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ORIGINAL ARTICLE

Results from an extended study on the reliability of a questionnaire for the diagnosis of sensitive skin: Confirmations and improvements

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Abstract

Objective: A recently proposed self-assessment questionnaire aimed at diagnosing sensitive skin provided promising results in a relatively small population. The main objectives were: (i) to assess the reliability of the aforementioned questionnaire in a larger population and verify the cut-off score previously found to predict skin sensitivity (defined as positivity to LAST, lactic acid stinging test) and (ii) to define a formula that yields the probability of a positive LAST result.

Methods: Adult volunteers were included in this observational, cross-sectional, extended study. Both LAST-positive subjects, who were considered as having sensitive skin ('patients') and negative ones ('controls') completed the questionnaire, which concerned sensitivity to possible triggers of unpleasant skin sensations in real life. A cumulative score (questionnaire-based skin sensitivity score, 0–10) was calculated from the sum of all items.

Results: Three hundred and sixty-four subjects were enrolled, 214 patients and 150 controls. The mean questionnaire-based skin sensitivity score was significantly higher among patients than controls. Using two different methods, cut-off values of 4 and 5 were defined for the identification of LAST-positive subjects, with 76.6% and 72.8% accuracy, respectively. Scores below 4 or above 5 showed a high (80% or better) negative or positive predictive value, respectively. The coefficients found that in multivariate analysis for each questionnaire item, gender and age allowed us to calculate the probability of LAST positivity with higher precision taking into account the 'relative weight' of each factor.

Conclusion: With small variations in the results, the self-assessment questionnaire confirmed its reliability for diagnosing sensitive skin in clinical practice.

Alessandro Borghi, Fabrizio Guarneri, and Leda Montesi contributed equally to this study and shared the first authorship: they conceived and designed the study, acquired, analyzed and gave the final interpretation of the data.

KEYWORDS
lactic acid stinging test, questionnaire, safety testing, sensitive skin, skin barrier, statistics

Résumé

Introduction: Un questionnaire d'auto-évaluation récemment proposé visant à diagnostiquer la peau sensible a fourni des résultats prometteurs dans une population relativement petite. Les principaux objectifs étaient: (i) d'évaluer la fiabilité du questionnaire susmentionné dans une population plus large et de vérifier la valeur du cut-off précédemment trouvé pour prédire la sensibilité cutanée (définie comme la positivité au LAST, de l'anglais « test de piqûre d'acide lactique »), et (ii) de définir une formule qui donne la probabilité d'un résultat LAST positif.

Méthodes: Des volontaires adultes ont été inclus dans cette étude observationnelle, transversale et étendue. Les sujets LAST-positifs, qui étaient considérés comme ayant la peau sensible ('patients'), et les sujets négatifs ('témoins') ont rempli le questionnaire, qui concernait la sensibilité aux possibles déclencheurs de sensations cutanées désagréables dans la vie réelle. Un score cumulatif (score de sensibilité cutanée basé sur un questionnaire, 0–10) a été calculé à partir de la somme de tous les éléments.

Résultats: Trois cent soixante-quatre sujets ont été recrutés, 214 patients et 150 témoins. Le résultat moyen de sensibilité cutanée basé sur le questionnaire était significativement plus élevé chez les patients que chez les témoins. En utilisant deux méthodes différentes, des valeurs seuils de 4 et 5 ont été définies pour l'identification des sujets LAST-positifs, avec une précision de 76,6% et 72,8%, respectivement. Les scores inférieurs à 4 ou supérieurs à 5 ont montré une valeur prédictive négative ou positive élevée (80% ou plus), respectivement. Les coefficients trouvés en différentes analyses pour chaque élément du questionnaire, sexe et âge nous ont permis de calculer la probabilité de positivité LAST avec une plus grande précision en tenant compte du « poids relatif » de chaque facteur.

Conclusions: Avec de faibles variations dans les résultats, le questionnaire d'auto-évaluation a confirmé sa fiabilité pour le diagnostic des peaux sensibles dans la pratique clinique.

