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ORIGINAL ARTICLE

Feasibility and Reliability of the Spanish Version of the Leeds Revised Acne Grading Scale

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KEYWORDS
Acne vulgaris;
Diagnosis of acne;
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Validation of scales

Abstract
Background: Although there are more than 25 acne grading systems, there is no consensus on which is most appropriate. Unification of the classifications is recommended in order to facilitate therapeutic decisions.
Objective: To assess the feasibility and reliability of the Spanish version of the Leeds revised acne grading (LRAG) scale in patients with acne vulgaris in Spain.
Patients and methods: We conducted a prospective, multicenter, observational study in Spain, including patients with acne affecting at least 1 of 3 regions: face, back, or chest. Patients were assessed using the LRAG scale and lesion counting. Changes in the scores were determined at 4-6 weeks, and were correlated with the lesion count. Physicians were asked 4 questions regarding difficulty using the scale and the time employed.
Results: A total of 259 sites of acne were assessed in 239 patients at 57 centers. The majority of physicians (89.5%) stated that the LRAG scale was not difficult to use. The mean administration time was 3.12 min. Cross-sectional validity ($P<.012$ for the face, $P<.001$ for the back and chest), longitudinal validity ($P<.0001$ for the face, back, and chest), and intraobserver and interobserver reliability (Cronbach α >0.8) were significant for inflammatory lesions in all regions. Sensitivity to change was demonstrated for lesions in all regions, based on the correlation between the difference in severity and the number of lesions recorded by the LRAG, and the difference in the lesion count between baseline and follow-up.
Conclusion: The Spanish version of the LRAG scale is a practical and reliable tool and is sensitive to change. It is a valid tool for the objective assessment of the severity of acne.

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PALABRAS CLAVE
Acné vulgar;
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Clasificación de acné;
Validación de escalas

Factibilidad y fiabilidad de la versión española de la escala revisada de gravedad de Leeds (LRAG) para pacientes con acné

Resumen

Introducción: Se describen más de 25 métodos para valorar la gravedad del acné y, aunque no hay consenso sobre una escala, se recomienda unificar su clasificación para facilitar las decisiones terapéuticas.

Objetivos: Validar la factibilidad y fiabilidad de la escala revisada de gravedad de Leeds (LRAG) en pacientes con acné vulgar en España.

Material y métodos: Estudio observacional prospectivo multicéntrico español que evaluó mediante la escala LRAG y el recuento de lesiones a pacientes con acné en al menos una de tres localizaciones (cara, pecho o espalda). Se analizaron los cambios en la puntuación a las 5 ± 1 semanas y se correlacionaron con el recuento de lesiones. El clínico respondió 4 preguntas sobre dificultad y tiempo de uso de la escala.

Resultados: Fueron evaluadas 259 localizaciones de acné en 239 pacientes y en 57 centros asistenciales. El 89,5% [IC: 85-92,9%] de los médicos opinaron que la escala se usó sin dificultad y su tiempo medio de administración fue de 3,12 min. La validez transversal ($p < 0,012$ facial, $p < 0,001$ espalda y pecho), validez longitudinal ($p < 0,0001$) y fiabilidad intra e interobservador (alfa de Cronbach ≥ 0,8) de la escala fue significativa en todas las localizaciones. En relación a sensibilidad al cambio de la escala, las lesiones observadas en todas las localizaciones en el seguimiento dependen de la diferencia de gravedad registrada por la escala LRAG y el recuento de lesiones basales.

Conclusiones: La versión española de la escala LRAG es factible, fiable, sensible y constituye una herramienta válida para objetivar clínicamente la gravedad del acné.

Introduction

Acne vulgaris, with a lifetime prevalence of between 70% and 90%,[1] is the most common dermatologic disorder. The vast majority of patients with acne have facial lesions but approximately half also have acne on the chest or on the chest and back. Diagnosis is clinical and also subjective because it is observer-dependent.[2] The need for an accurate, reproducible, and rapid system for grading acne that could be used in clinical practice became apparent at the end of the 1970s.[3] Currently, however, there are over 25 different methods for assessing acne severity,[4] most of which have been developed independently and use different terminology and scales,[5] explaining the lack of standardization that has been noted.[6] Furthermore, in clinical guidelines on the management of acne vulgaris, there is no consensus on which grading or classification system is the most appropriate.[7]

No Spanish studies to date have analyzed currently available acne grading systems, and there is also a lack of consensus in Spain regarding their use in clinical practice. In this context, the VEGA (Validación Escalas de Gravedad del Acné) study set out to validate the feasibility and reliability of the Leeds Revised Acne Grading (LRAG) scale in patients with acne vulgaris.

