Validation of a questionnaire to quantify the risk for skin cancer

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Abstract

Introduction: *Currently, strategies are required to identify the population at risk of suffering skin cancer in order to implement early prevention and diagnosis measures. There are no Spanish language-validated instruments identifying the risk of skin cancer.* **Objectives:** *To design and validate a self-administered questionnaire to identify the risk of melanoma and non-melanoma skin cancer among the Mexican population.* **Material and methods:** *A self-administered questionnaire was designed to measure skin cancer risk factors, the face and content validity of which was assessed by five experts. The value of each item was weighted according to the risk factors' relative risk. The instrument was applied to extreme groups in order to measure the validity of the construct, and consistency was assessed by means of test-retest at two weeks.* **Results:** *The questionnare was applied to CDP patients with and without skin cancer (147 and 249, respectively). Total score of the questionnaire was different in both groups (U = 2,104.5; p = 0.0001) and by means of the receiver operating characteristics curve (ROC) approach (area: 0.964; 95% confidence interval [CI]: 0.946-0.981; p = 0.0001), five or more points were determined to correspond to high risk for skin cancer. The consistency of the instrument was 0.971 (95% CI: 0.943-0.986; p = 0.0001.* **Conclusions:** *This is the first valid Spanish-language instrument for the measurement of the risk for skin cancer and, applied at the population-level, it would be a useful tool to identify at-risk individuals requiring preventive interventions.* (Gac Med Mex. 2014;150:409-18)

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Introduction

The incidence of skin cancer is increasing worlwide and it is at first place amongst the most common malignancies in Mexico[1]. Basal cell carinoma is the most frequent (74%), followed by squamous cell carcinoma (14%) and melanoma (3%)[2]; with the latter causing 90% of skin cancer-related deaths, due to its risk of metastasis.

Population-oriented skin cancer detection campaigns are generally not cost:effective, since few cases are detected in relation to the cost they represent[3,4]. Therefore, there is a need for easy-to-apply instruments to indentify the population at risk of skin cancer that requires dermatological surveillance and preventive measures.

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The risk factors for skin cancer are the following: sun exposure[5,6], family history of skin cancer[7], experiencing sunburns[8], use of tanning beds[9], incresed number of melanocytic nevi[10], fair skin and hair, blue or green eyes[7], previous treatment with radiotherapy[11] or phototherapy[12], organ transplant[13] and exposure to arsenic[14].

There are 7 instruments that assess the risk of suffering skin cancer, mainly melanoma[15-21]. The questionnaires were designed in English language, except for one in French language, and validated in Swedish, English, North-American, Austrian and French populations. There is no Mexican population-validated Spanish language instrument that identifies the risk of skin cancer. Previous instruments focus only on melanoma skin cancer and include items related with photoprotective activities, but no important basal and squamous cell carcinoma risk factors. In view of all this, we considered it necessary to create and validate a self-administered questionnaire

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that identifies the population at risk for skin cancer requiring dermatological examination and close follow-up in order to achieve an early skin cancer diagnosis.

Material and methods

Face and content validity

A systematic search was conducted looking for articles on risk factors for skin cancer in the following databases: Pubmed, Google Scholar, TRIP database, LILACS, IBECS, SciELO, Artemisa and Cochrane, with the words *skin neoplasms* and *risk factors* as MeSH terms, without limitations by age group, language or time frame, including only the following designs: meta-analysis, clinical trials, cohort, case-control and comparative cross-sectional. Following the literature review, risk factors for basal cell and squamous cell carcinoma and melanoma whose measurement was feasible by a self-administered questionnaire, with information being obtained by questioning the patient and without the need for further laboratory or imaging tests were selected. Candidate risk factors were: skin phototype, use of tanning beds, phototherapy, nevi count, dysplastic nevi, ephelides, recreational and occupational sun exposure, sunburns, radiotherapy, organ transplant and family and medical history of skin cancer. For each factor, information was obtained on its relative risk or odds ratio (OR) by selecting the values of the most recent article and with the highest scientific level methodological design. Based on this information, the first version of the instrument was constructed, which was sent to five dermato-oncology experts from the Centro Dermatológico Dr. Ladislao de la Pascua (CDP) in order for them to assess the face and content of the questionnaire in two occasions. The questionnaire was pilot-tested twice with 15 and 20 patients, respectively, aiming to identify confusing questions and problems with its administration, to determine if the questions explored exactly the variables to be investigated and to know the time of completion (Fig. 1). Modifications resulting from the experts review and pilot tests generated a 17-item (13 with a dichotomous nominal scale [yes/no] and 4 multiple-choice items) self-administered questionnaire that was used for empirical validation (Fig. 2). An 11-item section was added to be filled by the dermatologist after physical exam of the skin in order to identify other risk factors for skin cancer. Each item was weighted for its risk published in the literature. The lowest score of the questionnaire was 0 points (no risk factors) and the highest, 46 (all risk factors).

