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INFECTIO

Validation of the HPV Impact Profile in Portuguese women with human papilloma virus

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ABSTRACT

Objective: Human papilloma virus (HPV) is the world's most common causative agent in sexually transmitted viral infections; thus requiring clinical guidance, before and after treatment, to promote better quality of life in women diagnosed with HPV. The HPV Impact Profile (HIP) is a comprehensive instrument used to assess the psychosocial impact of HPV and related interventions in a wide range of domains. The main purpose of this study was to validate the HIP in Portuguese women, so that it can be used in this population, both in research and in clinical settings.

Methods: A sample of 178 Portuguese women infected with HPV were assessed with the following instruments: Index of Sexual Satisfaction, Hospital Anxiety and Depression Scale and HPV Impact Profile.

Results: The results of the confirmatory factor analysis showed some changes to the original model, which resulted in an adapted version with six domains, compared to the seven domains of the original model. The final model showed a good fit to the data. All Cronbach's alphas were higher than 0.79 indicating a high level of internal consistency of the subscales. As in the original HIP questionnaire, the exception was sexual impact, with a lower, but acceptable, Cronbach's alpha. Convergent and discriminant validities of the instrument were also assessed.

Conclusions: The Portuguese version of the HIP presents good psychometric properties, allowing its use in clinical trials as well as in clinical practice in order to evaluate quality of life in women with HPV.

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KEYWORDS

HPV; quality of life; validation; sexual satisfaction; morbidity

1. Introduction

The human papilloma virus (HPV) is a sexually transmitted virus that is lodged in mucous membranes or even on the skin, affecting both men and women. According to the American Centers for Disease Control and Prevention¹, HPV is the world's most common causative agent in sexually transmitted viral infections. According to the WHO there are 2.784 million women 15 years old or over at risk of developing cervical cancer (CC). According to current estimates, every year, 527.624 women are diagnosed with this type of cancer, while 265.672 die from the disease².

In Portugal, CC is considered the second most frequent gynecological malignant tumor in Portuguese women under 50. Moreover, between 2011 and 2015 this country showed a decrease in both incidence and mortality rate by CC³. The most common high-risk HPV types, 16 and 18, are associated with carcinoma, while type 6 and 11 are the most persistent in benign and premalignant lesions⁴. HPV represents a public health problem given the high prevalence of the infection leading to cancer, with the additional factor that the diagnosis carries a negative psychosocial impact on the patient's life⁵.

A qualitative study has revealed that an HPV diagnosis can cause two types of reaction in women: negative and positive. Negative impact concerns reactions such as shame or stigma, while the positive impact relates to reactions such as relief and happiness⁶. Also, studies show that both the clinical examinations and treatment cause suffering, anxiety and reduced quality of life (QoL)^{7,8}. Additionally, patients diagnosed with genital warts and diseases related to HPV have reported a negative impact on their psychosocial well-being and QoL⁹.

The diagnosis of a sexually transmitted infection (STI) and its treatment have a negative impact not only on women, but also on their marital relationship¹⁰. Factors such as fear of infection, and physical and psychosocial discomfort regarding the treatment were found to influence the sexual life of HPV-infected women and of their partners¹¹. Upon receiving the diagnosis, many women cease wanting sexual intercourse while others reduce their activity¹¹. The psychological, emotional and negative interpersonal aspects of having HPV are more relevant for sexual adjustment than the characteristics of the infection itself¹². Additionally, women with an STI are not merely aware of these social stigmas: they internalize them, reporting reduced sexual satisfaction

compared to men¹³. A study conducted at eleven hospitals including women diagnosed with HPV found a greater concern about sexuality and a negative impact in different stages of the infection, compared to the general population¹⁴. On the other hand, sexually satisfied women, having positive sexual self-esteem and an active sexual life, experience reduced anxiety when confronted with the diagnosis/treatment of HPV¹². Results may be related to how much they are satisfied with their own relationship and with the communication within the relationship itself, as these factors moderate the impact of an HPV diagnosis related to sexual wellbeing and QoL¹².

