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Proposal of a self-assessment questionnaire for the diagnosis of sensitive skin

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Abstract

Background: Sensitive skin is very common and distressing. Its diagnosis may be difficult with the tools/methods available at the moment.

Aims: To assess the reliability of a self-assessment questionnaire for the diagnosis of sensitive skin, using the results of lactic acid stinging test (LAST) as a reference for the identification of subjects suffering from this condition. A further objective was to identify the questionnaire cutoff score that better discriminates between subjects with or without sensitive skin.

Patients/methods: Among the adult volunteers included in this observational, cross-sectional study, both LAST-positive subjects, who were considered as having sensitive skin ("patients"), and negative ones ("controls") completed the questionnaire. It consisted of a part for self-assessing and quantifying (0–10) sensitive skin and another one that included 10 items, each referring to a specific, potentially triggering stimulus. A cumulative score (questionnaire-based skin sensitivity score, 0–10) was calculated from the sum of all items considered capable of triggering unpleasant skin sensations in real-life experience.

Results: One hundred and sixty-two subjects were enrolled, 102 patients and 60 controls; 98 subjects thought they had sensitive skin. The mean questionnaire-based skin sensitivity score was significantly higher among patients than controls and correlated with skin sensitivity self-assessments. A cutoff value of 3 was set for the identification of LAST-positive subjects, with 79% accuracy.

Conclusions: The study self-assessment questionnaire seems to be a reliable tool for diagnosing sensitive skin in clinical practice. These results led us to identify a numerical cutoff for detecting propensity to experience sensitive skin.

KEYWORDS
cutaneous hyper-reactivity, diagnosis of sensitive skin, reactive skin, self-assessment questionnaire, sensitive skin, stinging test

Monica Corazza, Fabrizio Guarneri and Leda Montesi contributed equally to this study and share first authorship.

1 | INTRODUCTION

Sensitive skin or reactive skin is defined, in the words of the special interest group of the International Forum for the Study of Itch (IFSI), as "a syndrome defined by the occurrence of unpleasant sensations (stinging, burning, pain, pruritus, and tingling sensations) in response to stimuli that normally should not provoke such sensations. These unpleasant sensations cannot be explained by lesions attributable to any skin disease. The skin can appear normal or be accompanied by erythema. Sensitive skin can affect all body locations, especially the face."[1] This condition may be very distressing and have a significant impact on the quality of life.[2,3]

Sensitive skin is very common: it affects about half of the European population, to different degrees, and is more frequent among young people and women.[4-9] Its pathophysiology is not well known; it appears to be caused by hyper-reactivity of the cutaneous nervous system and is associated in particular with the activation of sensorial proteins present on keratinocytes and nerve endings.[4,10] An impaired skin barrier function seems to underlie this hyper-reactivity.[11-15]

The diagnosis of sensitive skin can be assisted by several sensory testing methods. One of the most often used is the lactic acid stinging test (LAST).[16] The LAST is considered the best predictor for sensitive skin and is widely used to select volunteers for clinical trials.[17,18] LAST identifies "stingers," that is, subjects who perceive stinging sensations when lactic acid (LA) is applied on the nasolabial fold. This reaction is assumed to correspond to sensitive skin. The main disadvantages of LAST are that LA is not always available and that this test is considered disagreeable by subjects, because it triggers unpleasant sensations.

Patient-reported scales could bypass these limitations.[19] Moreover, as sensitive skin is a subjective symptom, collecting and, eventually, scoring sensations perceived by patients in response to various factors may represent the most appropriate method. Some scoring scales for subjective assessment of sensitive skin have been proposed, namely, the *Score d'Irritabilitè Global Local* (SIGL), formulated only in French, and a Sensitive Scale, available in both a 14-item and a 10-item version.[20,21] Indeed, the Sensitive Scale is a tool for the measurement of the severity of symptoms and treatment outcome, but is not specifically aimed at diagnosing sensitive skin. To our knowledge, only one self-assessment questionnaire has been proposed so far to select patients with sensitive skin[22]; the investigators evaluated the association between the answers given and the LAST scores. Subjects who answered 'yes' to at least five of the seven questions contained in this questionnaire were considered as having sensitive skin. However, more rigorous, objective, and reproducible tools should be available. A self-assessment questionnaire including a broader spectrum of potentially triggering factors and specifying different elicited symptoms would be more suitable for diagnosis. Moreover, a recent consensus of experts recommended the definition of a numerical cutoff based on empirical data to assess sensitive skin.[1]The aim of this study was to investigate whether a new self-assessment questionnaire could be reliable specifically for the diagnosis of sensitive skin, comparing its results with those of LAST used as a reference for the identification of subjects suffering from this condition. Further objectives were as follows: i) to identify the questionnaire cutoff score that better discriminates between subjects with and without sensitive skin; ii) to measure the "relative weight" of each potentially triggering stimulus, among those listed in the questionnaire, in the diagnosis of sensitive skin; and iii) to assess which demographic data and/or unpleasant sensations, among those considered, are more frequently associated with sensitive skin.

