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ORIGINAL ARTICLE

Factors affecting quality of life of asthma patients in Spain: The importance of patient education

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Abstract
Objectives: Assessment of demographic and clinical factors that have an impact on the quality of life (QoL) of patients with asthma in Spain.
Patients and methods: Multicenter, prospective, observational, cohort study, conducted in 40 Spanish Pneumology Units during a 12-month period. Data on sociodemographic, clinical variables, asthma treatment and QoL were collected in a case report form.
Results: 536 patients (64.6% women, mean age: 54) were recruited. Reported QoL was better for patients from Northern and Central Spain as compared with those from the South and the East ($p < 0.001$), students and employed patients as compared with housewives and unemployed ($p < 0.01$), for those who had received asthma information ($p < 0.01$), for those with milder daytime symptoms ($p < 0.01$) and for patients with higher level of education ($p < 0.05$).
Conclusions: Among the factors that have a significant effect on patients' QoL only symptom control and patient education on asthma control are modifiable. Therefore, all the strategies should be tailored to improve such factors when managing asthma patients.

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◊ The ASMACOST Study Group members are listed in Appendix A.

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Introduction

Asthma is a global health problem that affects around 300 million individuals of all ages, ethnic groups, and countries. It is estimated that 250,000 people die prematurely each year as a result of asthma.[1] In Spain, asthma prevalence ranges from 4.9% to 14.6% when the diagnostic criteria is based solely on the presence of symptoms indicative of disease, and from 2.4% to 4.7% when the presence of bronchial hyper-response is included for diagnosing.[2–5]

The pathogenesis of asthma involves the interplay of biological, social, and psychological factors.[6,7] Both educational and psychological interventions as a supplemental tool can help the pharmacologic management of asthma, although such interventions are often considered difficult to implement in daily clinical practice.[8]

In recent years we have seen an increased prevalence of asthma in the western world, with consequent rising burdens on health-related costs.[9,10] One action taken to deal with this problem has been to educate patients about their disease in order to promote self-management. Thus, asthma management studies have been shown to reduce the number of hospital admissions, days off work due to asthma exacerbations and improve symptom scores and inhalation techniques.[11–21] However, limited knowledge is currently available on the impact of different demographic and clinical factors on health-related quality of life (QoL).[8,13,17,22]

ASMACOST is an observational study whose main objective was to estimate the economic costs of the management of adult asthma patients in the context of daily clinical practice in Spain.[23] In addition among secondary aims included the assessment of demographic and clinical factors that have an impact on the QoL of patients with asthma in Spain.

Patients and methods

Study design

ASMACOST was a multicenter, prospective, observational, cohort study, conducted in 40 Spanish Pneumology Units. During the 12-month period of the study, 3 visits were scheduled at 0, 6 and 12 months, and data on sociodemographic, clinical variables, asthma treatment and quality of life were collected in a case report form.

Patients were required to give written informed consent before inclusion in the study. The study protocol was approved by the institutional review board of General Hospital of Vic (Barcelona, Spain), and the study was conducted in accordance with the principles of the Declaration of Helsinki.

Study population

Patient inclusion criteria

Adults patients diagnosed of asthma according to GINA criteria and adapted to the Spanish Asthma Management Guidelines, were included in the study.[24,25] Other inclusion criteria included the presence of stable disease (no exacerbations within the last four weeks that have required a change in treatment, that is, use of beta agonist whenever needed); absence of any physical, psychical or language limitation that prevented the correct completion of the case report form.

Patients' sample was stratified according to the following variables: severity of asthma disease: intermittent, mild persistent, moderate persistent; severe persistent; age group: 18–65 years; >65 years; geographical area: North (Galicia, Asturias, Cantabria, País Vasco and Navarra), East (Cataluña, Comunidad Valenciana, Baleares), Central (Rioja, Aragón, Castilla-León, Madrid, Castilla La Mancha), South (Andalucía, Extremadura, Canarias, Ceuta, Melilla).

Variables

Physician-reported

Among the clinical variables included: disease severity according to GEMA 2009 criteria (intermittent; mild persistent; moderate persistent and severe persistent)[25,27]; year since diagnosis; lung function [forced expiratory volume in 1 s (FEV_1) <60%; between 60% and 80% and >80%]; severity of diurnal and nocturnal symptoms and concomitant diseases.