Construct validity

Since there is no instrument or gold standard to measure the risk of skin cancer, the construct validity was measured by administering the questionnaire to extreme or known groups, as decribed by DeVellis[22] and Steriner et al.[23], in patients with and without skin cancer, and by comparing the scores obtained by them. Patients were recruited at the CDP; group 1 comprised patients from the Dermato-oncolgy Clinic with histopathologically confirmed basal cell or squamous cell carcinoma diagnosis and a follow-up time under 6 months, whereas group 2 comprised patients without skin cancer from the outpatient clinic of the same center.

Inclusion criteria for both groups were: time availability to complete the questionnaire and agreeing for a complete skin examination to be carried out. Exclusion criteria were: not knowing how to read and write, and being unable to answer the questionnaire autonomously. In group 2, patients with dermatosis whose treatment was, in part, sunscreen and sun exposure habits modification were also excluded, as well as patients whose reason for consultation were pre-malign lesions or lesions suspected to be skin cancer.

All patients who agreed to participate in the study signed an informed consent form approved by the CDP Research and Ethics Committee.

The patients filled the questionnaire without any help from the investigators, and were subjected to a skin examination by a dermatologist in order to identify other lesions associated with skin cancer risk, such as ephelides, actinic keratoses, solar lentigos, dysplastic nevi, giant congenital melanocytic nevi, genodermatosis, chronic radiodermitis, arsenical keratoses and chronic ulcers. In group-2 patients from the outpatient clinic with lesions suggestive of skin cancer, a biopsy was performed and they were not included in the study. Only the first 35 recruited patients were scheduled for a visit two weeks after the administration of the questionnaire in order to answer it again and measure the instrument's reproducibility or consistency over time using the test-retest method.

The data was analyzed with the Statistical Package for Social Sciences (SPSS), version 20.0 and GraphPad Software (http://graphpad.com/quickcalcs/kappa1.cfm?K=2) programs. Normality tests (Kolmogorov-Smirnov) were conducted, and consitency was measured with the kappa, weighted kappa and intra-class

