ORIGINAL ARTICLE

Adaptation and Validation of the Spanish Version of the Quality of Life in Latex Allergy Questionnaire (QOLLA)

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Abstract

Objective: The aim of the present study was to translate into Spanish and transculturally adapt the Quality of Life in Latex Allergy questionnaire (QOLLA) in order to provide a validated instrument for use in research and daily practice.
Methods: Patients diagnosed with latex allergy were invited to participate in an observational prospective multicenter study to validate the Spanish version of the QOLLA following the recommendations of the World Health Organization. The study included 3 phases—feasibility, reliability, and cross-sectional validation—and was approved by the Ethics Committee of Hospital Ramón y Cajal.
Results: Mean time to complete the questionnaire was 4.7 minutes. The maximum score was 28 (mean, 7.7; median, 4). The SF-12 score ranged from 25.8 to 51.6 in the physical domain and from 20.8 to 61.5 in the mental domain. Internal consistency was excellent (Cronbach α, 0.9348). The κ index fluctuated between 0.40 and 0.93. A κ of 0.84 was obtained for the global score in 5 categories. Sixty patients were included to evaluate construct validity. Mean age was 39 years and 49 patients were women (80%). The global score ranged between 0 and 30 (mean, 11.69; median, 11).
Spearman correlation coefficients between the QOLLA and a visual analog scale and the SF-12 physical, mental, and severity scales according to the researcher were –0.47, 0.37, 0.29, and 0.54, respectively.
Conclusion: The QOLLA is a feasible, valid, and reliable instrument for the measurement of disease-specific quality of life in adult patients diagnosed with latex allergy. It could play an important role in determining suitable treatment for latex-allergy.

Key words: Latex allergy. Quality of life. Questionnaire. Adaptation. Validation. Spanish.

Resumen

Objetivo: El objetivo del presente trabajo es la traducir y adaptar transculturalmente al español el cuestionario de Calidad de Vida en alergia al latex (QoLLA), desarrollando por lo tanto un instrumento validado en español que pueda ser utilizado tanto en investigación con en la práctica habitual.
Métodos: Pacientes alérgicos al latex de ambos sexos fueron invitados a participar en un estudio prospectivo observacional y multicéntrico para validar la versión española del QoLLA siguiendo las recomendaciones de la OMS. El estudio constó de 3 fases: factibilidad, viabilidad y validación. El estudio fue avalado por el comité ético del Hospital Ramón y Cajal.
Resultados: El tiempo medio empleado para cumplimentar el cuestionario fue 4.7 minutos. La puntuación maxima fue 28 (media 7.7, mediana 4). La puntuación del SF-12 en el domino físico varió entre 25.8 y 51.6 y entre 20.8 y 61.5 en el mental. La consistencia interna fue excelente con una α-Cronbach de 0.9348. El índice Kappa fluctuó entre 0.40 y 0.93. Se obtuvo un Kappa de 0.84 para la puntuación global en 5 categorías. Para evaluar la validez del constructo se reclutaron un total de 60 pacientes. La edad media fue 39, 49 fueron mujeres (80%). La puntuación global osciló entre 0 y 30 (media 11.69, mediana 11).
Los coeficientes de la correlación de Spearman entre QoLLA y VAS, ambos dominios de SF-12, y la escala de severidad según el criterio del investigador fueron -0.47, 0.37, 0.29 y 0.54 respectivamente.
Conclusión: QoLLA es un instrumento factible, viable y válido para medir la calidad de vida de los pacientes alérgicos al látex, permitiendo por lo tanto incluir la medición de la calidad de vida medida de los pacientes como una variable más en los estudios de intervención.

Palabras clave: Alergia a latex. Calidad de vida. Cuestionario. Adaptación. Validación. Español.

Introduction

Latex allergy emerged as an increasingly frequent health problem in the early 1980s. Reactions were sometimes severe, and the allergy was considered an occupational disease [1-3] affecting different collectives. The greatest impact is seen in rubber industry workers and health professionals [4-6], although hairdressers [7] and cooks have also been affected, as has anyone using latex products in their working environment. Pediatric patients repeatedly exposed to latex-containing products since early life are a special risk group. Such is the case of patients with spina bifida [8,9] and those with urogenital abnormalities who need multiple interventions and examinations involving latex products. A higher incidence has been confirmed in children on mechanical ventilation [10] and in those with atopic diseases [11]; consequently, both conditions are now considered risk factors.