Materials and Methods

We performed a prospective, multicenter, observational study in Spain in which we included patients of any age or sex who visited the dermatology departments at the participating hospitals complaining of acne on the face, chest, or back. All the patients were given an information leaflet and signed an informed consent form prior to participation. Excluded were patients with highly localized acne, concomitant dermatologic disorders, or physical features that would have made it difficult to assess the severity of their acne (eg, beards, tattoos, and very long hair). Recruitment was consecutive. All the patients were interviewed by their regular dermatologists, who completed a case report form for each patient and each acne site (face, chest, and back) at a baseline visit and follow-up visit (at 5±1 weeks). At these visits, the dermatologist took a photograph of each of the acne sites recorded for the patient. In some patients, different acne sites were evaluated in the 2 visits; separate data entries were generated for each site.

The aim of the VEGA study was to validate the LRAG scale in Spain. Accordingly, assessment using this system was the main variable of interest. The LRAG scale is a visual system that asks the observer to compare a patient's lesions with photographic standards for 3 sites: the face, the back, and the chest.[8,9] The criteria used to assess severity are degree of inflammation, lesion type and size, and associated erythema. To assess facial acne, 13 photographs showing 12 levels of severity, from grade 1 (least severe) to 12 (most severe), are used. For instance, patients with atypical acne (sporadic and asymmetric nodular lesions) are classified as having grade 12 acne. The severity of lesions on the chest and the back is assessed using 8 photographs graded from 1 to 8. For patients with predominantly noninflammatory acne, O'Brien et al[9] proposed using a scale comprising 3 photographs of noninflammatory lesions of increasing severity (grades 1 to 3).

In the current study, we assessed acne severity using the lesion count method followed by the LRAG scale, as described by O'Brien et al,[9] at the baseline visit and the follow-up visit in all patients except those who experienced complete remission. For the purpose of analysis, each grade on the scale was assigned a relative score (of 1 to 8 or 1 to 12 depending on the site), and it was assumed that the difference between grades was 1 in all cases.

The assessing dermatologist then answered 4 questions regarding the difficulty of the LRAG scale, the time it took to perform, and the lighting conditions under which the lesions were inspected. The feasibility of the LRAG scale as a diagnostic tool was analyzed by checking that it provided a simple method for assessing acne severity, that it could be completed in an average of 5 minutes or less, and that it could successfully be used to grade acne severity in at least 70% of patients.

To assess the cross-sectional validity of the LRAG scale, we tested whether or not it correctly discriminated between patients with differing levels of clinical severity, analyzing the correlation between the acne lesion count and the LRAG severity score at baseline by means of the Spearman correlation coefficient.

Longitudinal validity, which is a measure of the correlation between changes in LRAG severity scores and lesion count (a conventional method of assessing acne severity) was analyzed by comparing changes in LRAG scores and lesion counts between baseline and follow-up (comparison of means for paired data) and by calculating the Spearman correlation coefficient for the changes detected.

To analyze intraobserver and interobserver reliability, data for the 3 sites were combined. Intraobserver reliability was assessed in patients with clinically stable lesions, ie, in patients whose lesion count varied by no more than 1 lesion per site from baseline to follow-up. For this analysis, we calculated the intraclass correlation coefficient (ICC) and then performed an F test to confirm that an ICC of 0.80 could be considered significant and free of bias. Cronbach α, which provides the same measure as the ICC, was also calculated as another test of measurement reliability. With both of these measures, good agreement between scores provided by a single observer at different times will be indicated by a value close to 1. A score of 0.80 or higher was considered acceptable for the purpose of this study. Interobserver reliability, the reproducibility of scores provided by different observers, was also assessed.

An independent observer evaluated photographs of randomly chosen patients from the 2 visits using the same scales. Absolute agreement measures were used to calculate the level of ICC (agreement) between the severity scores given by the dermatologists and the independent observer. A level of 0.80 or higher was considered acceptable.

The sensitivity of the LRAG scale was tested using analysis of variance; in this test, the dependent variable was the severity score at follow-up and the independent variables were the number of baseline lesions and differences in scores between baseline and follow-up.

