<.000	0.860	0.079 (0.066–0.080)

Abbreviations. CFA, Confirmatory Factorial analysis; RMSEA, Root Mean Square Error of Approximation; CFI, comparative fit index; DF, degrees of freedom.

younger than 40 years and RMSEA = 0.072 and CFI = 0.920 for women older than 40 years. The multi-group CFA had good fit (RMSEA = 0.037, CFI/TLI:0.998/0.998) (Table 3, models 6, 7, and 8).

Reliability

We calculated Cronbach's alphas for each factor and the total score for each of the time measures. The Cronbach's alpha for the total score was 0.91. The factor with the highest Cronbach's alpha was worries and concerns (0.90) (Table 5). The factors partner issues/transmission, emotional impact, and interactions with doctors presented alphas between 0.61 and 0.64. The factor with the lowest reliability was sexual impact (0.49).

The instrument was applied to the same women at different times, which corresponds to a test-retest measurement. However, the retest results were mediated by the knowledge of the results of the triage tests. Therefore, changes in the measurement were found as can be seen in Table 2 and Figure 2. The results correspond to the findings of the invariance analysis.

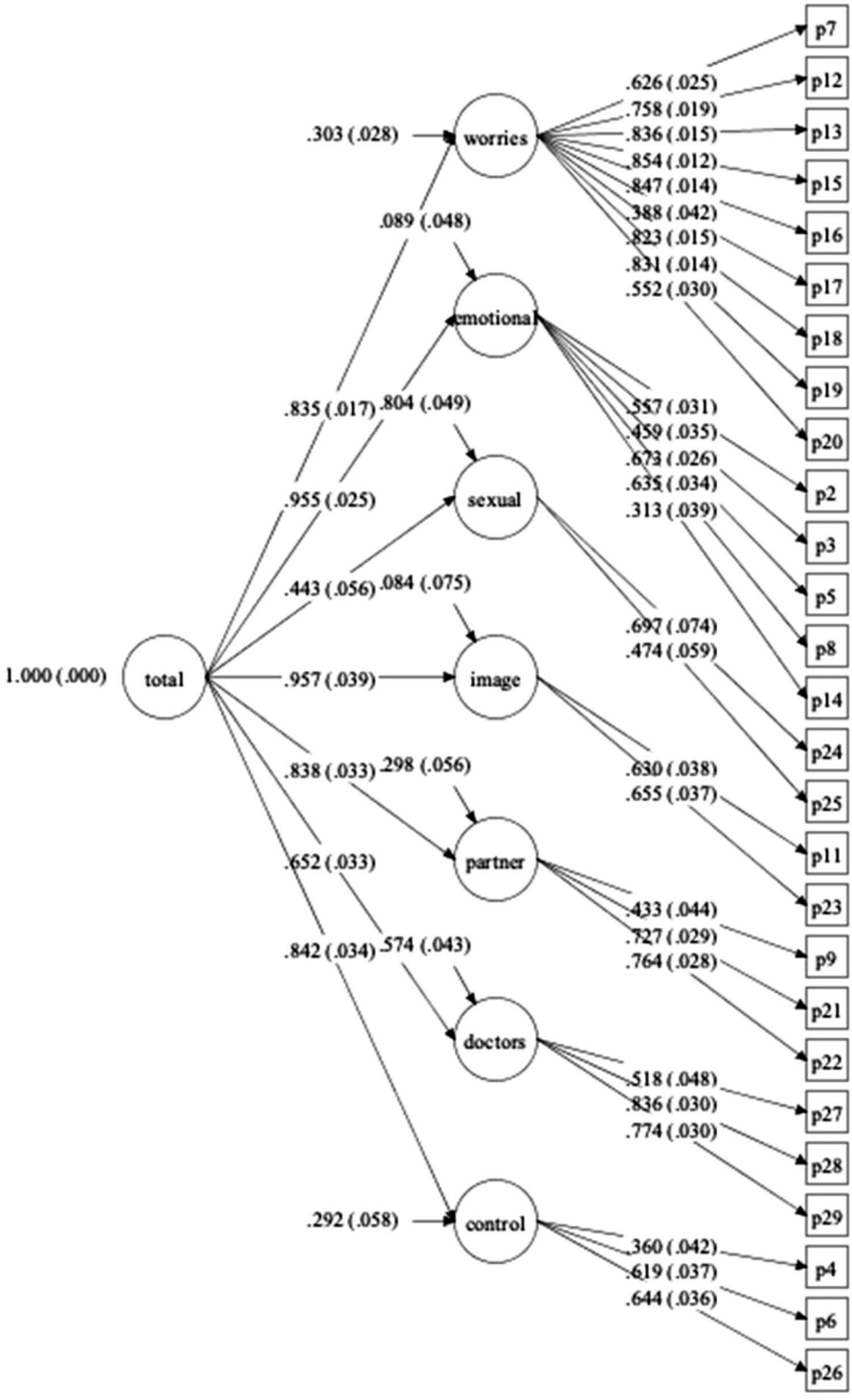

Figure 1. Confirmatory factor analysis HPV impact profile (HIP). χ^2 =1466.783, d.f. = 317, p value < .0001. Arrows show standardized loadings and standard errors.

Configurational invariance among three-time measures

The configurational invariance comparing three time measures showed a reduction in CFI and the indicator was lower than in the original model (0.86), with an acceptable fit according with the RMSEA = 0.079 (Log likelihood = 20,284.756, BIC = 40,999.483). Factor loadings had small differences across time, except for the partner issues factor and the interaction with doctor's factor (Figure 2). The second measure of these two factors had a lower loading compared with the first and third measures (Table 3, model 9).

Discussion

The Spanish version of the HIP had a seven-factor structure with appropriate adjustment indicators. In the Confirmatory Factor Analysis (CFA) the model two had acceptable goodness of fit and is more parsimonious that other models. The structure was similar according to age group and across the different time points.