Latex allergy affects 0.3% to 1% of the general population. In patients with spina bifida, these percentages increase dramatically to 26%-50% [12-14] and in health professionals to 3%-17%, depending on the study [6,7,15,16].

Reactions are potentially severe and they occur mainly in clinical settings when allergic patients seek medical assistance or require surgery. Reactions are triggered less frequently by domestic objects such as balloons, contraceptives, and gloves.

Immediate hypersensitivity reaction to latex was first reported in 1927. In 1979, Nutter [17] reported a case of contact urticaria. This report was followed by several studies documenting similar reactions, many of which reflected an increase in the incidence of intraoperative anaphylaxis and reactions to contrast media. The alarm was raised in the late 1980s, when over 1000 reactions were reported in 4 years in the USA [18,19]. This outbreak can be explained by the generalized use of latex gloves by health professionals to avoid emerging infectious diseases such as HIV infection. Growing demand affected manufacturing process, resulting in gloves with a higher content of allergenic particles.

Since 2000, preventive measures have been based mainly on the rational use of latex. Avoiding glove dust and promoting gloves with a low latex content [20] led to a decrease in new cases among health professionals, as well as decreased reactions by allergic patients during medical procedures. However, prevalence has remained unchanged, since no definitive treatment is available.

In recent years, several research projects have studied treatment of latex allergy, such as specific oral immunotherapy (Slit-Latex, ALK-Abelló) [21-23], which, although commercially available, has limited indications. Omalizumab has also been administered to health care workers with latex allergy [24]. Nevertheless, the only effective treatment is strict avoidance of the allergen to prevent contact (cutaneous, mucosal, or internal), inhalation (particles from balloons or gloves), and ingestion (meals manufactured using latex gloves). Avoidance must be stressed at several levels. In health care, the ubiquity of latex should be managed using protocols. In daily life, it is difficult to avoid latex, and permanent contact with tiny amounts of particles maintains patient sensitization [25,26].

Therefore, latex allergy can severely affect health-related quality of life (HRQOL). The first qualitative approach to the disease was made in 2005. A disease-specific HRQOL questionnaire was developed and validated in the UK. Research conducted in the Dermatology Department of Ninewells Hospital and Medical School in collaboration with The UK Latex Allergy Support Group (LASG) aimed to assess the HRQOL of latex-allergic adults and children. The adult survey concluded that type I latex allergy severely impaired HRQOL. Around 25% of patients needed to change their post due to their allergy. A similar trend was observed in the pediatric population: latex allergy greatly affected the daily activities of both children and parents [27,28].

A validated instrument to measure the HRQOL of latex-allergic patients is beneficial in 2 ways. First, it can provide information that will help develop preventive measures to avoid new sensitizations. Second, it enables us to evaluate the impact of new treatments on quality of life.

The aim of the present study was to translate into Spanish and transculturally adapt the Quality of Life in Latex Allergy questionnaire (QOLLA) in order to provide a validated instrument to be used in research and daily practice [29-31].

Methods

Study Population and Procedures

The study sample comprised male and female patients aged ≥18 years with a diagnosis of latex allergy. In addition, patients had to have suffered an immediate reaction after latex exposure (contact urticaria, respiratory symptoms, or anaphylaxis) and to have had a positive result in a skin prick test (SPT) and/or specific immunoglobulin (Ig) E (sIgE) determination against latex.

Patients were recruited from 2 allergy clinics (Hospital Ramón y Cajal [Madrid, Spain] and Centro Alergoasma [Salamanca, Spain]) and from the members of 2 patients' associations, namely, Asociación Española de Alérgicos a Alimentos y Látex (AEPNAA: Spanish Association of Patients Allergic to Foods and Latex) and Asociación Española de Alérgicos al Látex (Spanish Association of Latex-Allergic Patients).

Patients attending the 2 clinics were invited to participate, and members of patients' associations were recruited through their periodical bulletin and an announcement on their website. Due to the intrinsic characteristics of latex allergy, all patients were stable at the beginning of the study.

Patients with comorbid conditions affecting their quality of life or who were advised not to participate (researcher's criteria) were excluded.

Informed consent was obtained in all cases.