The size of the study sample was governed by the requirements of the sensitivity analysis. It was calculated that a sample of 142 patients would be necessary to detect a mean difference of 1 point on the scale assuming a maximum SD of 3, a correlation coefficient of 0.5 between the baseline and follow-up scores, a significance level of .05 in 2-tailed tests, and a statistical power of 80%. Allowing for a loss to follow-up of 30%, 185 patients (142×1.30) were enrolled. All statistical analyses were performed using SPSS (version 12) and statistical significance was set at a P value of less than .05.

Results

In total, 259 acne sites were analyzed in 239 patients who visited the dermatology departments of the 57 Spanish hospitals that participated in the study between November 6, 2006 and March 9, 2007. The demographic and clinical characteristics of the patients are shown in Tables 1 and 2.

Feasibility of the LRAG System

The LRAG system was rated as easy to use by 89.5% (confidence interval [CI], 85%-92.9%) of the dermatologists who participated in the study, indicating a clearly significant positive assessment of feasibility ($P<.001$). The mean (SD) administration time was 3.11 (2.77) minutes, which is significantly shorter than the maximum allocated time of 5 minutes ($P<.001$).

Cross-Sectional Validity of the LRAG System

There was a significant association between lesion count and LRAG scores at baseline for noninflammatory lesions ($P<.050$), inflammatory lesions ($P=.012$), and chest and back lesions ($P<.001$) (Table 3).

Longitudinal Validity of the LRAG System

Lesion count and LRAG scores for all the sites analyzed were significantly reduced in the follow-up visit compared to the baseline visit ($P<.001$, Table 4). The Spearman correlation was significant for inflammatory lesions at all sites ($P<.001$ for the face and chest and $P<.05$ for the back). The correlation was not significant for noninflammatory lesions on the back ($P=.070$) (Table 5).

Intraobserver and Interobserver Reliability for the LRAG System

Intraobserver reliability was confirmed with a Cronbach α of 0.82, which was identical to the ICC obtained. Interobserver reliability was analyzed using 140 of the 259 acne sites evaluated. The correlation between the LRAG scores provided by the independent observer and the dermatologists was considered to be statistically significant, even though the ICC was 0.72, given that the upper limit of the CI was 0.80 (95% CI, 0.62-0.80), indicating statistical equivalence between 0.72 and 0.80.

Sensitivity of the LRAG System

The number of inflammatory lesions at follow-up was significantly associated with both the difference in LRAG scores between baseline and follow-up ($P<.05$) and baseline lesion count ($P<.0001$) (Table 6).

Table 1 Sociodemographic and Clinical Characteristics of Patients With Acne Participating in the Study (n = 329)

Mean age, y (SD)	21.29 (±7.17)		
Sex, % of patients			
Women	48.3		
Male	51.7		
Educational level, %of patients			
Literate but no formal education	0.4		
Primary education	12.2		
Secondary education	64.1		
University education	23.2		
Acne site, %of patients			
Face	48.6		
Back	30.1		
Chest	21.2		
Lesion count by type of lesion	*Mean*	*SD*	*95%CI*
Noninflammatory lesions			
Face	27.66	32.38	[21.76-33.57]
Back	28.01	29.51	[21.07-3.94]
Chest	21.26	29.82	[12.78-29.73]
Superficial inflammatory lesions			
Face	20.51	15.64	[17.67-23.35]
Back	34.27	29.94	[27.28-41.26]
Chest	22.65	19.09	[17.33-27.97]
Deep inflammatory lesions			
Face	4.82	6.13	[3.69-5.94]
Back	12.82	22.17	[7.54-18.11]
Chest	5.78	8.36	[3.40-8.15]
Residual lesions			
Face	13.82	15.91	[10.88-16.76]
Chest	19.46	21.33	[14.41-24.51]
Back	13.98	17.32	[9.10-18,85]
Associated erythema			
Acne site	Associated erythema, % (No. of patients with erythema at site/total of patients with lesions at site)		
	No		*Yes*
Face	33.6 (41/122)		66.4 (81/122)
Back	45.1 (32/71)		54.9 (39/71)
Chest	48.1 (25/52)		51.9 (27/52)
Lost to follow-up (all sites)	5.4 (14/259)		—
Total (all sites)	43.2 (112/259)		56.7 (147/259)

Abbreviation: CI, confidence interval.