2 | MATERIALS AND METHODS

2.1 | Study design

The present study was conducted between December 2018 and January 2019 at the Dermatology Unit and Cosmetology Centre of the University of Ferrara. It was set up as a single-center, observational, cross-sectional study. The research protocol was reviewed and approved by the Ethics Committee of the University Hospital of Ferrara, Italy (number of ethical approval 170583).

2.2 | Study population

Adult volunteers were recruited through announcements posted at the university notice boards and on the university website. These announcements made explicit reference to an observational study on sensitive skin. The only inclusion criteria for the volunteers were that they were aged ≥18 years, accepted to participate, and provided informed consent. Exclusion criteria were as follows: i) subjects younger than 18 years, ii) personal history and/or clinical signs of any skin disease (such as acne, rosacea, seborrheic dermatitis, atopic dermatitis, psoriasis, and skin infections), iii) intensive exposure to sunlight or artificial ultraviolet rays or use of any topical or systemic treatment, for any reason, within the previous month, iv) pregnancy or breastfeeding, and v) inability to understand and/or answer the questionnaire.

Written informed consent was obtained from all subjects before inclusion in the study.

2.3 | Study procedures and assessment

2.3.1 | Self-administered questionnaire

The questionnaire used in the study was formulated through literature research, theoretical analysis, practical experience, preliminary formulation, pilot test, and final revision by our group in consensus.[1] The guidelines of a standardized method for developing

self-assessment questionnaires inspired its construction.[23] Before the study, to assess reliability, the questionnaire was administered twice to 20 subjects, with a time interval of three weeks between the first and second administration.

In the first part of the questionnaire, the definition of sensitive skin proposed by the International Forum for the Study of Itch (IFSI)[1] was reported (Table S1). The interviewed person was requested to read this part and to state whether, in the light of this definition, he/she thought they had sensitive skin. Next, the participant was requested to self-assess and quantify his/her skin sensitivity, using a visual analogue scale (VAS), with a score from 0 to 10 (0=no sensitivity, 10=very high sensitivity).

The second part of the questionnaire consisted of 10 items, each referring to a specific potentially triggering stimulus. The stimuli included were chosen because they met the following requirements: to be recognized as real, potential triggers by adequate evidence from the literature and clinical experience; to cover a wide and heterogeneous spectrum of factors, both exogenous and endogenous; and to be clearly understandable, identifiable, and unambiguous by readers. The list was as follows: 1) exposure to sun, 2) exposure to hot/dry weather/environment, 3) exposure to cold/wet weather/environment, 4) exposure to wind, 5) contact with water, 6) physical exercise, 7) use of hygiene soaps/cleansers, 8) use of cosmetics, 9) exposure to smog/pollutants, and 10) psychological stress. The interviewees had to state whether each of the above stimuli triggered abnormal, unpleasant skin sensations in their real-life experience. One point was given for each positive answer, none for a negative one. A cumulative score was then calculated from the sum of all items (questionnaire-based skin sensitivity score). Finally, it was requested to specify the symptom(s)/sensation(s) elicited by each of the above stimuli: stinging, burning, pain, pruritus, and/or tingling (multiple answers were allowed).

All people enrolled in the study were asked to carefully read and complete the self-administered questionnaire. Once the questionnaire was completed, each participant underwent the lactic acid test, regardless of the answers given.