INTRODUCTION

Sensitive skin is characterized by the abnormal occurrence of unpleasant sensations in response to stimuli that are normally harmless [1, 2]. These unpleasant sensations can affect all body locations, especially the face, and cannot be explained by concurrent skin diseases. Sensitive skin is very common and may be distressing and affect the quality of life [3–6].

Its pathophysiology is not well known, but a hyperreactivity of the cutaneous nervous system associated with an impaired skin barrier function seems to underlie this condition [7–11].

For the diagnosis of sensitive skin, several testing methods have been proposed so far, including both physical tests and questionnaires. However, there is currently no consensus on a single method or tool that combines objectivity, reproducibility and feasibility in clinical practice.

With specific reference to a suitable diagnostic self-assessment questionnaire, it should ideally include both a broad spectrum of potentially triggering factors and different elicited symptoms. Moreover, a consensus of experts recommended the definition of a numerical cut-off based on empirical data to assess sensitive skin [1, 2, 12].

In a recent study [13] we evaluated the reliability of a self-assessment questionnaire specifically aimed at diagnosing sensitive skin, using lactic acid stinging test (LAST) positivity as a reference for the identification of subjects suffering from this condition [12, 14, 15]. The questionnaire consists of 10 items, each referring to a

stimulus potentially triggering unpleasant skin sensations in real-life experience. These stimuli cover a wide and heterogeneous spectrum of factors, both exogenous and endogenous (Table S1). The interviewees had to state whether each of these stimuli triggered abnormal, disturbing skin sensations. One point was given for each positive answer. A cumulative score ranging from 0 to 10, the so-called questionnaire-based skin sensitivity score, was calculated from the sum of all the items included.

As a result, a cut-off value of 3 was set for the identification of LAST-positive subjects, with 79% accuracy. The proposed self-assessment questionnaire seemed to be a reliable and suitable tool for noninvasively diagnosing sensitive skin in clinical practice. Ease of comprehension and readability, as well as the speed of compilation, are further prerogatives of this questionnaire.

The aim of the present extended study, which included a larger population, was to further assess the validity of the promising results obtained in the previous study ('relative weight' of each parameter and significance of the differences between LAST-positive and LAST-negative subjects). In particular, we were interested in (i) assessing whether the previously found cut-off score for discriminating subjects with or without sensitive skin was confirmed, (ii) providing a formula to calculate the probability of a positive LAST, using the coefficients of association found in the multivariate analysis for gender, age and each variable included in the questionnaire.

MATERIAL AND METHODS

Study design and population

The present single-center, observational, cross-sectional study was conducted between February 2019 and February 2020 at the Dermatology Unit and Cosmetology Centre of the University of Ferrara.

The subjects enrolled during this study period were added to those already included in the previous study (162 subjects, 116 women and 46 men, mean age 29 ± 11.1 years) [13] and assessed cumulatively. The population included in this extension of the study shared the same inclusion and exclusion criteria adopted for the previous one. More in detail, all adult volunteers recruited through announcements posted at the university notice boards and on the university website who accepted to participate were eligible. Exclusion criteria were: (i) subjects younger than 18 years, (ii) personal history and/or clinical signs of any skin disease, (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, (v) inability to understand and/or answer the questionnaire. All subjects gave informed consent for participation in this study prior to enrollment, were administered the same questionnaire (Table S1) and underwent LAST like those previously included. The research protocol was reviewed and approved by the Ethics Committee of the University Hospital of Ferrara (number of ethical approval 170 583).

Statistical analysis

The statistical analysis performed on the data was virtually identical to that used in the previous study [13].

A database 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 categorical variables were expressed as frequencies (absolute and percentage).

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. To compare groups of categorical variables, contingency tables were made and analysed by the chi-square test or, in the case of values of 5 or less, by Fisher's exact test. The correlation between variables was calculated with the 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 (PPV), negative predictive value (NPV) and accuracy were calculated for each possible value of the questionnaire-based skin sensitivity score. A ROC (Receiver Operating Characteristic) curve was plotted and two methods were used to best define a cut-off to identify those with sensitive skin: the point of the curve closer to the left top edge of the diagram (Euclidean distance) and Youden's Index (J).