Patients' associations in the UK (LASG) and Spain (AEPNAA) collaborate regularly and promote joint actions to improve the quality of life of latex-allergic patients. This partnership led to a study with the objective of measuring HRQOL in allergic patients at the Dermatology Department of Ninewells Hospital and Medical School (Dundee, United Kingdom). The study produced a new instrument to evaluate

HRQOL in latex allergy, namely the QOLLA). AEPNAA obtained permission from the original authors of the questionnaire (Drs JG Lowe and MS Lewis-Jones) to translate the questionnaire into Spanish and validate it following World Health Organization (WHO) criteria. Once a Spanish version of the instrument was available, AEPNAA contacted the Allergy Department and Clinical Biostatistics Unit of Hospital Ramón y Cajal to conduct the validation phase. The study was supported by the Latex Committee of the Spanish Society of Allergy and Clinical Immunology (SEAIC).

Design

An observational prospective multicenter study to validate the Spanish version of the QOLLA was performed in 3 phases:

a) Feasibility: A sample of 25 patients completed 3 self-administered questionnaires, namely, the QOLLA questionnaire (adult form), the Short Form-12 health questionnaire (SF-12), and a visual analog scale (VAS) to evaluate subjective self-perception of patient heath status. The time to complete the QOLLA was measured and confusing questions were identified. The attending physician was asked to evaluate severity of latex allergy according to clinical records as mild, moderate, or severe.

b) Reliability: Ten days later, the same patients were invited to complete the QOLLA and SF-12. This second version of the QOLLA version contained the same questions in a different order. The second set of questionnaires were completed at home and returned by mail.

c) Cross-sectional validation: The last phase was conducted in a wider sample of patients from the participating allergy clinics and members of AEPNAA, who were invited to complete the initial version of the questionnaire (QOLLA-A), the SF-12 questionnaire, and the VAS of self-perceived heath status.

The study was approved by the Ethics Committee of Hospital Ramón y Cajal.

Description of Questionnaires

QOLLA: QOLLA is a disease-specific questionnaire to measure HRQOL in latex-allergic patients. The original instrument was developed in English. Translation and transcultural adaptation into Spanish followed WHO guidelines [32]. In brief, the first Spanish version was distributed among a small sample of patients to evaluate general comprehension of the instrument and the relevance of each question to allergic patients. The second version was then back-translated and sent to the original authors for approval.

The final version contains 13 items covering different aspects affecting the daily activity of patients with latex allergy. Question 14 examines the effect of latex allergy on daily life in the last 3 months. Every item scores on a 4-point scale (0 to 3), except for question 11 (0 to 4): 0 indicates no effect and 3 (4 in question 11) indicates maximum effect. The global score was obtained from a mean score of the 13 items, ranging between 0 (minimum score) and 40 ($12 \times 3 + 1 \times 4$). Five severity categories of QOLLA were established following the guidelines of the original version: ≤4, >4 to ≤9, >9 to ≤14, >14 to ≤19, and >19. The timeframe was the last 3 months.

SF12: SF-12 is a generic quality of life questionnaire and the short version of SF-36. It has been translated into Spanish and validated and has been used in other allergic conditions as asthma, atopic dermatitis, and rhinitis. It is considered a valid alternative to SF-36 for evaluation of physical and psychological domains [33-37].

VAS: VAS is a horizontal scale measuring 10 cm in length. One end is labeled worst health state possible and the other best health state possible. The score ranges from 0 to 10. Individuals must visually indicate how good or bad they perceive their health to be.

Latex allergy severity: Allergy to latex was graded as mild, moderate, or severe. The attending physician assigned the category according to the reactions experienced by the patient after latex exposure. History of anaphylaxis was specifically recorded.

Statistical Analysis

To investigate feasibility, we recorded time to complete the questionnaire and percentage of patients with unanswered items (by domain and overall). Internal consistency was evaluated by obtaining Cronbach α values for every score.

Test-retest reliability, or agreement, was estimated using the κ index for each item in the QOLLA and overall, the intraclass correlation coefficient (ICC), and a Bland-Altman plot. Reliability was evaluated using recommended psychometric standards, namely, Cronbach α and ICC ≥0.7.

The Spearman correlation coefficient was calculated between the QOLLA and question 14 (general wellbeing), the SF-12 score, and severity (researcher's criteria) to assess construct validity. A Spearman correlation coefficient lower than 0.25 indicates minimum or no correlation, from 0.25 to 0.50 indicates a moderate to good correlation, and greater than 0.75 indicates a good to excellent correlation.