2.3.2 | Lactic acid sting test

LA was diluted at 10% concentration in distilled water and 50 μL of the LA solution was applied with a cotton swab on the right nasolabial fold, whereas an equal volume of inert control substance (saline solution) was applied to the contralateral site. The participants were asked to grade the intensity of stinging using a 4-point scale (0=none, 1=mild, 2=moderate, and 3=strong) at 0, 2.5, and 5 minutes after application of both LA and saline solution. The global LAST score was calculated as the sum of the scores recorded at 2.5 and 5 minutes (range 0–6). Participants with a global score ≥3 were considered as having sensitive skin, that is, positive at the LAST,[16,22] and defined as "patients," while the others were defined as "controls."

2.4 | Statistical analysis

In the preliminary phase of the study, Cohen's kappa coefficient was used to evaluate agreement between the two questionnaires of each subject.

In the main study, for each subject enrolled, a database record was created containing gender, age, and all data obtained from the questionnaire and the LAST. Results represented by continuous variables were summarized using mean and standard deviation, while frequencies (absolute and percentage) of values were used for categorical variables. Comparisons between groups of values were performed with Student's t test for independent samples or Mann-Whitney's U test, as appropriate, in the case of quantitative variables; for categorical variables, contingency tables were made and analyzed by chi-square test or Fisher's exact test, as appropriate. Correlation between variables was calculated with Spearman's rank correlation test. A p value <0.05, with Bonferroni correction for multiple comparisons, was considered statistically significant.

Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were calculated for each possible value of the questionnaire-based skin sensitivity score. To define the best cutoff value to identify subjects with sensitive skin, a ROC (receiver operating characteristic) curve was plotted and the point of this curve, which was closer to the left top edge of the diagram (Euclidean distance), was considered.

A multivariable logistic regression model was used to assess the association between sensitive skin and each of the variables considered. Microsoft Excel (Microsoft Corporation, Redmond, USA) with the Real Statistics Resource Pack software add-in (http://www.real-statistics.com/) was used for computation.

3 | RESULTS

3.1 | Preliminary phase

The test-retest showed that the questionnaire was reliable, with Cohen's kappa values higher than 0.7 for all items. None of the subjects involved reported problems in understanding or answering the questions.

3.2 | Patient characteristics

One hundred and sixty-two subjects (116 women, 71.6%, and 46 men, 28.4%) met the inclusion criteria and were enrolled. Their mean age was 29±11.1 years (range 19–70.2). In this population, 102 subjects (62.9%) were qualified as patients (positive to LAST, i.e., with a global score ≥3) and 60 (37.1%) as controls (negative to LAST). Among the patients, 76 (74.5%) were women and 26 (25.5%) men; their mean age was 25.7±7.3 years (range 19.2–68.8). Among the controls, 40 were women (66.7%) and 20 men (33.3%), with a mean age of 34.8±14.0 years (range 19–70.2). The male/female ratio was similar in the two groups

(p=0.29), while the controls were significantly older than the patients (p=2.68x10^{-5}).

3.3 | Self-assessment of skin sensitivity

With reference to the first question of the questionnaire ("Do you think that you have sensitive skin?"), 98 subjects (60.5%) answered positively (group A), the other 64 (39.5%) negatively (group B). The rate of positive answers was significantly (p=8.96x10^{-15}) higher among patients (85/102, 83.3%) than controls (13/60, 21.7%).

Table 1 shows the demographic characteristics of the two groups. Overall, the mean age was significantly lower in group A than in group B; a clear statistical trend toward a much higher female/male ratio in group A than in group B was observed, although statistical significance was not reached after Bonferroni correction. An almost identical situation was observed among patients for the female/male ratio, while the age difference between group A and B was far from statistical significance; among controls, the difference in female/male ratio was far from significant, but subjects belonging to group A were significantly younger.

As shown in Table 2, the mean value of self-assessed skin sensitivity score (VAS associated with a numeric rating scale 0–10) was 4.4±2.7 in the entire population. The mean value among patients was significantly higher than that of controls, overall and also when considering males and females separately. In the entire study population and in the group of patients, mean scores attributed by women tended to be clearly higher than those attributed by men, although statistical significance was not reached after Bonferroni correction.