HPV infection is associated with anxiety, depression, fear of developing CC^{15,16} and worse QoL^{17,18}. In addition, the ever-present concern associated with ongoing examinations, invasive and painful treatments, and consultations which increase in case of relapses, contribute even further to women's vulnerability regarding both emotional and sexual wellbeing¹⁹.

Psychosexual counseling is a key aspect to prevent further negative psychosexual results during the treatment of HPV-related lesions²⁰, in order to provide better clinical guidance, before and after treatment, and to promote a better QoL²¹.

The existing instruments that assess QoL in the presence of HPV are scarce. Thus, finding measures capable of assessing QoL associated with the health and the psychological impact of HPV is not only needed, but also relevant in order to design interventions that can meet the patients' needs within clinical practice²². Therefore, there is a need for instruments to assess the impact of this infection.

The HPV Impact Profile (HIP) was the first HPV-specific questionnaire able to assess, at once, a broader spectrum of HPV-related disease or conditions, including genital warts²³. This instrument includes 29 items and aims at assessing the psychosocial impact of HPV in the following seven domains: 1 – worries and concerns; 2 – emotional impact; 3 – sexual impact; 4 – self-image; 5 – partner issues and transmission; 6 – interactions with doctors; 7 – control/life impact. Potential uses of this questionnaire include general research about HPV (e.g. study of evolution trends about the psychosocial impact of the HPV and analysis of predictors associated with higher psychosocial burden), as well as clinical settings, helping clinicians to identify impaired domains and, as such, to promote better QoL in this population.

The purpose of this study was to adapt the HIP²³ to Portuguese women with HPV. This instrument has already been validated in Mandarin Chinese in order to avoid spelling and grammar mistakes, and wording errors, while preserving the original version and guaranteeing its cultural adequacy. It was applied as a pilot test²⁴. However, the authors have not reported psychometric properties for this Chinese version. Therefore, to the best of our knowledge, this is the first HIP validation study in a foreign language.

2. Methods

2.1. Participants

The sample included 178 women with HPV who were receiving treatment in two major public hospitals in the Northern

Region of Portugal. Criteria for inclusion were: (i) adult women, with an HPV diagnosis; (ii) having a sexual partner. Exclusion criteria included being pregnant or having another STI.

2.2. Instruments

2.2.1. HPV Impact Profile

This questionnaire aims to assess the psychosocial impact of HPV infection²³. It is made up of 29 items that are divided into seven domains: Worries/Concerns (e.g. "I am worried about having abnormal Pap test results"); Emotional Impact (e.g. "When I think about my recent gynecology exam or test results, I feel anxious"); Sexual Impact (e.g. "After my recent gynecology exam or test results, I am having less sex"); Self-Image (e.g. "When I think about my recent gynecology exam or test results, I feel my body is sexually attractive"); Partner/Transmission (e.g. "After my recent gynecology exam or test results, I am worried that having sex with my partner may give him/her and infection"); Interaction with Doctors (e.g. "I felt my recent gynecology procedures were embarrassing"); and Health Control/Life Impact (e.g. "After my recent gynecology exam or test results, I feel I can concentrate as well as usual on everyday matters"). Answers are provided on a Likert scale ranging from zero (Not at all) to ten (Extremely). The ranking of each domain is calculated through the sum of its items, divided by the number of items of the domain, multiplied by ten. The same formula is valid to calculate the total score. Higher scores indicate worse QoL.

2.2.2. Index of Sexual Satisfaction

This instrument is a 25-item unidimensional scale with the purpose of assessing the level of sexual satisfaction in a marital relationship (e.g. "Our sex life is very exciting" and "My partner seems to avoid sexual contact with me")²⁵. Answers are provided on a Likert scale ranging from one (Never feel) to seven (Always feel). Higher results indicate higher levels of sexual dissatisfaction.