A multivariable logistic regression model was used to assess the association between sensitive skin and each of the variables considered.

Microsoft Excel (Microsoft Corporation) with the Real Statistics Resource Pack software add-in (http://www.real-statistics.com/) was used for computation.

RESULTS

Patients' characteristics

A further 202 subjects met the inclusion criteria and were enrolled and added to the original database created for the previous study [13], bringing the total of subjects up to 364, of which 271 were women (74.5%), and 93 were men (25.5%). Their mean age was 26.76 ± 10.01 years (range

15–70.2). In this population, 214 subjects (58.8%) were qualified as 'patients' (i.e. positive to LAST) and 150 (41.2%) as 'controls' (negative to LAST). Among the patients, 168 (78.5%) were women and 46 (21.5%) men. Among the controls, 103 were women (68.7%) and 47 men (31.3%).

Self-assessment

With reference to the first question of the questionnaire ('Do you think that you have sensitive skin?'), 222 subjects (61%) answered positively (group A) and the other 142 (39%) negatively (group B). The rate of positive answers was higher among patients (78.4%) than controls (21.6%).

Table 1 shows the demographic characteristics of the two groups: it is interesting to note how, overall, the mean age was significantly lower ($p = 3.3\times10^{-6}$) in group A (24.6 ± 7.3 years) than in group B (30.1 ± 12.5).

As shown in Table 2, the mean value of the self-assessed skin sensitivity score (VAS associated with a numeric rating scale 0–10) was 4.6 ± 2.4 in the entire population. The mean value among patients was significantly higher than that of controls. Scores in group A were significantly higher than in group B overall and also when considering patients and controls separately.

Questionnaire reliability

The mean questionnaire-based skin sensitivity score, calculated from the sum of all items, ranging from 0 to 10, was 3.7 ± 2.6 in the study population. As shown in Table 3, the mean score was significantly higher among patients than controls overall, as well as among males and females separately; subjects belonging to group A reached a mean score significantly higher than those in group B. Moreover, the correlation between the skin sensitivity scores given by the subjects and the results of the questionnaire was statistically significant. For the whole study population ρ was 0.71 ($p = 1.2\times10^{-56}$), for the patients ρ = 0.56 ($p = 1.2\times10^{-19}$) and for the controls ρ = 0.63 ($p = 6.1\times10^{-18}$).

Table 4 shows sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy of all of the possible cut-off values of the questionnaire-based skin sensitivity score, with reference to LAST positivity. Figure 1 shows the ROC curve obtained from multivariate logistic regression (AUC = 0.82). In this study, a cut-off of 4 (Youden Index) or 5 (minimal distance from the upper left-hand corner method) was set as the best compromise in terms of both specificity and sensibility, with an accuracy of 76.6% and 72.8%, respectively.

The results of the multivariate analysis (for which $\chi^2 = 123.40$, $p = 1.3\times10^{-20}$) are shown in Table 5.

The items that are associated with a higher chance of positive LAST in a significant way are (in ascending order of *p* value): use of cosmetics, such as creams, detergents, lotions, sensitivity to sun exposure, sensitivity to exposure to wind, sensitivity to hot/dry air and sensitivity to cold/humid air. Older age is associated with a slight but significant reduction in the probability of having a positive LAST.

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 = 364)			
Males, n	45	48	0.0039
Females, n	177	94	
Age (years), mean ± SD	24.6 ± 7.3	30.1 ± 12.5	**3.3×10^{-6}**
Patients (n = 214)			
Males, n	32	14	0.02
Females, n	142	26	
Age (years), mean ± SD	24.9 ± 7.8	24.2 ± 4.2	0.45
Controls (n = 150)			
Males, n	13	34	0.44
Females, n	35	68	
Age (years), mean ± SD	23.6 ± 4.6	32.5 ± 13.8	**3.9×10^{-8}**

Note: *p* values, which are significant after Bonferroni correction, are written in bold.
Abbreviation: SD, standard deviation.