Scores in group A were significantly higher than in group B overall, and also when considering patients and controls separately. In both groups, patients had higher scores than controls, but statistical significance was reached only in group B (the p value of 0.044 in group A was not significant when considering Bonferroni correction, although it showed a clear statistical trend).

3.4 | Questionnaire reliability in identifying subjects with sensitive skin

The mean questionnaire-based skin sensitivity score was 3.4±2.8 in the study population. The mean score was significantly higher among patients than controls overall, as well as among males and females separately, as reported in Table 3. Subjects who declared having a sensitive skin reached a mean score significantly higher than that of subjects who did not think they had a sensitive skin, overall and also when considering patients and controls separately. In group A, the difference evidently tended toward statistical significance when comparing patients with controls (p=0.02, not significant after Bonferroni correction). Females reached a significantly higher mean score than males, mainly because of the differences among patients (p=0.009, not significant after Bonferroni correction). There was a significant correlation between self-assessed and questionnaire-based skin sensitivity scores: the results of Spearman's rank correlation test were ρ=0.75 (p=6.1x10^{-31}) in the whole population, ρ=0.62 (p=3.6x10^{-12}) in the patient group, ρ=0.53 (p=1.6x10^{-5}) in the control group.

Table 4 shows sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of all of the possible cutoff values of the questionnaire-based skin sensitivity score, with reference to LAST positivity. With reference to the ROC curve, an optimal cutoff value of 3 was identified for the questionnaire used. Based on the data collected, a score of 3 or higher identifies LAST-positive subjects with 78.4% sensitivity and 80% specificity and has a positive predictive value of 87%, a negative predictive value of 68.6%, and an accuracy of 79%.

3.5 | Relevance of the single items of the questionnaire-based skin sensitivity score

When considering the items separately, we found relevant differences in sensitivity, specificity, positive predictive value, negative

TABLE 1 Demographic characteristics of the study subjects who claimed having / not having sensitive skin

	Answer to the question "Do you think that you have sensitive skin?"		
	Yes	No	p value
Total (n=162)			0.005
males, n	20	26	
females, n	78	38	
age (years), mean±SD	25.7±7.7	33.9±13.6	**5.2x10^{-5}**
Patients (n=102)			0.004
males, n	17	9	
females, n	68	8	
age (years), mean±SD	25.9±7.9	24.7±2.6	0.31
Controls (n=60)			0.42
males, n	3	17	
females, n	10	30	
age (years), mean±SD	24.8±5.6	37.6±14.4	**2.5x10^{-5}**

Note: p values which are significant after Bonferroni correction are written in bold.

TABLE 2 Self-assessed skin sensitivity scores (VAS, 0–10) of patients and controls, grouped i) by sex and ii) by their answer to the question "Do you think that you have sensitive skin?"

	Overall	Patients	Controls	*p* value (patients *vs* controls)
Gender				
All	4.4±2.7	5.9±1.7	2.0±2.2	**$2.1x10^{-17}$**
males	3.7±2.7	5.1±2.0	2.0±2.4	**0.0001**
females	4.7±2.6	6.1±1.6	2.0±2.1	**$4.2x10^{-14}$**
p value (males *vs* females)	0.036	0.019	0.75	
Answer to the question "Do you think that you have sensitive skin?"				
yes (group A)	6.1±1.6	6.2±1.5	5.2±1.6	0.044
no (group B)	1.9±1.9	4.1±1.6	1.1±1.3	**$1.7x10^{-7}$**
p value (yes *vs* no)	**$1.3x10^{-21}$**	**10^{-5}**	**$2.1x10^{-7}$**	

Note: p values which are significant after Bonferroni correction are written in bold.

TABLE 3 Reaction to potentially triggering stimuli: mean cumulative scores of patients and controls, grouped i) by sex and ii) by their answer to the question "Do you think that you have sensitive skin?"