2.2.3. Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale (HADS)²⁶ assesses psychological morbidity in patients with physical pathologies in outpatient treatment. It is made up of 14 items, divided into two subscales: Anxiety (e.g. "I get a sort of frightened feeling as if something awful is about to happen") and Depression (e.g. "I get sudden feelings of panic"). Scores range from 0 to 21 for both subscales. Higher scores indicate higher levels of psychological distress.

2.3. Procedure

This study used a cross-sectional design. Data was collected in two hospitals in the Northern Region of Portugal, namely, Hospital of Braga and Hospital of Santa Luzia (ULSAM). The study was approved by the Portuguese Data Protection

Authority (CNPD) and by each hospital's ethics committee. Patient identification was carried out by each patient's gynecologist who invited them if they fulfilled the inclusion criteria. In the diagnostic appointment, all women having a positive HPV result were informed by the gynecologist about the infection, including the specific HPV type. HPV type was then used to group patients into only two categories: low risk or high risk.

All patients were duly informed regarding the nature of the study itself, data confidentiality and voluntary participation, signing informed consent. All invited patients accepted to take part in this study. All data was collected in paper format and stored securely in locked file cabinets.

2.4. Sample characteristics

The sample included 178 women with HPV, ages ranging from 21 to 63 (*M* = 39, *SD* = 9.85). Participants' education varied considerably, from 2 to 17 years. More specifically, 45.5% of the sample had at most nine school years, 36.5% attended a secondary school (10–12 years) and 18.0% had a university degree. The mean number of years of schooling is large (10.15) and so this sample is highly educated. Regarding marital status, 43.3% of participants were married. In this sample, 42.1% presented a high-risk HPV diagnosis. Table 1 presents the sample characterization.

2.5. Data analysis

Descriptive analyses were used to describe the sociodemographic and clinical characteristics of HPV women. A confirmatory factor analysis (CFA) was applied to the Portuguese version of the HIP²³. The HIP questionnaire was applied in a survey with 178 Portuguese women.

The CFA was performed using the structural equation modeling (SEM) technique, following the main recommendations presented by Brown²⁷. The observed variables were analyzed as continuous data²⁸. The robust ML estimator was used to compute non-normality robust standard errors and chi-square, through a scaling correction factor for the Satorra–Bentler method²⁹. Reliability of the latent variables

was assessed using Cronbach's alpha and composite reliability CR³⁰, with CR >.7 suggesting good factor reliability³¹. Convergent validity and discriminant validity were inspected using the average variance extracted³⁰ and the Heterotrait–monotrait (HTMT) ratio of correlation criterion³². According to Hu and Bentler³³ and Kline³⁴, good model fit is indicated by a ratio chi-square over the number of degrees of freedom smaller than 3, CFI, TLI and RNI values "close to" .95 (or higher), RMSEA values "close to" .06 (or smaller), and SRMS values "close to" .08 (or smaller).

Statistical analyses were performed using the R statistical environment RStudio, version 3.4.3,³⁵ through "lavaan" packages³⁶ and "semTools"³⁷.

2.6. Construct validity

Mast et al. grouped the 29 items from the HIP²³ into the following seven hypothesized domains (asterisks denote reverse scores): Domain 1 – Worries/Concerns (Items 7, 12, 13, 15, 16, 17, 18, 19, 20); Domain 2 – Emotional Impact (Items 2, 3, 5, 8, 14*); Domain 3 – Sexual Impact (Items 24, 25*); Domain 4 – Self-Image (Items 1*, 10*, 11, 23), Domain 5 – Partner/Transmission (Items 9*, 21, 22), Domain 6 – Interaction with Doctors (Items 27*, 28, 29); Domain 7 – Health Control/Life Impact (Items 4*, 6*, 26). The adequacy of this item division to the sample of this study was explored. Extremely similar wordings were observed for items 21 and 22 in the Portuguese version and, thus, the corresponding residual correlation was included in the model.