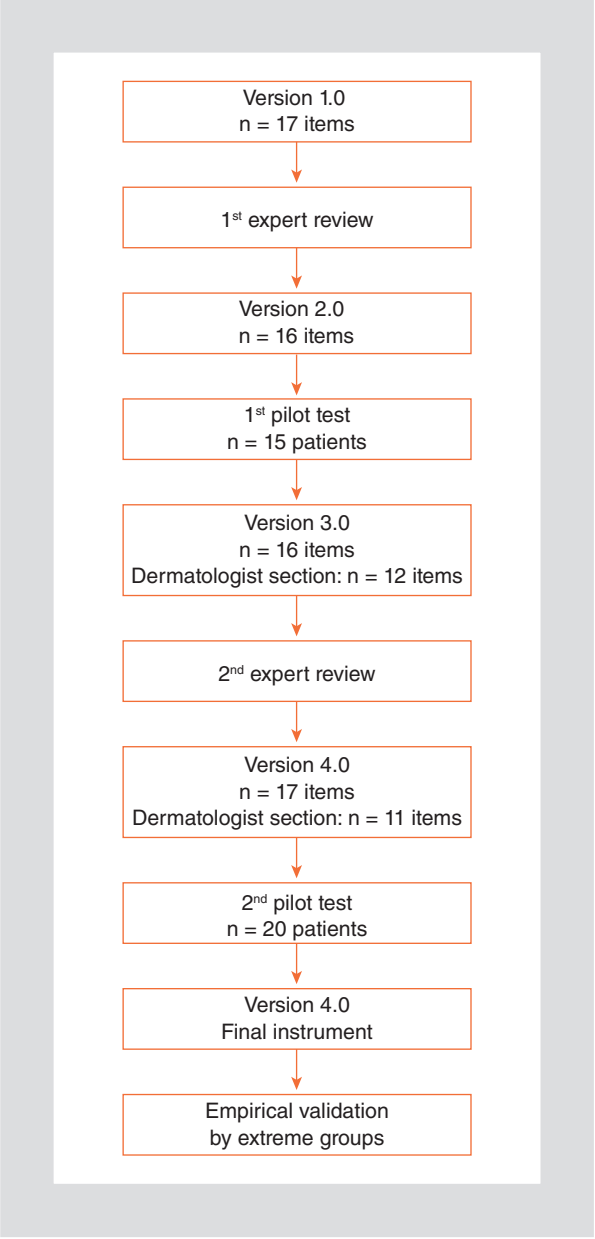

Figure 1. *Instrument construction and theoretical validation flow chart.*

coefficients. For discrimination between items, the Spearman correlation was calculated, and the chi-square test and the Mann-Whitney U test were used for the total scores of the questionnaire. The ROC curve was constructed to decide the cut-off points for the instrument.

Results

From June to December 2011, 396 patients were recruited, 147 with histopathological diagnosis of skin cancer (basal cell carcinoma [81.6%], squamous cell carcinoma [15.6%] and melanoma [2.7%]) and 249 without skin cancer but with other dermatoses (alipic skin [10.8%], acrochordons [6.8%], scars [6%], tattoos [5.6%], epidermal cysts [5.2%] and contact dermatitis [4%], among the most common). Patient demographics are shown in table 1. Statistically significant differences were found between both groups on age, marital status, education and occupation. Group 1 had a higher median age than group 2 (63 vs. 49 years; p = 0.0001). Primary education was the most frequent level of education (47.6 vs. 26.9%; p = 0.001). Marital status and occupation had different distribution; however, in both groups, the majority were married (50.3 vs. 58.6%), and their main occupation was housekeeping (45.6 vs. 41.8%). When the proportion of occupation outdoors or with solar exposure was compared between both groups, no statistically significant differences were found (16.3 vs. 10.8%).

Findings on skin examination of the study groups showed that skin cancer patients had a higher proportion of ephelides, actinic keratoses, solar lentigos and dysplastic nevi, lesions that are considered to be risk factors for skin cancer (Table 2).

Construct validity

Although these were extreme groups and the risk for skin cancer increased as age also did, an analysis of the instrument was performed excluding patients under 40 years of age in both groups in order to exclude age as a confounder. Data from 139 patients with skin cancer and 184 without skin cancer were assessed.

In order to know the items' discriminating capability, both groups' answers were compared. Of the 17 questions of the questionnaire, 11 were discriminating between both groups, i.e., the answers were different between groups. The six questions that were non-discriminating were the following: 5 (family history of skin cancer), 7 (number of nevi), 8 (sunburns), 12 (use of tanning lamps or beds), 13 (organ transplant) and 15 (phototherapy). Question 16, on beach vacations, was discriminating between groups; however, the analysis showed that, in this sample of patients, it behaved as a protective factor when it was present (Table 3).

Correlations were conducted between each item in order to identify those that could be measuring the same, and Spearman correlations under 0.676 were obtained, most of them without statistical significance.