	Overall	Patients	Controls	*p* value (patients *vs* controls)
Gender				
All	3.4±2.8	4.6±2.5	1.4±2.0	**$4.8×10^{-13}$**
males	2.3±2.4	3.5±2.6	0.8±1.0	**0.0001**
females	3.8±2.8	4.9±2.4	1.7±2.3	**$2.7×10^{-9}$**
p value (males *vs* females)	**0.001**	0.009	0.16	
Answer to the question "Do you think that you have sensitive skin?"				
yes (group A)	5.1±2.1	5.3±2.0	3.8±2.4	0.02
no (group B)	0.7±1.1	0.8±1.0	0.7±1.1	0.48
p value (yes *vs* no)	**$4.9×10^{-24}$**	**$4.5×10^{-10}$**	**$1.1×10^{-6}$**	

Note: p values which are significant after Bonferroni correction are written in bold.

predictive value, and accuracy, with reference to LAST positivity (Table 5). This suggests that these items/stimuli have different "relative weights" in determining sensitive skin and orienting the diagnosis. The highest values of accuracy in the prediction of the result of LAST were associated with the answers about sensitivity to sun exposure, exposure to cold/wet weather/environment, use of cosmetics, and psychological stress (accuracy: 0.704, 0.698, 0.685, and 0.660, respectively).

3.6 | Relevance of single elicited sensations in sensitive skin

Analysis of the types of unpleasant sensations reported by patients and controls after exposure to the stimuli included in the questionnaire revealed that burning was the most frequent symptom among patients (OR 2.8327, 95% CI: 1.7450 to 4.5984, $p<0.0001$ vs controls), mainly after sun exposure. Itching (OR 2.5354, 95% CI: 1.6462 to 3.9051, $p<0.0001$ vs controls), elicited mainly by psychic stress, was also significantly associated with LAST positivity. A clear, statistical trend was observed for stinging (OR 1.6266, 95% CI: 1.0518 to 2.5157, $p=0.0288$ vs controls, not significant after Bonferroni correction), induced mainly by the use of cosmetics. No significant association was found with tingling and pain.

3.7 | Logistic regression analysis

Multivariate logistic regression was used to assess the relevance of different variables in determining the positive result to the LAST. Table 6 shows the results of this analysis (parameters of overall model fit: $\chi^2=73.97$, $p=5.8x10^{-11}$). Coefficients and odds ratio values indicated that an unpleasant sensation after use of cosmetics, wind exposure, and sun exposure were, in decreasing order, the main predictors of having LAST positivity; *p* values were significant in the first two cases and showed a clear trend toward statistical significance in the other one ($p=0.06$). LAST positivity was slightly, but significantly, inversely related with increasing age.

TABLE 4 Sensitivity, specificity, positive and negative predictive values, and accuracy of the possible cutoff values of questionnaire-assessed skin sensitivity score for the correct diagnosis of sensitive skin, that is, positivity to the LAST. The best cutoff value and related values are written in bold

Score	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Accuracy
0	1.000	0.000	0.630	---	0.630
1	0.912	0.500	0.756	0.769	0.759
2	0.853	0.650	0.806	0.722	0.778
3	**0.784**	**0.800**	**0.870**	**0.686**	**0.790**
4	0.667	0.867	0.895	0.605	0.741
5	0.578	0.917	0.922	0.561	0.704
6	0.382	0.950	0.929	0.475	0.593
7	0.235	0.967	0.923	0.426	0.506
8	0.098	0.983	0.909	0.391	0.426
9	0.039	0.983	0.800	0.376	0.389
10	0.020	1.000	1.000	0.375	0.383

TABLE 5 Sensitivity, specificity, positive and negative predictive values, and accuracy of the items of the questionnaire-based skin sensitivity score for the correct diagnosis of sensitive skin, that is, positivity to LAST

	Unpleasant reaction to potentially triggering stimuli						
Stimulus	Patients *total 102*n (%)	Controls *total 60*n (%)	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Accuracy
Sun exposure	62 (60.8%)	8 (13.3%)	0.608	0.867	0.886	0.565	0.704
Exposure to hot/dry weather/ environment	50 (49%)	7 (11.7%)	0.490	0.883	0.877	0.505	0.636
Exposure to cold/wet weather/ environment	67 (65.7%)	14 (23.3%)	0.657	0.767	0.827	0.568	0.698
Exposure to wind	44 (43.1%)	8 (13.3%)	0.431	0.867	0.846	0.473	0.593
Contact with water	6 (5.9%)	1 (1.7%)	0.059	0.983	0.857	0.381	0.401
Physical exercise	49 (48%)	9 (15%)	0.480	0.850	0.845	0.490	0.617
Use of hygiene soaps/cleansers	45 (44.1%)	11 (18.3%)	0.441	0.817	0.804	0.462	0.580
Use of cosmetics	59 (57.8%)	8 (13.3%)	0.578	0.867	0.881	0.547	0.685
Exposure to smog/pollutants	23 (22.5%)	2 (3.3%)	0.225	0.967	0.920	0.423	0.500
Psychological stress	62 (60.8%)	15 (25%)	0.608	0.750	0.805	0.529	0.660