As summarized in Table 2, applied to this study's sample, the model revealed poor reliability, validity problems and poor fitting to the data. Therefore, a new item division was developed based on both an exploratory factor analysis and a theoretical understanding of the literature review. This confluence between theory and statistics allowed the following six hypothesized domains to be obtained: Domain 1 – Worries/Concerns (Items 3, 7, 12, 13, 15, 16, 17, 20), Domain 2 – Emotional Impact (Items 2, 5, 8, 26), Domain 3 – Sexual Impact (Items 9*, 24, 25*), Domain 4 – Future Treatment/Transmission (Items 18, 19, 21, 22), Domain 5 – Positive Emotions (Items 1*, 4*, 6*, 10*, 14*, 27*), Domain 6 – Negative Emotions (Items 11, 23, 28, 29).

A CFA was conducted to confirm the effectiveness of this factorial division. As before, the same residual correlation due to very similar wordings was added to the model. In general, this model presented good reliability and acceptable convergent validity (AVE values lower than the .5 threshold are indeed very close to this limit). Nevertheless, all the considered goodness-of-fit indices lay outside the recommended range, as summarized in Table 2.

The model fit was improved by removing all items with small factor loadings (less than .4). This procedure led to the elimination of six items out of 29, namely items 7, 11, 12, 13, 20 and 26. Table 2 also presents the results of the CFA applied to the reduced model, with 23 indicators, which is depicted in Figure 1.

Table 1. Sociodemographic characterization of women with HPV (*N* = 178).

Continuous measure	Min	Max	Mean	SD
Age	21	63	39	9.85
Categorical measure				%
Basic education				45.5
Secondary education				36.5
Higher education				18
Civil status				
Single				1.7
Married/common law union				57.9
Partner				40.4
HPV type				
Type 6/11 low risk				57.9
Type 16/18 high risk				42.1
Duration of treatment				24.2
Low risk, short HPV duration				33.7
Low risk, long HPV duration				17.4
High risk, short HPV duration				24.7
High risk, long HPV duration				

Table 2. Results of the confirmatory factor analysis.

Model	Factor	Validity/reliability measures			Fitting measures (scaled versions)
		Alpha	CR	AVE	
Original HPV model (Mast et al. ²³)	Worries/Concerns 7, 12, 13, 15, 16, 17, 18, 19, 20	0.88	0.88	0.57	Chi-square = 907.51, <i>df</i> = 355 CFI = .78 TLI = .75 RNI = .83 RMSEA = .094 RMSEA upper 90% CI = .100 SRMR = .97
	Emotional Impact 2, 3, 5, 8, 14	0.8	0.8	0.45	
	Sexual Impact 24, 25	0.74	0.74	0.59	
	Self-Image 1, 10, 11, 23	0.76	0.76	0.47	
	Partner/Transmission 9, 21, 22	0.66	0.54	0.33	
	Interaction with Doctors 27, 28, 29	0.69	0.77	0.56	
	Health Control/Life Impact 4, 6, 26	0.66	0.66	0.44	
Total	0.93	0.96	0.5		
Initial model	Worries/Concerns 3, 7, 12, 13, 15, 16, 17, 20	0.82	0.82	0.5	Chi-square = 868.17 <i>df</i> = 361 CFI = .80 TLI = .77 RNI = .85 RMSEA = .089 RMSEA upper 90% CI = .095 SRMR = .111
	Emotional Impact 2, 5, 8, 26	0.81	0.81	0.52	
	Sexual Impact 9*, 24, 25*	0.69	0.7	0.48	
	Future Treatment/Transmission 18, 19, 21, 22	0.86	0.85	0.61	
	Positive Emotions 1*, 4*, 6*, 10*, 14*, 27*	0.83	0.84	0.48	
	Negative Emotions 11, 23, 28, 29	0.76	0.79	0.55	
	Total	0.93	0.96	0.52	
Final model (reduced model)	Worries/Concerns 3, 15, 16, 17	0.86	0.87	0.64	Chi-square = 296.27 <i>df</i> = 214 CFI = .951 TLI = .943 RNI = .966 RMSEA = .046 RMSEA upper 90% CI = .056 SRMR = .076
	Emotional Impact 2, 5, 8	0.79	0.79	0.55	
	Sexual Impact 9*, 24, 25*	0.69	0.71	0.48	
	Future Treatment/Transmission 18, 19, 21, 22	0.86	0.85	0.61	
	Positive Emotions 1*, 4*, 6*, 10*, 14*, 27*	0.83	0.84	0.48	
	Negative Emotions 23, 28, 29	0.83	0.85	0.71	
	Total	0.92	0.96	0.57	