Our analyses presented a factor structure similar to that proposed by Mast et al.[11], except for two items that presented low factor loads (items 1 and 10) in the self-image factor. We also coincide with a high Cronbach's Alpha (0.90) for the worries and concerns dimension and a low Alpha for interaction with doctors (0.61 and 0.69-Mast). Sexual impact presented the lowest Alpha in the research by Mast and ours, although the Alphas were not similar (0.64 and 0.49, respectively). The other dimensions had lower Alphas than those presented by Mast et al. Given the high Alpha in the worries/concern factor, we consider as well as suggested by Mast et al.,[11] that the factor could be reduced.

A validation carried out in Portuguese proposed another structure with six factors (worries/concerns, emotional impact, sexual impact, negative emotions, positive emotions, and future treatment/transmission), they also eliminated six items (7, 11, 12, 13, 20, and 26), and some items were assigned to other factors[22]. Our results, partially coincide with worries/concerns, emotional impact, and sexual impact factors. The two items in our study with low factor loads (items 1 and 10) were not eliminated in the Portuguese version.

As a strength of the study, we highlight an adequate sample size to estimate the CFA[27]. The sample also included women of different age groups, economic, and educational levels. The present study also included a CFA which was not tested in previous validations of the same test. Finally, we tested the variation of the factor structure according to age group and over time, which provides information about how this test will perform in subpopulations and in longitudinal studies.

Among the limitations of the study, we report a low internal consistency for the sexual impact factor. A lack of cultural appropriateness of the questions may be a reason for this finding. Alternatively, additional questions may be needed to better measure the construct. Additionally, due to the lack of specific tests that measure the impact of HPV a convergence analysis was not carried out. Since there is not a gold standard to make comparisons we were not able to calculate the sensitivity and specificity of the test either. Pirottta et al. reported that the HIP measures more sensitively the psychosocial impact of HPV related diseases than other generic quality of life surveys[20]. Attempts to calculate convergent validity in previous studies have not been successful, the Hospital Anxiety and Depression Scale (HADS) that assesses psychological morbidity in patients with physical pathologies in outpatient treatment, and the Sheehan Disability Scale were used by Mast et al. in the convergent validation of the scale; however, the correlations were moderate (0.49 and 0.58)[11]. The HADS and the Index of Sexual Satisfaction (ISS) were used by Santos *et al.*; however, reported only one factor with a correlation >0.6 for each of the scales[22].