Discussion

In the VEGA study we have confirmed that the LRAG system is feasible, reliable, and sensitive in our setting. Our description of methodological assumptions is a feature that distinguishes our study from others in the literature that have been found to have serious shortcomings in terms of methodology reporting.[6] The fact that we found the LRAG system to be feasible for clinical use and to have both intraobserver and interobserver reliability responds to the need for standardization of outcome measures used in acne vulgaris research in Spain. Furthermore, the sensitivity of the scale we have validated makes it particularly appropriate for use in studies of the effectiveness of therapeutic intervention. Our results provide evidence that the LRAG grading system can be used for the purpose for which it was designed by O'Brien et al.[9] We found that the Spanish version of the LRAG can be administered both quickly and simply; the dermatologists who participated in this study used it often and took just a short time to complete it. This view differs from that of Dreno et al,[10] who felt the LRAG was complicated to use. Bergman et al[11] reported

Table 2 Assessment of Acne Severity With the Leeds Revised Acne Grading (LRAG) Scale

LRAG Scores for Noninflammatory Facial Lesions				
	Mean	**Median**	**SD**	**Min-Max**
LRAG score	1.69	2.00	0.67	1.0-3.0
	Frequency, n/total	*%*	*Valid, %*	
1	18/126	14.3	41.9	
2	20/126	15.9	46.5	
3	5/126	4.0	11.6	
Total	43/126	34.1	100.0	
LRAG scores for inflammatory lesions				
LRAG scores for face				
	Mean	*Median*	*SD*	*Min-Max*
LRAG score	5.21	5.00	2.52	1.0 -11.0
	Frequency. no./total	*%*	*Valid, %*	
1	3/126	2.4	3.2	
2	13/126	10.3	13.8	
3	10/126	7.9	10.6	
4	16/126	12.7	17.0	
5	15/126	11.9	16.0	
6	7/126	5.6	7.4	
7	5/126	4.0	5.3	
8	17/126	13.5	18.1	
9	4/126	3.2	4.3	
10	1/126	0.8	1.1	
11	0/126	0.0	0.0	
12	3/126	2.4	3.2	
Total	94/126	74.6	100.0	
LRAG scores for back				
	Mean	*Median*	*SD*	*Min-Max*
LRAG score	3.57	3.00	1.70	1.0-8.0
	Frequency, no./total	*%*	*Valid, %*	
1	5/78	6.4	7.2	
2	12/78	15.4	17.4	
3	21/78	26.9	30.4	
4	19/78	24.4	27.5	
5	3/78	3.8	4.3	
6	3/78	3.8	4.3	
7	2/78	2.6	2.9	
8	4/78	5.1	5.8	
Total	69/78	88.5	100.0	
LRAG scores for chest				
	Mean	*Median*	*SD*	*Min-Max*
LRAG score	3.1	3.00	1.65	1.0 -7.0
	Frequency, no./total	*%*	*Valid, %*	
1	6/55	10.9	11.5	
2	19/55	34.5	36.5	
3	6/55	10.9	11.5	
4	10/55	18.2	19.2	
5	5/55	9.1	9.6	
6	4/55	7.3	7.7	
7	2/55	3.6	3.8	
8	0/55	0.0	0.0	
Total	52/55	94.5	100.0	

Abbreviations: Min, minimum; max, maximum.

low interobserver reliability in a recent study in which acne severity was graded at a distance via the examination of digital images using the LRAG system. Those authors also reported high reliability for the lesion count method. Our study, in contrast, showed agreement between lesion count performed by a dermatologist and severity assessed using the Spanish version of the LRAG scale. It also showed agreement between LRAG grades provided by dermatologists and an independent observer, demonstrating the reliability of the system. We also found the scale to be sensitive to changes in clinical and health status, which, in turn, were correlated with changes observed using the lesion count method.

The most recent systematic review of acne outcome measures[6] confirmed previous reports of a lack of standardization between different systems used to classify severity.[12] Acne grading systems based on photographic standards are widely used in the dermatology literature because they are practical and also because global outcome measures are considered primary outcome measures of treatment efficacy in clinical research settings, as they have greater clinical value than the lesion count method used in isolation.[3,13-16] Because of its level of accuracy and detail, the LRAG system is used not only to evaluate the clinical status of patients but also to compare results obtained using other photographic approaches.[17-19]

In the systematic review mentioned above, Barratt et al[6] stressed the existence of serious methodologic shortcomings in articles describing the use of new scales or the validation of existing ones, and explained that these shortcomings result in considerable variability in terms of the outcomes in clinical trials of acne treatment.