Each item on the questionnaire was weighted according to the relative risk value of the risk factor it

Questionnaire: Risk factors for skin cancer

1. What is the color your skin?

☐ Very fair, ivory white ☐ Fair ☐ Light brown ☐ Dark brown ☐ Black

2. What is the natural color of your hair, that which you had when you were 20 years of age?

☐ Red ☐ Blonde ☐ Light or medium brown ☐ Dark brown ☐ Black

3. What is the color of your eyes?

☐ Blue ☐ Green ☐ Light brown ☐ Dark brown ☐ Black

4. Does your skin turn red after being exposed to the sun without any protection? ☐ Yes ☐ No

5. Do you have a close relative (father, mother, siblings) who has or has had skin cancer? ☐ Yes ☐ No

6. Have you ever had skin cancer? ☐ Yes ☐ No

7. About how many moles do you have in your body?

☐ 0-15 ☐ 16-40 ☐ 41-60 ☐ 61-80 ☐ 81-100 ☐ More than 100

8. Sunburn is painful reddening of the skin lasting more than 12 h, after exposure to the sun. Have you ever suffered any sunburn? ☐ Yes ☐ No

9. Up to date, have you ever had any outdoor job? ☐ Yes ☐ No

10. Have you ever lived or do you live in a geographical zone with intense sun, such as the beach, desert or mountain? ☐ Yes ☐ No

11. Do you practise or have ever practised any outdoor recreation activity? ☐ Yes ☐ No

12. Have you ever used tanning lamps or beds? ☐ Yes ☐ No

13. Have you received any organ transplant (for example, kidney, liver, heart, lung or pancreas? ☐ Yes ☐ No

14. Have you received any radiotherapy treatment for cancer? ☐ Yes ☐ No

15. Have you received any phototherapy treatment for some skin condition? ☐ Yes ☐ No

16. During your vacations, do you go to the beach? ☐ Yes ☐ No

17. Have you consumed well water for 10 years or more? ☐ Yes ☐ No

Figure 2. *Self-administered questionnaire used to validate the construct.*

represented. Most items had a 1-point value, except for number 3, with half point, and 2, 6 and 11, with three points. Total score for the questionnaire was the sum of the points obtained in case of an affirmative answer on each item. The total score could range from 0 (no risk factors) to 16.5 points (all the risk factors).

The Mann-Whitney U-test demonstrated that the skin cancer patients' questionnaire scores were different ($p = 0.0001$) from those of the subjects without skin cancer, thus confirming that the questionnaire measures the risk of skin cancer, since higher scores are obtained by the group with this diagnosis.

Consistency over time or reproducibility of the questionnaire

Interobserver agreement was measured with the kappa and the weighted kappa coefficients for each item two weeks after the first administration of the questionnaire. The items with the lowest agreement were 7 and 8, which inquired on the number of nevi in the body and sunburns, respectively. Item 13, on organ transplant, and 15, on phototherapy, were constant. The remaining items had agreements that were rated as good and almost perfect (Table 4). When the scores

Table 1. Study groups socio-demographic characteristics

Variables	Cancer, % (n) n = 147	No cancer, % (n) n = 249	X^2	p
Sex				
– Female	63.3 (93)	63.9 (159)	0.14	0.906
– Male	36.7 (54)	36.1 (90)		
Age*	63 (54-75)	49 (38-61)	8,913.0	0.0001
Marital status				
– Single	16.3 (24)	25.7 (64)	18.880	0.0001
– Married/cohabitating	50.3 (74)	58.6 (146)		
– Widow	23.1 (34)	9.2 (23)		
– Separated/divorced	10.2 (15)	6.4 (16)		
Education			18.435	0.001
– Primary	47.6 (70)	26.9 (67)		
– Secondary	19.0 (28)	27.7 (69)		
– High school/technician	19.0 (28)	26.5 (66)		
– College education	14.3 (21)	18.1 (45)		
– Postgraduate studies	0	0.8 (2)		
Occupation			2.477	0.115
– Outdoors†	16.3 (24)	10.8 (27)		
– Indoors	83.7 (123)	89.2 (222)		

*Median, p25-p75, Mann-Whitney's U-test.
†Outdoor occupation or with solar exposure: farmer, construction worker, driver, trader.

obtained on the questionnaire were compared, the baseline one and the one conducted at two weeks, an intraclass correlation coefficient of 0.971 (95% CI: 0.943-0.986; p = 0.0001) was observed, which was rated as very good, almost perfect, concordance.