4 | DISCUSSION

The identification of sensitive skin is complex and there is still a lack of international consensus on the best method for its diagnosis.[18] Tests based on provocation with chemical irritants are invasive and may be unpleasant for some people. On the other hand, the available self-reported perceptions or scales do not appear particularly suitable for diagnosis.[20-22]

In the present study, we chose to use the lactic acid stinging test (LAST) to distinguish subjects with or without sensitive skin. Based on this method, the first noteworthy finding of our study was that about 63% of enrolled patients had sensitive skin. On the one hand, this confirms that sensitive skin is highly prevalent in Caucasians. On the other hand, the prevalence found in our population tended to be higher than that observed in other studies.[4-8] This may be explained, at least in part, by recruitment methods: the enrolled subjects came to observation as volunteers, after reading announcements that referred to a study on sensitive skin. For this reason, a recruitment bias possibly occurred in our study, because subjects suffering from sensitive skin are presumably more inclined to undergo investigations on their problem. In our population, subjects positive to LAST ("patients") were younger than negative ones ("controls"), whereas no significant differences regarding gender were observed.

The clarity, unambiguousness, and understandability of the questions aiming to self-assess skin sensitivity in our questionnaire were confirmed by the good test-retest reliability. Our findings suggest that most of the subjects with sensitive skin were aware of it. In fact, the number of subjects who thought they had a sensitive skin was significantly higher among patients than among controls, and the mean self-assessed skin sensitivity score was higher in the patient group than in controls (Table 2). Females indicated they had a sensitive skin more frequently than males and reported higher skin

TABLE 6 Multivariate logistic regression showing the relevance of different variables in determining the positive result to LAST

Variable	Coefficient	*p*	Odds ratio
α	0.519		1.681
Female	−0.542	0.252	0.581
Age (years)*	−0.048	**0.005**	0.953
Unpleasant sensations with sun exposure	1.110	**0.034**	3.034
Unpleasant sensations with exposure to hot/dry weather/environment	0.590	0.351	1.804
Unpleasant sensations with exposure to cold/wet weather/environment	0.203	0.711	1.225
Unpleasant sensations with wind exposure	1.144	0.060	3.139
Unpleasant sensations with contact with water	−1.281	0.378	0.278
Unpleasant sensations with physical exercise	0.665	0.209	1.945
Unpleasant sensations with use of hygiene soaps/cleansers	−0.204	0.730	0.815
Unpleasant sensations with use of cosmetics	1.278	**0.018**	3.588
Unpleasant sensations with exposure to smog/pollutants	0.608	0.481	1.836
Unpleasant sensations with psychological stress	0.423	0.433	1.526

Note: Significant p values are written in bold.

*valid within the age range of the study population (19–70.2 years).

sensitivity scores, although no significant difference in gender distribution was observed. The association between younger age and perceived skin sensitivity matched the actual data of positivity to LAST.

We also found that the cumulative score resulting from the number of stimuli capable of triggering unpleasant sensations (questionnaire-based skin sensitivity score) was strongly associated with the LAST results (Table 3). Based on the ROC curve, a score of 3 or higher represents the best cutoff for the identification of subjects positive to LAST and may be adopted as a reliable threshold for a highly probable diagnosis of sensitive skin. If these data are confirmed on a larger scale, use of our questionnaire could be considered a first screening in order to narrow down the number of LASTs carried out to assess skin sensitivity.