Abbreviations. CR, Composite reliability; AVE, Average variance extracted; CFI, Comparative fit index; TLI, Tucker–Lewis Index; RNI, Relative noncentrality index; RMSEA, Root–mean–square error of approximation; SRMR, Standardized root mean square residual. Asterisks denote reverse scores.

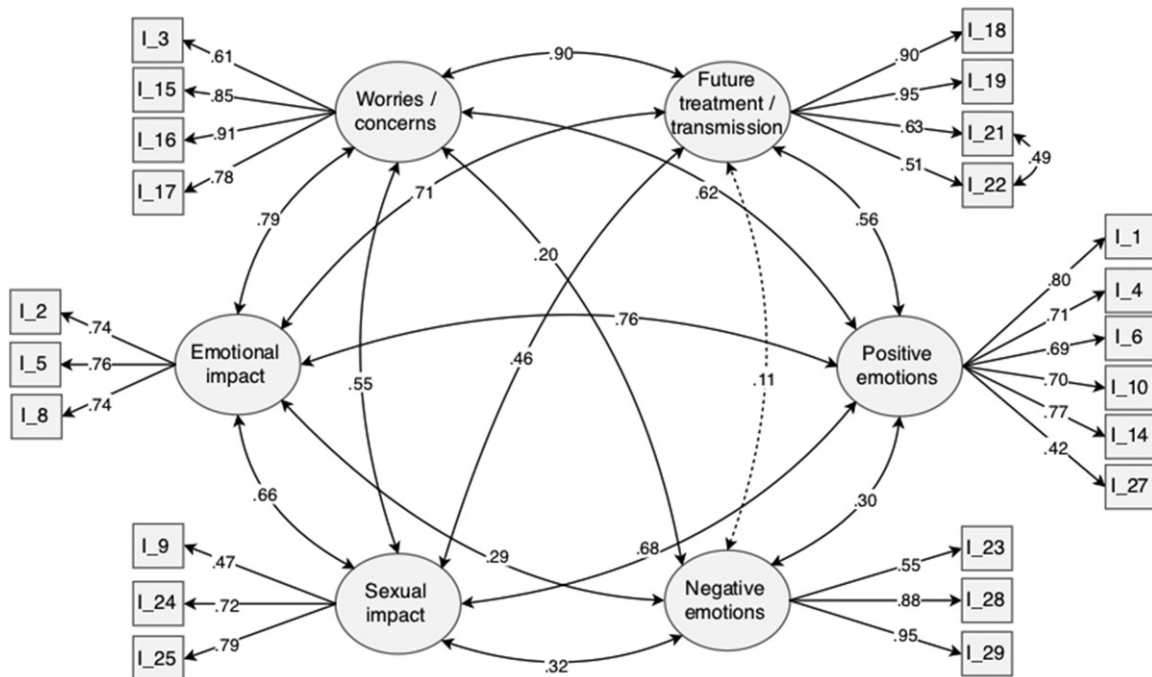


Figure 1. The final structural equation model for the HIP, fitting for Portuguese women diagnosed with HPV. Ellipses are the latent constructs (factors or scales) and rectangles are the indicators (items). All values are standardized parameter estimates. Solid lines represent significant relationships and the dashed line denotes a non-significant residual covariance. For clarity, errors of endogenous variables are not shown, but were included in the analysis.