Elimination of items from the questionnaire

The items that were removed from the questionnaire for not being discriminating and for being poorly reproducible between both groups were the following: number 7

Table 2. Study groups physical examination characteristics

Variables	Cancer, % (n) n = 147	No cancer, % (n) n = 249	X^2	p
Skin phototype				
– I	0.7 (1)	–	82.925	0.0001
– II	34.0 (50)	3.2 (8)		
– III	30.6 (45)	28.5 (71)		
– IV	34.0 (50)	68.3 (170)		
– V	0.7 (1)	–		
Ephelides	37.4 (55)	7.2 (18)	56.014	0.0001
Actinic keratoses	36.1 (53)	1.6 (4)	89.015	0.0001
Solar lentigos	94.6 (139)	38.2 (95)	121.652	0.0001
Dysplastic nevi	5.4 (8)	1.2 (3)	6.145*	0.022-0.017
Chronic radiodermitis	1.1 (2)	–	3.405*	0.137
Arsenical keratoses	0.7 (1)	–	1.698*	0.371
Chronic ulcers	0.7 (1)	–	1.698*	0.371

*Fisher's exact test.

Table 3. Item discrimination by study group

Question	RF prevalence % (n = 323)	Cancer % (n = 139)	No cancer % (n = 184)	X^2	p	$_{prev}OR$	95% CI
1	29.4 (95)	46.8 (65)	16.3 (30)	35.382	0.0001	4.509	2.697-7.538
2	32.8 (106)	40.2 (56)	27.2 (50)	9.489	0.05	1.808	1.131-2.891
3	9.6 (31)	13.7 (19)	6.5 (12)	4.662	0.031	2.269	1.062-4.850
4	65.3 (211)	73.4 (102)	59.2 (109)	6.991	0.008	1.897	1.177-3.058
5	8.4 (27)	11.5 (16)	6 (11)	3.164	0.075	2.046	0.918-4.561
6*	43 (139)	100 (139)	0	323.0	0.0001	–	–
7	26.3 (85)	28.8 (40)	24.5 (45)	3.602	0.608	1.248	0.759-2.053
8	36.5 (118)	38.8 (54)	34.8 (64)	0.565	0.263-0.485†	1.191	0.755-1.880
9	69.6 (128)	54.7 (76)	28.3 (52)	23.094	0.0001†	3.062	1.927-4.866
10	23.3 (75)	33.1 (46)	15.8 (29)	13.151	0.0001†	2.627	1.544-4.468
11	34.2 (110)	42.4 (59)	27.9 (51)	7.463	0.005-0.009†	1.909	1.197-3.043
12	1.2 (4)	1.4 (2)	1.1 (2)	0.08	0.577-1.0†	1.328	0.185-9.549
13‡	0.3 (1)	0.7 (1)	0	1.328	0.430†	–	–
14	5.6 (18)	8.6 (12)	3.3 (6)	4.343	0.037	2.803	1.025-7.666
15	1.5 (5)	2.9 (4)	0.5 (1)	2.831	0.111-0.169	5.422	0.599-49.061
16	39.9 (129)	33.1 (46)	45.1 (83)	4.765	0.019-0.030†	0.602	0.381-0.951
17	15.8 (51)	24.5 (34)	9.2 (17)	13.797	0.0001†	3.181	1.692-5.980

*Group-defining variable.
†Fisher's exact test
‡One box had 0 elements.

(number of nevi in the body), number 8 (sunburns), number 12 (use of tanning lamps or beds), number 13 (organ transplant) and number 15 (phototherapy treatment). Item 16 (vacations on the beach) discriminated between both groups, but the proportion of afirmative answers was higher in the group of patients without skin cancer and thus, its inclusion in the instrument as a risk factor was not supported. Item 5 (family history of skin cancer) did not discriminate between both groups, which can be attributed, due to the sizes of the OR confidence intervals, to the sample size. Therefore, it was decided to keep it in the questionnaire, due to its importance as a risk factor. The final version of the questionaire comprises 11 items (Fig. 3).

Internal consistency of the questionnaire

The internal consistency of the questionnaire was calculated with the Kuder-Richardson (KR-20) formula with the entire patient sample and considering the weightings of each item. The result, with the 17 items, was 0.501, which was regarded as acceptable but poor. After the removal of non-discriminating or non-reproducible items, the result was 0.592 (average: 3.9; standard deviation [SD]: 2.96) for the 11-item questionnaire.