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	4.6 ± 2.4	5.7 ± 1.8	3.0 ± 2.4	$\mathbf{1.4\times10^{-23}}$
Males	4.0 ± 2.5	5.2 ± 1.8	2.9 ± 2.5	$\mathbf{6.97\times10^{-6}}$
Females	4.7 ± 2.4	5.8 ± 1.8	3.0 ± 2.3	$\mathbf{1.1\times10^{-18}}$
p value (males vs females)	0.015	0.04	0.61	
Answer to the question 'Do you think that you have sensitive skin?'				
Yes (group A)	6.0 ± 1.6	6.1 ± 1.6	5.5 ± 1.6	0.035
No (group B)	2.4 ± 1.8	3.9 ± 1.6	1.8 ± 1.6	$\mathbf{2.6\times10^{-9}}$
p value (group A vs B)	$\mathbf{5.0\times10^{-42}}$	$\mathbf{6.7\times10^{-11}}$	$\mathbf{3.7\times10^{-23}}$	

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	3.7 ± 2.6	4.8 ± 2.3	2.1 ± 2.2	$\mathbf{1.8\times10^{-21}}$
Males	2.5 ± 2.2	3.5 ± 2.2	1.5 ± 1.8	$\mathbf{1.5\times10^{-5}}$
Females	4.1 ± 2.7	5.1 ± 2.3	2.4 ± 2.4	$\mathbf{2.2\times10^{-16}}$
p value (males vs females)	$\mathbf{8.2\times10^{-7}}$	$\mathbf{7.6\times10^{-5}}$	0.03	
Answer to the question 'Do you think that you have sensitive skin?'				
Yes (group A)	5.2 ± 2.0	5.5 ± 1.9	4.4 ± 2.0	0.001
No (group B)	1.2 ± 1.4	1.8 ± 1.5	1.0 ± 1.3	0.004
p value (group A vs B)	$\mathbf{3.7\times10^{-46}}$	$\mathbf{1.5\times10^{-21}}$	$\mathbf{1.3\times10^{-15}}$	

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

TABLE 4 Sensitivity, specificity, positive and negative predictive values and accuracy of the possible cut-off values of questionnaire-assessed skin sensitivity score for the correct diagnosis of sensitive skin, i.e. positivity to the LAST

Score	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Accuracy
0	1.000	0.000	0.588	–	0.588
1	1.000	0.200	0.641	1.000	0.670
2	0.986	0.347	0.683	0.945	0.723
3	0.958	0.447	0.712	0.882	0.747
4	0.869	0.620	0.765	0.769	0.766
5	0.724	0.733	0.795	0.651	0.728
6	0.542	0.807	0.800	0.553	0.651
7	0.402	0.900	0.851	0.513	0.607
8	0.140	0.980	0.909	0.444	0.486
9	0.042	1.000	1.000	0.423	0.437
10	0.000	1.000	–	0.412	0.412

DISCUSSION

Despite its frequency and its potential impact on the well-being of those who suffer from it, to date, there are no adequately structured tools for diagnosing sensitive skin Our proposal was intended to fill this gap.

For the present study, we considerably expanded our case series with two main purposes: (i) to verify the