The Global Acne Grading System, which gives a score based on the number of lesions per surface area at different sites, has several disadvantages: its sensitivity has not been proven,

Table 3 Cross-Sectional Validity of the Leeds Revised Acne Grading (LRAG) Scale in Patients With Acne in Spain

Baseline Lesions and LRAG Scores (Nonparametric Correlations)		
	Baseline lesions	
	ICC	*P* Value
Face		
Inflammatory acne lesion score	0.32*	.050
Noninflammatory lesion score	0.26*	.012
Back		
Inflammatory lesion score	0.47**	.0001
Chest		
Inflammatory lesion score	0.57**	.0001

Abbreviation: ICC, intraclass correlation coefficient.
*$P<.05$.
**$P<.001$.

Table 4 Longitudinal Validity of the Leeds Revised Acne Grading (LRAG) Scale in Patients With Acne in Spain

Lesion count	Mean	SD	95% CI	*P* Value
Face				
Change, difference in No. of lesions at baseline and follow-up	14.53	14.62	[11.58-17.48]**	<.0001
LRAG scoring	*Mean*	*SD*	*Z-score*	P *Value*
Baseline, noninflammatory lesions	1.69	0.67	–2.773	.006
Follow-up, noninflammatory lesions	1.35	0.58		
Baseline, inflammatory lesions	5.21	2.52	–6.129**	<.0001
Follow-up, inflammatory lesions	3.15	1.77		
Back				
Change, difference in No. of lesions at baseline and follow-up	22.67	30.81	[14.34-31.00]**	<.0001
LRAG scoring	*Mean*	*SD*	*Z-score*	P *Value*
Baseline, inflammatory lesions	3.57	1.70	–5.652**	<.0001
Follow-up, inflammatory lesions	2.52	1.50		
Chest				
Change, difference in No. of lesions at baseline and follow-up	15.67	13.41	[11.20-20.14]**	<.0001
LRAG scoring	*Mean*	*SD*	*Z-score*	P *Value*
Baseline, noninflammatory lesions	3.18	1.55	–4.290**	<.0001
Follow-up, noninflammatory lesions	2.25	1.33		

Abbreviations: CI, confidence interval.
*P<.05.
**P<.001.

Table 5 Spearman Correlation Coefficients for Longitudinal Analysis of Reliability of Assessments With the Leeds Revised Acne Grading (LRAG) Scale in Patents With Acne in Spain

Spearman Correlation Coefficient	Between Baseline and Follow-up Assessment	
	ICC	*P* Value
Face		
Noninflammatory lesion score	0.35	.070
Inflammatory lesion score	0.47*	.000
Back		
Inflammatory lesion score	0.29**	.041
Chest		
Inflammatory lesion score	0.54*	.001

Abbreviation: ICC, intraclass correlation coefficient.
*P<.001.
**P<.05.

it is complex to implement, and it requires mathematical calculations. Another 2 systems, the Investigators' Global Assessment Scale (IGA) (which uses detailed descriptions of acne features instead of photographs to define different levels of severity) and the grading system proposed by Cook et al[3] (which also uses photographic standards) have

Table 6 Longitudinal Sensitivity of the Leeds Revised Acne Grading (LRAG) Scale in Patients With Acne in Spain[a]

	Mean	SD
Facial inflammatory lesions		
Baseline lesions	29.47	14.74*
Lesions at follow-up[a]	12.17	9.43
LRAG score difference	2.72	2.61**
Noninflammatory facial lesions		
Baseline lesions	18.11	14.24*
Lesions at follow-up[a]	6.85	7.62
LRAG score difference	0.51	0.84**
Back		
Baseline lesions	45.97	44.72*
Lesions at follow-up[a]	23.68	24.91
LRAG score difference	1.11	1.24**
Chest lesions		
Baseline lesions	27.48	19.99*
Lesions at follow-up[a]	12.06	12.73
LRAG difference	1.09	1.04*

Assessed by analysis of variance.
[a]Dependent variable.
*P<.001.
**P<.05.

been found to correlate poorly with the LRAG system when used by dermatologists with little training, making standardization difficult in clinical practice.[12] Our search of the literature published in Spain and other Spanish-speaking countries revealed no validation studies of visual acne grading systems, although we did find a Spanish study describing the development of a questionnaire assessing patient satisfaction with treatment of acne.[20] The Spanish version of the LRAG scale will thus now provide clinicians with a valid tool to assess acne severity in routine practice.

Conclusions

The Spanish version of the LRAG system is feasible, reliable, and sensitive and as such is a valid tool for objectively assessing acne severity in clinical practice.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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