The Kruskal-Wallis and Mann Whitney tests were used to compare global QOLLA score by patient variables.

The questionnaire responses were coded and double entered to ensure data quality. SPSS 16.0 and R 2.9 were used for analysis. A *P* value of .05 or less was considered significant.

Results

Feasibility

In this phase, 23 out of 25 (92%) latex-allergic patients completed the questionnaire. Mean age was 40.7 (range, 20-59) years and 19 patients were women (82.6%). Thirteen patients had mild allergy (56.5%), 6 moderate allergy (26.1%), and 4 severe allergy (17.4%). Mean time to complete the questionnaire was 4.7 (1-15) minutes. The maximum score on the QOLLA was 28 (mean, 7.7; median, 4). The SF-12 score ranged from 25.8 to 51.6 (mean, 47.6; median, 51.6) in the physical domain and from 20.8 to 61.5 (mean, 50.4; median, 51.1) in the mental domain.

The questions on which the highest score was reached were *En los últimos 3 meses, ¿le ha preocupado la posibilidad de sufrir una reacción grave (anafiláctica) al látex? (During the last 3 months, have you been worried about having a severe*

Table 1. Clinical Characteristics

Sex	Male	12 (20%)
	Female	48 (80%)
SF-12 physical Mean (range)	48.1 (25.3-59.5)	
SF-12 mental Mean (range)	48.6 (20.8-63.1)	
Severity		
	Mild	15 (50%)
	Moderate	9 (30%)
	Severe	6 (20%)

[anaphylactic] reaction to latex?) (mean, 1.16 points) and En *los últimos 3 meses, ¿le han preocupado otros aspectos de su alergia al látex? p. ej., visitas al hospital, dentista, etc. (During the last 3 months, have you been worried about other aspects of your latex allergy, eg, visits to hospital, your dentist?)* (mean, 1.28 points). The lowest score was obtained for *En los últimos 3 meses, ¿ha tenido problemas con otros tratamientos para la alergia al látex, como cremas, antihistamínicos, inhaladores, etc.? (During the last 3 months, have you had problems with other treatments for your latex allergy, eg, creams, antihistamines, inhalers?)*

The questions that were most difficult to understand were as follows:

¿Lleva usted consigo Adreject o adrenalina autoinjectable? En caso afirmativo: En los últimos 3 meses, ¿hasta qué punto cree que tendría problemas para usarlo en caso de necesitarlo? (Do you carry your self-injecting adrenaline? If yes, with reference to the last 3 months, to what extent do you think you would have difficulty using it if necessary?). One patient did not answer this question.

En los últimos 3 meses, ¿ha tenido problemas con otros tratamientos para la alergia al látex, como cremas, antihistamínicos, inhaladores, etc.? (During the last 3 months, have you had any problems with other treatments for your latex allergy, eg, creams, antihistamines, inhalers?). Two patients did not answer this question.

En los últimos 3 meses, *¿le ha causado problemas la alergia al látex para hacer deporte? p. ej., en mango de raquetas, neumáticos o ruedas de caucho, gorros de natación, etc.? (During the last 3 months, has your latex allergy caused problems with participating in sports, eg, racket grips, rubber tires or wheels, swimming caps?).* One patient did not answer this question.

Internal Consistency

Internal consistency was excellent (Cronbach α, 0.9348).

Test-retest Reliability

Both the QOLLA and the SF-12 were readministered

Table 2. Test-Retest Reliability. κ Index for Every Question in the QOLLA and Global Score in 5 Categories.