FIGURE 1 ROC curve obtained from multivariate logistic regression

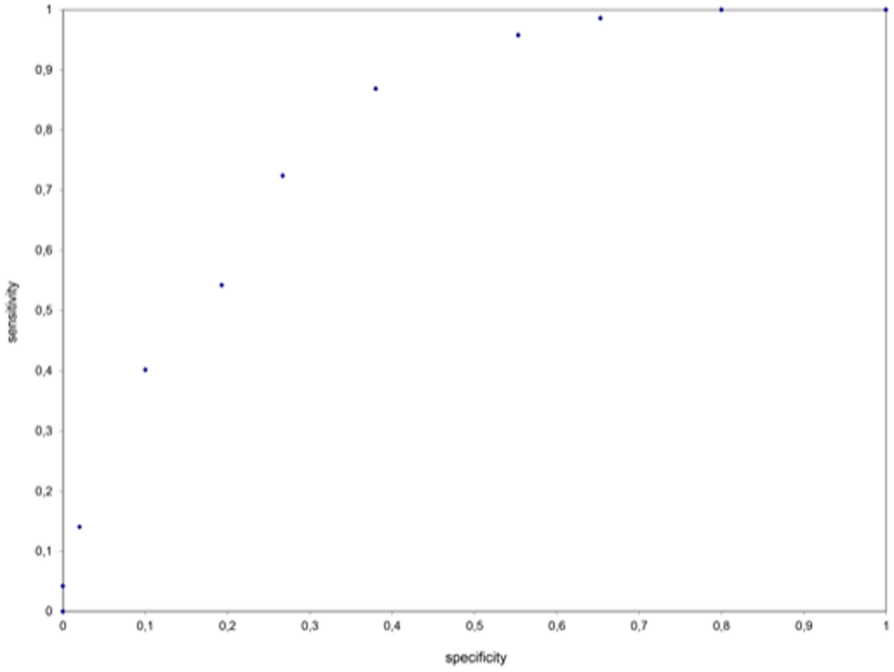

TABLE 5 Multivariate logistic regression showing the relevance of different variables in determining the positive result to LAST

Variable (values: Yes = 1, no = 0, unless otherwise specified)	Coefficient	*p*	Odds ratio
α	0.015		
Female	−0.273	0.366	0.761
Age (years)[a]	−0.042	**0.006**	0.959
Unpleasant sensations with sun exposure	0.814	**0.005**	2.257
Unpleasant sensations with exposure to hot/dry weather/environment	0.712	**0.029**	2.038
Unpleasant sensations with exposure to cold/wet weather/environment	0.569	**0.042**	1.767
Unpleasant sensations with wind exposure	0.779	**0.012**	2.178
Unpleasant sensations with contact with water	0.185	0.774	1.204
Unpleasant sensations with physical exercise	0.211	0.488	1.235
Unpleasant sensations with use of hygiene soaps/cleansers	−0.443	0.170	0.642
Unpleasant sensations with use of cosmetics	1.108	$\mathbf{9.43 \times 10^{-5}}$	3.028
Unpleasant sensations with exposure to smog/pollutants	0.049	0.903	1.050
Unpleasant sensations with psychological stress	0.186	0.527	1.204

Note: Significant *p* values are written in bold.

[a]Valid within the age range of the study population (15–70.2 years).

accuracy of the questionnaire-based skin sensitivity score cut-off, which had previously been found and (ii) to define a formula that, based on the interviewees' answers, may predict the probability of having sensitive skin, with a high degree of plausibility. As in our previous paper [13], in this study as well subjects who were positive at LAST were considered as having sensitive skin.

The results found in this extended study are somewhat coherent with what had previously been found [13]. However, the findings obtained considering a larger

population also revealed some relevant differences from the previous study.

In the previous study, a cut-off of 3 was established with 79% accuracy (i.e., being able to predict whether the subject would be positive or negative on the LAST test). When applying the cut-off of 3 to the larger population of this study, accuracy decreases to 74.7%, with a more noticeable decrease in specificity and an increase in sensitivity when compared with the previous results [13].

The optimal cut-off values of 4 (Youden Index) and 5 (minimal distance from the upper left-hand side corner method) were identified in this new study for the questionnaire used. These two values form a 'grey zone' where the positive and negative predictive values are rather similar. Scores above or below this range are highly predictive (80% or more) of a positive or negative LAST result, respectively. Based on these data, LAST could be performed only in subjects with a questionnaire score of 4 or 5, while in all other cases at the clinician's discretion.

When considering the relative weights for each separate item in the diagnosis of sensitive skin, we found two more stimuli with statistical significance in comparison with our previous study (Table 5). Exposure to hot/dry air and exposure to cold/humid air showed lower p values than the 4 already known items, namely age, sensitivity to sun exposure, use of cosmetics and exposure to wind but were significant too. In addition, the significance of the 4 items found in the previous study [13] was further strengthened.

Through multivariate analysis, each stimulus was shown to have a different odds ratio for LAST positivity (Table 5). The 6 previously mentioned items had significant p value, which means that reacting to these stimuli or falling into a specific age/gender group is particularly predictive of sensitive skin, more than for other items.