ROC curve construction

The group without skin cancer had a median of 2 points in the questionnaire (1-3 points; p25-p75) versus a 6-point median for the skin cancer group (5-8 points; p25-p75), showing a statistically significant difference (U = 2,104.5; p = 0.0001) between total scores of the questionnaire by group. In order to establish a cut-off point to determine the risk of skin cancer, a ROC curve was constructed using the data of the entire sample and the 11 final items (area: 0.964; 95% CI: 0.946-0.981; p = 0.0001).

Considering the overlap of total scores by group according to the percentiles and contrasting it with the values of the ROC curve, 5 points (p95 of the group

Table 4. Intraobserver agreement: kappa and weighted kappa coefficients

Question	Value	Standard error	95% CI	p	Agreement
1	0.779	0.092	0.60-0.959	0.0001	Good
2	0.870	0.070	0.734-1.007	0.0001	Very good
3	0.726	0.103	0.525-0.927	0.0001	Good
4	0.699	0.124	0.455-0.942	0.0001	Good
5	1.0	0	1.0-1.0	0.0001	Perfect
6	1.0	0	1.0-1.0	0.0001	Perfect
7	0.675	0.098	0.484-0.867	0.0001	Good
8	0.565	0.145	0.280-0.850	0.001	Moderate
9	0.711	0.119	0.477-0.945	0.0001	Good
10	0.842	0.154	0.540-1.144	0.0001	Very good
11	0.885	0.078	0.732-1.039	0.0001	Very good
12	1.0	0	1.0-1.0	0.0001	Perfect
13*	–	–	–	–	–
14	1.0	0	1.0-1.0	0.0001	Perfect
15*	–	–	–	–	–
16	0.943	0.056	0.833-1.053	0.0001	Very good
17	0.785	0.207	0.380-1.190	0.0001	Good

*Constant values.

without cancer and p25 of the group with cancer) were found to have a sensitivity of 89.1% and specificity of 92.7% for the diagnosis of skin cancer. Therefore, the cut-off point to consider high risk for skin cancer was decided to be 5 points or more (Fig. 4).

Discussion

The resulting questionnaire showed face and content validity, since it met the following criteria, as pointed out by Feinstein[24]: focus on basic evidence (based on the risk factors identified by scientific evidence), biological consistency of the components (all items identified the risk), patient collaboration (individuals were motivated to answer it due to the benefit of detecting their risk of suffering skin cancer), items weighted by risks published in scientific literature, and simple, undestandable and mutually exclusive answer scales.

The results of the questionnaire validation demonstrate that the instrument has good consistency over time, also known as external consistency, reproducibility or intraobserver agreement, as well as low or poor internal consistency between items, and that it measures the skin cancer risk construct.

The intraobserver agreement of the instrument can be attributed to the time between measurements – a minimum required – and to the fact that the questions involve concrete and easily verifiable facts; i.e., it is difficult for an individual to forget or change his/her answer on the colour of his/her eyes, about his/her father having suffered skin cancer or having worked outdoors. In fact, those questions with low agreement, such as the number of nevi and history of sunburns, were removed from the final version of the instrument.

The internal consistency of the instrument had a result that was regarded as acceptable but low, since the variables that made up the skin cancer risk costruct were not homogeneous. Not all variables included in the questionnaire had a close relationship with each other, since this is an instrument with clinical, not cognitive-behavioral variables, as in psychometric tests. However, this was expected considering that, in clinimetrics, homogeneity of components is not a compulsory requirement, according to Feinstein[24]. As a matter of fact, in an

Questionnaire: risk factors for skin cancer

The following questionnaire will help you to assess your personal risk of having skin cancer. Mark the answer to each question with an X in the corresponding box and/or write the information you are asked for. At the completion of the questionnaire, the physician will conduct a short interview with you and an examination of your skin in order to assess the characteristics of your moles.