3. Results

3.1. Reliability

As observed in Table 2, all six domains showed good construct reliability. Each domain exhibited acceptable Cronbach’s alpha (from .69 to .86), good composite reliability and acceptable average variance extracted (only two values bordering below

the .5 threshold). Goodness-of-fit measures are within the recommended range and thus good fit is achieved.

3.2. Goodness-of-fit measures

The results revealed a good adjustment of this model to the data: chi-square = 296.27; *df* = 214; CFI = .951; TLI = .943;

Table 3. The HTMT ratio of correlations for the six-factor final model depicted in Figure 1, and the HADS and ISS scales.

Factor	F1	F2	F3	F4	F5	F6	HADS	ISS
F1								
F2	.828							
F3	.618	.713						
F4	.849	.692	.507					
F5	.638	.749	.713	.549				
F6	.275	.399	.414	.303	.418			
HADS	.390	.667	.538	.362	.599	.331		
ISS	.195	.334	.772	.175	.435	.347	.564	

Abbreviations. F1, Worries/Concerns; F2, Emotional Impact; F3, Sexual Impact; F4, Future Treatment/Transmission; F5, Positive Emotions; F6, Negative Emotions; HADS, Hospital Anxiety and Depression Scale; ISS, Index of Sexual Satisfaction.

RNI = .966; RMSEA = .046; RMSEA upper 90% CI = .056; SRMR = .076.

3.3. Discriminant validity

The Heterotrait–monotrait (HTMT) ratio of correlations criterion³² was used to establish the discriminant validity. This type of validity is used to guarantee that indicators of theoretically distinct constructs are not highly intercorrelated²⁷. The HTMT matrix (Table 3) shows the discriminant validity of the model according to the HTMT criterion, as no entry exceeds the common prescribed cutoff of 0.85³². Comparing the HIP with the other two instruments (HADS and ISS), the discriminant validity was established, as before, through the HTMT matrix (Table 3), using the same argument.

3.4. Convergent validity

Convergent validity is indicated by evidence that different indicators of theoretically similar or overlapping constructs are strongly interrelated²⁷. Convergent validity was established between the scales of HIP and psychological morbidity (HADS) and sexual satisfaction (ISS). Results are summarized in Table 4 and values greater than .5 were taken as evidence of convergent validity^{38,39}. As expected, among all HIP domains, the strongest relationship of ISS was observed for Sexual Impact, and the strongest relationship of HADS was observed for Emotional Impact. ISS was also associated with the depreciation of Positive Emotions, and HADS was also related to both Sexual Impact and depreciation of Positive Emotions.

3.5. Differences in quality of life according to HPV type and women’s education level

Quality of life showed differences according to the type of HPV ($t [176] = -5.161, p < .001$). Women with high-risk HPV reported worse QoL when compared to those with low-risk HPV. However, there were no differences in QoL according to the women’s level of education ($F [3, 174] = .662, p = .576$).

4. Discussion

The purpose of this study was the validation of the HIP²³ in a sample of Portuguese women diagnosed with HPV.

Table 4. Correlations between the HIP subscales and both the HADS and ISS measures.

Factor	F1	F2	F3	F4	F5	F6
HADS	.389	.661	.533	.371	.597	.357
ISS	.161	.324	.756	.096	.429	.362

Abbreviations. F1, Worries/Concerns; F2, Emotional Impact; F3, Sexual Impact; F4, Future Treatment/Transmission; F5, Positive Emotions; F6, Negative Emotions; HADS, Hospital Anxiety and Depression Scale; ISS, Index of Sexual Satisfaction. Bold values are significant at ($p < .05$).