We also evaluated the importance of each of the triggering stimuli included in the questionnaire for the outcome of skin sensitivity. By means of multivariate analysis, unpleasant sensations after the use of cosmetics, sun exposure, or wind exposure were found to have a higher odds ratio for LAST positivity than the other triggers (Table 6); only in the first two cases, however, the *p* value was significant. Therefore, reacting to these stimuli seems to be particularly predictive of sensitive skin. In accordance with the aforementioned data, a significant role was also demonstrated for age (increasing age reduced the probability of having sensitive skin). This may have implications from a diagnostic point of view, too. Indeed, preparing a spreadsheet that uses the coefficients found for each variable included in the questionnaire, namely, demographics and answers to the 10 questions concerning triggering stimuli, it would be possible to calculate the probability of a positive LAST.

In the diagnostic perspective, although sensory discomfort is widely subjective,[24] burning, itching, and stinging could be considered the most evocative symptoms of sensitive skin. In fact, they were elicited in patients significantly more often than in controls. Our finding was in line with previous reports.[18]

It is necessary to consider some study limitations. First, the study population was relatively small and a selection bias was likely. In particular, since the announcements were located in university rooms and website, a selection in terms of age and education level was unavoidable. As already mentioned, the rather high rate of volunteers with sensitive skin enrolled could be not casual, and consequently, the study population could not be adequately representative of the general population. We arbitrarily chose to consider the LAST as the tool for discriminating sensitive from non-sensitive skin, so the questionnaire and its results were calibrated to this assumption. We cannot exclude that referring to other methods could lead to somewhat different results. Further validation of the questionnaire is required before it can be used in future studies. This study was conducted in Caucasian subjects, so the results cannot be extended to other ethnic groups without proper verification. Moreover, it was carried out in a limited period of the year, characterized by particular climatic conditions. Namely, in the province of Ferrara, an area located in Northern Italy, in the months of December and January the mean daily temperature is about 2–4°C, humidity ~85%, the hours of sunshine during the day are ~4.5, UV index is 2 and wind speed 7.5 km/h. These environmental conditions may have influenced the responses provided by the study subjects in completing the questionnaire. We did not include any objective feature and, unlike other previous studies,[21] we chose to exclude subjects with skin disorders, especially chronic inflammatory diseases, to avoid possible confounding variables. However, since we specifically addressed diagnosis of sensitive skin, this latter could indeed be considered a study strength.

In conclusion, we designed and tested a self-assessment questionnaire, which included a broad spectrum of triggers and typical symptoms, with the aim to diagnose sensitive skin in clinical practice. Its predictable practical applications may include i) support in the diagnostic process in cases of poor tolerance to topical products, drugs, or cosmetics, especially when other objective conditions are not evident, and ii) aid in setting up tailored therapeutic approaches, mostly topical and physical, with the highest tolerability possible and adherence by patients. Moreover, this self-assessment questionnaire could be extensively used in clinical, basic, and translational research. The study assessments, although only preliminary, led us to identify a numerical cutoff for detecting propensity to experience sensitive skin with a high degree of accuracy. Our findings also led to define a profile of the sensitive skin patient, in terms of the most relevant stimuli and perceived symptoms. This may also be expected to represent a tool for increasing the patients' empowerment on their skin sensitivity, with potential benefit on its proper management and self-care, as previously shown.[25]

Further studies are needed to confirm the validity and reliability of this questionnaire in larger and diverse populations, as well as to assess its suitability in clinical trials, for example, for measuring therapeutic outcomes. The role of some variables, associated with both the subject and the environment, in determining skin sensitivity and its severity could be assessed as well. With this specific aim, it could be interesting stratifying the questionnaire scores by several variables, including skin phenotype and phototype, ethnicity, skin biometrics, concomitant skin dermatoses and dermatitis, atopy, contact sensitization, use of cosmetics, indoor *versus* outdoor occupation, geographical area of residence, and seasonal factors.

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CONFLICTS OF INTEREST

The authors report no conflict of interest in this work.

ETHICAL STATEMENT

All patients gave informed consent fo participation in this study prior to enrollment. This study was reviewed and approved by the institutional board of the University Hospital of Ferrara, Italy (number of ethical approval 170583).

AUTHORS' CONTRIBUTIONS

Study concept and design: MC, AB, and LM. Acquisition of data: MC, LM, GT, and ID. Analysis and interpretation of data: MC, AB, FG, and LM. Drafting of the manuscript: AB, GT, and FG. Critical revision of the manuscript for important intellectual content: MC, AB, FG, and LM. Statistical analysis: FG.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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