Name of the patient: _____

Sex: Female ☐ Male ☐ Age: _____ years Occupation: _____

Marital status: Single ☐ Married or cohabitating ☐ Widow ☐ Separated or divorced ☐

Education: Primary ☐ Secondary ☐ Senior high school, baccalaureate or techician ☐ College ☐ Postgraduate ☐

Telephone: _____ (to contact you later if needed due to your risk of skin cancer)

1. What is the color your skin?

☐ Very fair, ivory white ☐ Fair ☐ Light brown ☐ Dark brown ☐ Black

2. What is the natural color of your hair, that which you had when you were 20 years of age?

☐ Red ☐ Blonde ☐ Light or medium brown ☐ Dark brown ☐ Black

3. What is the color of your eyes?

☐ Blue ☐ Green ☐ Light brown ☐ Dark brown ☐ Black

4. Does your skin turn red after being exposed to the sun without any protection? ☐ Yes ☐ No

5. Do you have some close relative (father, mother, siblings) that has or has had skin cancer? ☐ Yes ☐ No

6. Have you ever had skin cancer? ☐ Yes ☐ No

7. Until now, have you ever had any outdoor job? ☐ Yes ☐ No

If yes, how many hours per day were you exposed to the sun ____ h.
For how long? _____ years,_____ months.

8. Have you ever lived or do you live in a geographical zone with intense sun, such as the beach, desert or mountain • Yes • No

If the answer is yes, please specify:

Place: _____ For how long did you live or have lived in that place?_____ years

9. Do you practise or have ever practised any outdoor recreation activity? • Yes • No

If the answer is yes, please specify:

Activity: _____ Hours per week: _____Time: _____ Years: _____ Months: _____

10. Have you received any radiotherapy treatment for cancer? • Yes • No

11. Have you consumed well water for 10 years or more? • Yes • No

Figure 3. *Final version of the self-administered questionnaire (version 5.0 instrument).*

instrument of this type, a high correlation between items would indicate that the questions are redundant and it would not contribute to increase its sensitivity.

It is important pointing out that the existence of a statistically significant difference between the scores of the extreme groups demonstrates that this questionnaire is valid for measuring the risk of skin cancer; i.e., the questionnaire behaves differently in individuals with and without skin cancer and is useful to differentiate them.

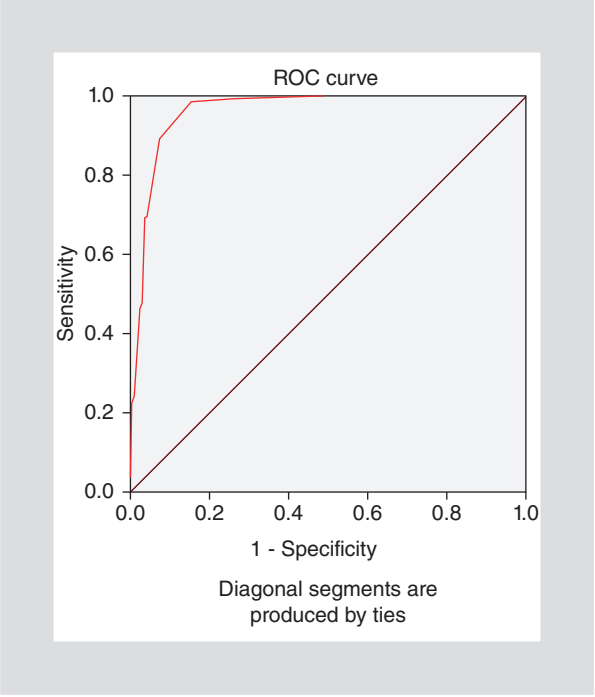

Figure 4. *ROC curve of the 11-item questionnaire.*

With regard to the excluded items, its lack of discrimination can be attributted to the low prevalence of the risk factor and to the size of the employed sample, which reflects on the confidence intervals width. In the item on the number of nevi, the width of the scale would likely be affecting the results, and therefore, it could be dichotomized, as in the questionnaire by Quéreux et al., to less than 50 nevi and more than or equal to 50[19]. An item that deserves special attention is the one related with vacations on the beach, since it behaved as a protecting factor for being more common in individuals without skin cancer. This can be related with the access to this type of vacations in the patient sample, which could be influenced by economical and social characteristics that were not controlled or measured in this validation study. In other populations, the inclusion of items such as the use of tanning beds, history of organ transplant and treatment with phototherapy could be considered in order to observe their behavior and usefulness according to their prevalence.