Table 4. Mean of each factor of the HPV Impact Profile (HIP) and differences by study group.

Factor	Pap-smear	Colposcopy	HPV	*p*-Value
Worries and concerns	−0.01 (0.54)	0.03 (0.55)	−0.02 (0.50)	.8410[a]
Emotional impact	−0.01 (0.51)	0.02 (0.50)	0.00 (0.47)	.8350[a]
Sexual impact	0.04 (0.51)	0.01 (0.51)	−0.02 (0.47)	.2050[a]
Self-image	−0.01 (0.58)	0.02 (0.56)	0.01 (0.53)	.8689[b]
Partner issues/transmission	−0.01 (0.37)	0.02 (0.36)	−0.01 (0.35)	.9010[a]
Interactions with doctors	0.01 (0.42)	0.03 (0.42)	0.02 (0.42)	.8786[b]
Control/life impact	0.00 (0.32)	0.00 (0.30)	0.01 (0.29)	.8121[b]
Score total	−0.01 (0.49)	0.02 (0.02)	0.00 (0.45)	.8401[b]

[a]*p*-Value for Anova.
[b]*p*-Value for Kruskall–Willis test.

Table 5. Cronbach's Alpha per HIP factors.

Factors	Cronbach's Alpha
Worries and concerns	0.90
Emotional impact	0.62
Sexual impact	0.49
Self-image	0.59
Partner issues/transmission	0.64
Interactions with doctors	0.61
Control/life impact	0.54
Total score	0.91

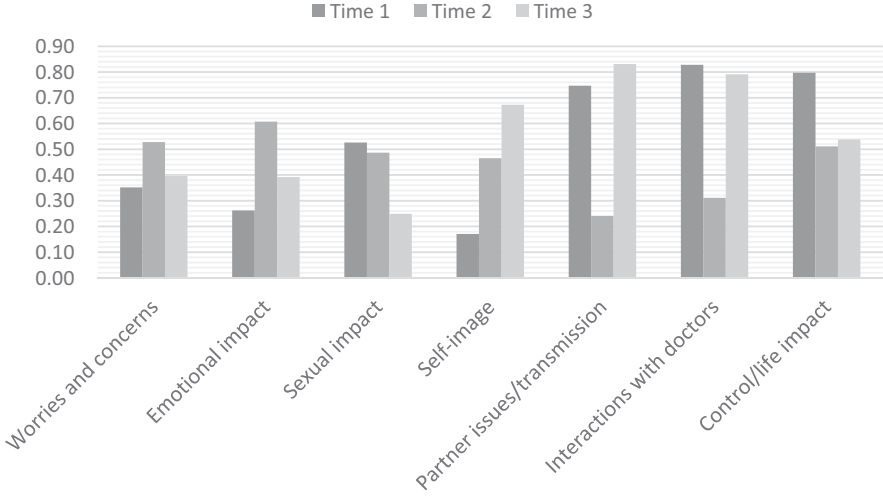

Figure 2. HIP factor loading across measures.

Validation of the scale in other Latin American countries or Spain may be appropriate; however, local idioms could play a role in the understanding of the questionnaire. Based on the results of this validation, we consider that HIP in Spanish could be used in health services in order to assess the impact of the HPV test, either as a primary screening test or a triage test. The good adjustment of the factor structure and internal consistency demonstrated utility in different age groups. Furthermore, when evaluating different measurements over time, we obtained a similar factor structure supporting its utility in longitudinal evaluations. We recommend that subsequent studies conduct an analysis focused on the self-image factor to determine how it could be improved.

Conclusion

The Spanish version of the HIP presented adequate reliability and construct validity. This tool could be used with different age groups, different screening tests, diagnostic tests, and to assess the impact of interventions.

Transparency

Declaration of funding

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Declaration of financial/other relationships

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Author contributions

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