Question	κ
1. ¿Le ha preocupado la posibilidad de sufrir una reacción grave? (Have you been worried about suffering a severe reaction?)	0.65
2. ¿Le han preocupado otros aspectos de su alergia al látex? (Have you been worried about other aspects of your latex allergy?)	0.56
3. ¿Se ha visto afectado su estado de ánimo por la alergia al látex? (Has your state of mind been affected by your latex allergy?)	0.73
4. ¿Ha presentado síntomas causados por su alergia al látex? (Have you had symptoms caused by your latex allergy?)	0.40
5. ¿Le ha causado problemas la alergia al látex para asegurarse de que el ambiente en su propio hogar esté libre de látex? (Has your latex allergy caused you problems in ensuring that your home is latex-free?	0.61
6. ¿Le ha causado problemas la alergia al látex para realizar las actividades de la vida diaria? (Has your latex allergy caused you problems when carrying out your daily activities?)	0.77
7. ¿Le ha causado problemas la alergia al látex para hacer deporte? (Has your latex allergy caused you problems when participating in sports?)	0.47
8. ¿Le ha causado problemas la alergia al látex para sus relaciones sociales? (Has your latex allergy caused you problems in your relationships with others?)	0.80
9. ¿Se han visto afectadas sus relaciones personales o su vida sexual por la alergia al látex? (Has your latex allergy affected your personal or sexual relations?)	0.79
10. ¿Ha tenido algún problema por las actitudes poco comprensivas de colegas, amigos,…? (Have you had problems due to poor understanding of your condition from your colleagues, friends, or other people?)	0.93
11. ¿Le ha causado la alergia al látex problemas económicos? (Has your latex allergy caused you financial problems?)	0.61
12. ¿Lleva consigo adrenalina autoinyectable? (Do you carry self-injectable adrenaline with you?)	0.73
13. ¿Ha tenido problemas con otro tratamientos para la alergia al latex? (Have you had any other problems with your latex allergy?)	0.65
14. ¿Cuánto diría que la alergia al látex ha afectado a su calidad de vida general? (How would you say your latex allergy has affected your quality of life in general?)	0.82
Global score in 5 categories	0.84

10 days later. The overall score ranged between 0 and 28 (mean, 7.7; median, 4) at the first measurement and between 0 and 30 (mean, 8.8; median, 5) at the second. Table 2 shows test-retest reliability with the κ index for every question in the QOLLA as well as for the overall score graded in 5 categories. The κ index fluctuated between 0.40 *(En los últimos 3 meses, ¿ha presentado usted síntomas causados por su alergia al látex, como erupciones cutáneas, labios hinchados, moqueo o lagrimeo, dificultad para respirar o tragar, desvanecimientos?" (During the last 3 months, have you presented symptoms caused by your latex allergy, such as rash, lip swelling, runny nose or tears, difficulty breathing or swallowing, fainting?)* and 0.93 *(En los últimos 3 meses, ¿ha tenido algún problema por las actitudes poco comprensivas de colegas, amigos u otros?"(During the last 3 months, have you had problems due to poor understanding of your condition from your colleagues, friends, or other people?)*. A κ of 0.84 was obtained for the overall score in 5 categories.

Agreement was not perfect, as is shown in the Bland-Altman plot (Figure); all differences were inside the confidence interval (CI) except for 1 patient who had a latex exposure between 2 determinations. The ICC was 0.876 (95% CI, 0.74-0.94).

Construct Validity

A total of 60 patients completed the questionnaire in this phase. Mean age was 39, and 49 patients were women (80%). The overall score ranged between 0 and 30 (mean, 11.69; median, 11).

The physical domain score in SF-12 ranged from 25.3 to 59.5 (mean, 48.1; median, 51.3) and that of the mental domain from 20.8 to 63.6 (mean, 48.6; median, 50.3).

No differences were observed between men and women.

The Spearman correlation coefficients between the QOLLA and VAS, and the SF-12 physical, mental and severity scale according to researcher were –0.47, –0.37, –0.29, and 0.54 respectively. Ad hoc analysis revealed a higher QOLLA score in patients with severe disease: mean (SD) score was 5.93 (6.02) in patients with mild allergy, 10 (8.40) in patients with moderate allergy, and 18.83 (SD 8.68) in patients with severe allergy, *P*=.004.

Discussion

The QOLLA is the only available specific questionnaire to evaluate quality of life in latex-allergic patients. In the present study, we evaluated the Spanish version of this questionnaire.

The Spanish version was obtained following the recommendations of the WHO [38,39]. Our results show that the questionnaire is feasible, valid, and easy to complete, with an acceptable number of missing answers.

The main difficulties in translation arose from the idiosyncratic nature of latex allergy, which cannot be easily compared with other allergic diseases such as venom allergy and food allergy. Besides, assessment of latex allergy is further affected by the lack of suitable treatment (other than avoidance), which makes it difficult to observe and measure changes in a patient's status, except in cases of accidental exposure.