It is necessary pointing out that statistically significant differences were found between the groups with and without skin cancer, which were related with age, marital status and education. The group with skin cancer had a higher median age: 63 years versus 49 in the control group. This is explained because the most important risk factor for skin cancer is solar exposure: the more the time of solar exposure, the higher the risk of suffering skin cancer, especially basal cell carcinoma. Differences in marital status between both groups might be age-related: in the group with skin cancer, there were a higher proportion of widows than in the control group. The distribution by education was homogeneous in the control group, but primary education predominated in the skin cancer group. Education is a variable that can determine access to healthcare, especially to information on skin cancer prevention measures, but it is not a risk factor for suffering skin cancer.

Finally, when comparing our questionnaire with those previously published, we can conclude that there are differences related with the risk factors included, number of items, consistency and the validation process.

All previous instruments, except for the one by Glanz et al.[21], have focused on measuring the risk for melanoma skin cancer and, therefore, they have not considered other risk factors such as radiotherapy, phototherapy, organ transplant and exposure to arsenic, which are present in basal cell and squamous cell carcinoma.

The number of items in our instrument (11) allows for it to be answered quickly and is similar to the number of items in the questionnaire by Glanz et al. (18), but superior to that in the instruments by Jackson et al. (4), Harbauer et al. (8), Fears et al. (2), Quéreux et al. (7) and Williams et al. (7). Yet, it is shorter than Westerdahl's questionnaire, which comprises a total of 42 questions[16-21].

Consistency values of previous instruments, as measured by the intraobserver agreement, were similar to those in our instrument, with values rated as good and very good agreements. As a matter of fact, in the questionnaires by Jackson et al., and Harbauer et al., where the patient-physician agreement was measured for each one of the questions, kappa values rated as good were also obtained, except for the questions on dysplastic nevi[16,17].

Of all previously-validated questionnaires, only those by Quéreux et al. and Williams et al., who performed a construct validation by extreme groups, are similar to ours; the rest of the authors considered a criterion validity, with the physician's assesment being the gold standard for skin cancer risk[19,20].

Finally, it is important pointing out that only Quéreaux et al., Willimas et al. and us weighted each item by the value of its risk[20,25]. The difference is that these authors weighted by the value obtained on the logistic regression of their samples, and us, by the risks described in literature. For the cut-off points and to define high and low risk for suffering skin cancer, we considered that, since these are extreme groups, we should use the ROC curve, in a similar process as Quéreaux et al.

and Williams et al., considering its sensitivity and specificity for the diagnosis of skin cancer[20,25]. This way, our sensitivity and specificity values were superior (89.1 and 92.7%) to those of the Quéreaux et al. (64.9 and 68.4%) and Williams et al. (61 and 80%) questionnaries, since our questionnaire was applied to and developed in extreme groups[20,25]. We deemed it necessary to apply the questionnaire to the general population in order to establish percentile-based cut-off points, similarly as Quéreaux et al. did[25].

It is important pointing out that the limitations to this study are those inherent to the selected sample, and that, although it has validity for the measurement of melanoma and non-melanoma skin cancer risk, 81.6% of the skin cancer group patients had a diagnosis of basal cell carcinoma. We should also stress that the dermatological center where the validation of the instrument was conducted takes care of patients coming from the center of the country, mainly from Mexico City and neighboring Sate of Mexico.

Conclusions

This instrument was shown to be valid and reproducible to identify the state of high risk of skin cancer in adults. It is useful to identify the population with risk factors for skin cancer that requires dermatological consultation, preventive measures and follow-up in order to achieve an early diagnosis. It is proposed applying it to the general population as a screening tool, especially to population older than 40 years of age, and including patiens from all healthcare levels. Being a self-administered questionnaire, it is only required for the individual to know how to read and write, although help could be provided to answer it. It is easy to use, since it is a short instrument that is answered in an average of 5 min, and for its administration, the use of electronic means for score-addition is recommended, as well as for the respondent to obtain immediate feedback.

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