The original scale includes 29 items and seven domains. Cronbach alphas were .90 for Worries/Concerns, .77 for Emotional Impact, .64 for Sexual Impact, .82 for Self-Image, .82 for Partner/Transmission, .69 for Interaction with Doctors and .71 for Health Control/Life Impact. In the present study, the CFA produced a final model with 23 items and six domains. Cronbach alphas were .86 for Worries/Concerns (with four items), .79 for Emotional Impact (with three items), .69 for Sexual Impact (with three items), .86 for Future Treatment/Transmission (with four items), .83 for Positive Emotions (with six items) and .83 for Negative Emotions (with three items). Therefore, when comparing the Cronbach alphas obtained in this study with the original version one finds they are relatively better, which demonstrates a high degree of internal consistency.

Compared with the original model, this study presents a first domain with the same name (Worries and Concerns), having removed six items (7, 12, 13, 18, 19 and 20), and included item 3, thus composing a final domain with four items. Items 7, 12, 13 and 20 were removed from the final model due to low factor loadings (below .4), granting a better model fit. In addition, particularly in this first domain, items 12 and 13 concerning worries about “genital warts” may not have been saturated because 81% of women claimed to have no lesions associated with HPV, and were therefore “not worried” about it. Nevertheless, undergoing pelvic examinations, Pap smear in particular, generates discomfort, fear and concern⁴⁰.

In this study, the second domain maintains the name Emotional Impact, but left out item 3 (saturated in the first domain) and item 14 (saturated in the fifth domain). Consequently, this domain was left with three items. Flynn and collaborators⁴¹ report that women diagnosed with HPV experience a certain emotional impact upon diagnosis, often feeling anxiety and shame.

Regarding the Sexual Impact domain, this study added only item 9. Thus, the domain consisted of three items and maintained the same name. In general, items describe the sexual impact on women after the Pap smear, as well as a negative impact on marital relationships. Faced with a diagnosis and treatment of cervical dysplasia, women develop a sense of loss of control over their bodies, anxiety regarding their personal and genital health, compromising their body image and self-esteem, sexual life and marital adjustment, with an impact on sexual well-being¹⁷.

The fourth domain of this study comprises four items (18, 19, 21 and 22). It was named Future Treatment/Transmission due to item saturation and according to the semantics of the content within them, which deal with the fear of developing

CC and concerns about transmitting the infection. In fact, HPV diagnosis, being significantly associated with anxiety, entails additional concerns for patients regarding sexual intercourse, decreasing sexual activity and fear of developing CC. In addition to these concerns, women feel guilt, fear and anguish when receiving a positive HPV result^{42,43}.

The fifth domain refers to positive emotions (all items in this factor are reverse scored) and is made up of six items. As such, it was named Positive Emotions, since the semantics of the content focuses on women's positive feeling after the examination and feeling good about themselves. Thornton et al.⁴⁴ studied patients diagnosed with breast or gynecologic cancers and found that, in contrast to the great negativity observed, they were able to experience positive emotions which provided information on their own coping strategies.

The last domain of this study refers to negative emotions and consists of three items (23, 28 and 29). Thus, this sixth domain was named Negative Emotions due to item saturation and semantics. The content addresses issues about women feeling sick, embarrassed and uncomfortable. An HPV diagnosis affects self-esteem and sexual satisfaction, generating frustration, embarrassment, annoyance and discomfort, influencing women's QoL^{20,42,43}.

Despite the differences regarding the domains and composing items, the final model presents a good fit to the data.

With regard to convergent validity, this study used the Index of Sexual Satisfaction (ISS) instrument, per the prediction that QoL domains, namely Sexual Impact, were related to sexual satisfaction within the conjugal context. The internal consistency of this questionnaire is very high and, more precisely, Cronbach alpha in the original version was .93, .95 in the Portuguese version and .96 in this study. As expected, among all the HIP domains, ISS was strongly related to the Sexual Impact domain, together with a depreciation in Positive Emotions. The Hospital Anxiety and Depression Scale (HADS) was also used in this study and it evidenced convergent validity with the following HIP subscales: Emotional Impact, Sexual Impact and Positive Emotions. This convergence indicates that the HIP domains are strongly related to women's depression and anxiety. The literature suggests that the different stages of diagnosis and treatment of HPV infection may have different impacts on women and on couples⁴⁵, with negative effects on sexual health and QoL throughout time⁴⁶. Moreover, the literature also reports that an HPV positive result causes a negative impact on women's psychosocial and emotional lives, triggering feelings such as hopelessness, anger, fear, anxiety and depression⁴⁷. Patients with lesions associated with HPV see their sexuality affected, thus experiencing a negative impact on their QoL^{9,48}.