Patients need less than 5 minutes to complete the QOLLA. Other questionnaires, such as ESPRINT [40] or RQLQ, have a mean completion time of 7 and 9.6 minutes, respectively.

Our nonanswer rate was low (2/25, 8%), and patients only found difficulty answering 3 questions. The question on carrying self-injecting adrenaline may be difficult to understand for patients with mild reactions who have never been prescribed adrenaline and who, consequently, are not aware of the consequences of not carrying it. In the case of the question on problems with other treatments, the patients had not experienced accidental exposure to latex and, consequently, did not require medication. In the question referring to difficulty participating in sports, the patient who did not answer did not participate in sports and, therefore, did not find the question relevant.

Despite the low nonanswer rate, the question on epinephrine could be reformulated to make it more understandable without changing its sense. Clearer instructions could be given before the patient completes the questionnaire. The nonanswer rate was lower than that of ESPRINT and RQLQ [40].

The QOLLA showed internal consistency and test-retest reliability, with coefficients within recommended psychometric

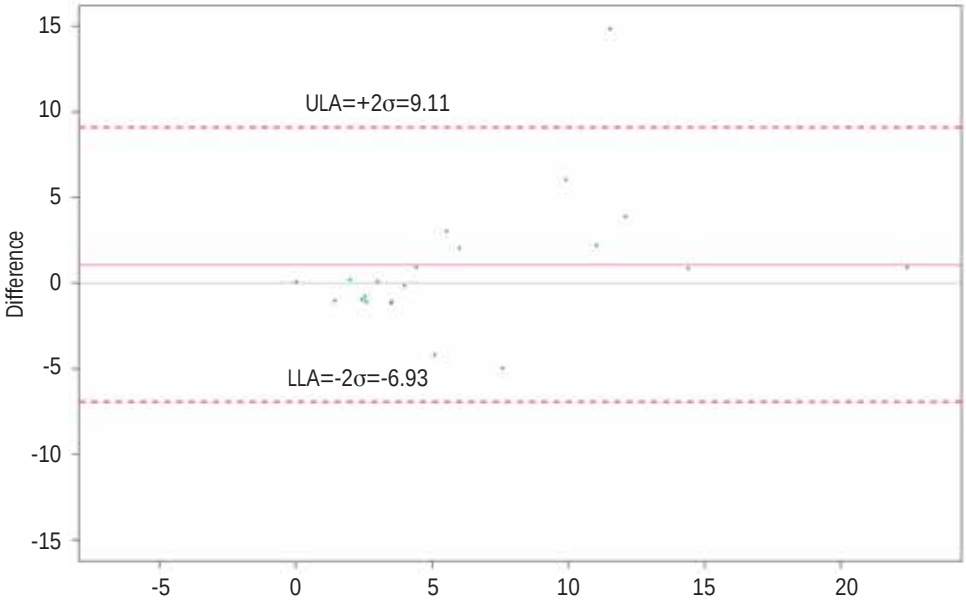

Figure. Agreement. Bland-Altman difference plot. LLA indicates lower limit of agreement; ULA, upper limit of agreement.

standards. Internal consistency was excellent, with a Cronbach α of 0.8967. The ICC between QOLLA-A and QOLLA-B was 0.876 (95% CI, 0.74-0.94). Similarly, the Bland-Altman plot showed all differences to be within the confidence interval, except for 1 case (accidental exposure between 2 measurements).

In terms of validity, Spearman correlation coefficients between the QOLLA and VAS, SF-12 physical domain, SF-12 mental domain, and severity scale (researcher's criteria) were –0.47, –0.37, –0.29, and 0.54, respectively. A higher correlation was obtained with severity as evaluated by the patient's physician, because this criterion is more specific than the SF-12 physical and mental domains used to evaluate quality of life in general and not impairment caused by latex allergy. The specificity of quality of life questionnaires has been described previously, and some authors stress the need for parallel measurement of quality of life using a generic questionnaire and a disease-specific questionnaire, if available [31,41].

In conclusion, the QOLLA is a feasible, valid, and reliable instrument for measurement of disease-specific quality of life in adult patients diagnosed with latex allergy. It could be used when deciding on the interventions to be applied in latex-allergic patients.

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The Spanish version of the QOLLA is available upon request from AEPNAA and Sociedad Española de Alergología e Inmunología Clínica (SEAIC).

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