In the light of these data, two main considerations may be drawn. On the one hand, the approach based on the total score obtained with this questionnaire appears easy, quick and reliable overall. On the other hand, the use of a mathematical function that takes into account the differences between the predictive value of each stimulus/item, using the coefficients found for each variable, and the role of age and gender would allow the physician to calculate with high accuracy the probability, expressed in percentage, of a positive LAST. Table 5 can be used to create such formula. In detail:

$$k = \alpha + \beta_1 x_1 + \beta_2 x_2 + \beta_3 x_3 + \beta_4 x_4 + \beta_5 x_5 + \beta_6 x_6 + \beta_7 x_7 + \beta_8 x_8 + \beta_9 x_9 + \beta_{10} x_{10} + \beta_{11} x_{11} + \beta_{12} x_{12}$$

where the values of α, β_1 to β_{12} (coefficients for each of the 12 parameters considered) and x_1 to x_{12} (answers to the corresponding 12 questionnaire items) are defined according to the order and rules shown in Table 5. After calculating the value of k, the probability of a positive LAST test (hereafter indicated with p) is given by:

$$p = e^k / 1 + e^k$$

where e is the mathematical constant, which represents the base of the natural logarithm (value: 2.718281828459). The result of this formula will be a number between 0 and 1; to obtain the corresponding percentage value, it has to be multiplied by 100.

This tool could avoid the execution of LAST in a relevant number of cases, with important advantages both in clinical settings and for future trials.

It is necessary to consider some study limitations, some of which mirror those of the previous study [13]. A selection bias was likely since the announcements were located at the University buildings and on the Website and explicitly stated that a study on sensitive skin was being conducted. This probably led to a selection in terms of age and level of education but also to a higher rate of subjects with sensitive skin. Thus the study population cannot be considered entirely representative of the general population. Furthermore, all subjects belonged to the Caucasian ethnicity so the results, as they stand, cannot be extended to other ethnic groups. On the other hand, the recruitment of volunteers over a longer time span than in the previous study limited the possible climatic conditioning on the responses to the questionnaire. In the preliminary phase of the previous study [13], the test–retest showed that the questionnaire was reliable, with Cohen's kappa values higher than 0.7 for all items. It would have been convenient to repeat this procedure for all subjects and retest them across different seasons for ascertaining its reliability even more rigorously and overtime. However, this would have been difficult to achieve, considering that the subjects included were volunteers. None of the subjects involved reported problems in understanding or answering the questions. Finally, LAST was arbitrarily chosen as the discriminating factor between sensitive and nonsensitive skin, so the questionnaire and its results were based on this assumption.

In conclusion, although expanding the population inevitably led to slight changes in the proposed model, the proposed self-assessment questionnaire can be considered a well-built model since the variation in accuracy between the two populations still falls under 5%.

A 'grey zone', which corresponds to scores ranging from 4 to 5, appears to strongly discriminate between subjects with and without sensitive skin. The use of a formula, which takes into account the role of the multiple factors that can influence skin sensitivity, would

be beneficial for both the physician and the patient in terms of accuracy for diagnosis, especially when applied to clinical practice.

AUTHOR CONTRIBUTIONS

MC, AB and LM involved in the study concept and design. LM, MC, ID and LP involved in the acquisition of data. AB, FG, MC and LM involved in the analysis and interpretation of data. AB, FG and LP involved in the drafting of the manuscript. MC, AB, FG and LM involved in the critical revision of the manuscript for important intellectual content. FG involved in statistical analysis.

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CONFLICT OF INTEREST

The authors report no conflict of interest in this work.

ETHICS STATEMENT

The authors confirm that the ethical policies of the journal, as noted on the journal's author guidelines page, have been adhered to and the appropriate ethical review committee approval has been received. The research protocol was reviewed and approved by the Ethics Committee of the University Hospital of Ferrara, Italy (number of ethical approval 170583). All subjects were given written informed consent for participation in the study prior to enrollment.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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