Discriminant validity was also demonstrated, showing that all HIP subscales were not highly correlated, either between themselves or with the ISS and HADS scales. This latter instrument showed high internal consistency: in the original version alphas were .85 for anxiety and .81 for depression; in the Portuguese version they were .76 and .81, respectively; and in this research, alphas were .91 and .88, respectively. In

this study, only the total scale was used. Among all the HIP domains, HADS was strongly related to the Emotional Impact domain. In addition to this association, HADS was related to both the Sexual Impact domain and a depreciation in positive emotions. When receiving an abnormal result in their Pap smear, women experience psychological distress, which causes a negative emotional impact, thus influencing their QoL⁴⁹. In fact, women experience a strong emotional impact when receiving an HPV diagnosis⁵⁰, with stigma and negative emotions⁵¹ such as anxiety, depression, anguish and concerns^{16,52}. This is because it precedes CC, regardless of a positive or negative result⁵³. Furthermore, there is an increased negative psychological burden due to the infection's relapse rates, causing concern and anxiety in women⁵⁴.

This study found that women with high-risk HPV (types 16/18) reported worse QoL than the low-risk ones. This result is in accordance with the literature that shows that when receiving a high-risk HPV diagnosis, patients experience greater suffering due to higher anxiety and fear of developing CC⁵⁵. Additionally, STIs trigger conjugal, emotional, psychological and sexual consequences for women⁵⁶. This study found no differences concerning participants' education level on QoL, probably because this sample is highly homogenous and highly educated. In the literature, the studies have mixed results. There are studies reporting that women with higher levels of education are more aware of the infection, which lessens their anxiety^{57,58} and improves their QoL. Conversely, the study by Daley and collaborators⁵¹ found that women with higher levels of education reported more negative emotions (anxiety/depression/fear). Hence, future studies should replicate these results in samples with women with lower education levels and assess the role of education on QoL.

This study had some underlying limitations: the sample was highly educated and there was a predomination of women with low-risk HPV. Consequently, future studies should include less educated women. It will also be important to evaluate the relationship between women's QoL and their partners' QoL, taking into account the type of HPV and the duration of the diagnosis.

In brief, the model outlined in [Figure 1](#) with six latent constructs was applied to a sample of Portuguese women with HPV and showed goodness of fit, as well as good construct reliability and internal consistency. Convergent and discriminant validity were also established. These good psychometric properties give HIP the capacity to assess the psychosocial impact of HPV and related interventions in a wide range of domains in the Portuguese population. In particular, this instrument is of utmost importance in the HPV field, not only for future research studies, but also for clinical purposes. Indeed, clinicians may also apply HIP to identify QoL domains that need intervention and to promote better QoL in this population.

5. Conclusions

The results of this study show the importance of assessing psychosocial factors in women dealing with an HPV diagnosis. The HIP presents good psychometric qualities, showing

good convergent validity, with significant associations with sexual satisfaction, along with good divergent validity regarding psychological morbidity (anxiety/depression). The confirmatory analysis revealed that the model presented good goodness-of-fit measures. The Portuguese version includes six domains (Worries/Concerns, Emotional Impact, Sexual Impact, Future Treatment/Transmission, Positive Emotions and Negative Emotions), being a relevant tool to be used in clinical trials, as well as in clinical practice, in terms of intervention, in order to assess the impact of HPV on women's QoL.

Transparency

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Data availability

The data set used in this research is not available since this study is part of an ongoing PhD project.

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