Patient-reported

Socio-demographic data: Age, gender; educational level, job status and geographical distribution (regional location, habitat, size).
Asthma control information: Information received about asthma; participation in an asthma educational plan; asthma self-management.
Self-estimated health status question: Instrument that categorizes the responses using the Likert scale, from 1 (very good health) to 7 (very poor health).
QoL measurements: European Quality of Life-5 Dimensions (EQ-5D): Visual Analogue Scale (VAS); Juniper Mini Asthma Quality of Life Questionnaire (Mini-AQLQ)[26]: it is a validated 15-question, self-administered instrument where the questions are grouped into four domains: activity limitations (4 items), symptoms (5 items), emotional functions (3 items) and environmental stimuli (3 items). The questions are scored on a scale of 1–7 (where 1 is greatest impairment and 7 is least impairment) and grouped in a global score.

Statistical analysis

Sample size: The implementation of a stratified sampling, with a total of 32 strata and 35 patients per stratum, required a total sample of 1120 patients, with an expected follow up loss of 20%.[27,28]
Statistical analysis: For the description of continuous variables, the mean and standard deviation, the median and the interquartile range in the case of asymmetry and the maximum and minimum values observed were used. For the description of categorical variables, the number and percentage of patients per response category were used. The qualitative variables were compared using the chi-squared test and the quantitative variables using the t-Student test or variance analysis after study of variance homogeneity. A multivariate analysis using optimal scaling as regression procedure was also conducted.[29]

For the statistical analysis, the PASW Statistics package, version 18.0. A level of statistical significance of $p < 0.05$ was be used for all statistical tests performed.

Results

Sociodemographic and clinical characteristics

A total of 536 patients were recruited in 40 Pulmonology Units throughout Spain. The majority were women ($n = 346$, 64.6%) with a mean age of 54 years (SD = 17.8 years) and 38.7% were active workers at the time of the study. Approximately 60% of the participants had primary studies and most of them lived in urban (76%) and inland (61%) areas with more than 50,000 inhabitants (57.6%). Only 8% of the participants were current smokers (Table 1).

Approximately 68% of the patients were overweight (BMI $\geq 25\,kg/m^2$) and 75% of the patients had mild to moderate disease (21.6% intermittent; 23.7% mild and 28.2% moderate disease). In addition, in 45.5% of the patients the lung function was >80%. With regards to asthma diurnal symptoms, 31% of the patients did not have daily symptoms (24.2% less than once a week and 26.7% more than once a week but less than once a day), while the remaining had daily exacerbations (in 27.2% the exacerbations could affect activity and sleep and in 21.8% the exacerbations were recurrent). Asthma nocturnal symptoms were frequent in 21.4% of the patients, while the rest experienced infrequent exacerbations [less than twice a month (32.9%), more than twice a month (23%) or more than once a week (22.6%)]. Considering comorbidities, more than 40% of the patients had rhinitis (41.6%) and some degree of atopy (45.7%) (Table 2).

Table 1 Sociodemographic information.

1A) Demographic characteristics ($N = 536$)	
Age in years (mean, SD)	(54, 17.8)
Gender: *N* (%)	
Male/female	190 (35.4)/346 (64.6)
Years since diagnosis in years (mean, SD)	15.7 (14.0)
Job status: *N* (%)	
Active working	207 (38.7)
Unemployed	10 (1.9)
Retired/disabled	165 (30.8)
Housewife	134 (25)
Student	20 (3.7)
Educational level: *N* (%)	
Primary	309 (57.6)
Secondary	144 (26.9)
University	71 (13.2)
Smoking status: *N* (%)	
Non smoker	341 (63.6)
Former smoker	150 (28.0)
Current smoker	43 (8.0)
Geographical distribution: *N* (%)	
Regional location:	
Center	141 (26.3%)
East	198 (36.9%)
North	100 (18.7%)
South	97 (18.1%)
Habitat:	
Rural	129 (24.1%)
Urban	407 (75.9%)
Coast/inland:	
Coast	207 (38.6%)
Inland	326 (60.8%)
Size (inhabitants):	
<5000	86 (16.0%)
5000–50,000	141 (26.3%)
>50,000	309 (57.6%)

Table 2 Clinical characteristics.

Body mass index (BMI, kg/m²): N (%)	
BMI <25	167 (31.6%)
BMI: 25–29	222 (42.0%)
BMI ≥30	139 (26.3%)
Unknown	8 (1.5%)
Disease severity (GINA 2008/GEMA 2009) (N, %):	
Intermittent	116 (21.6)
Mild persistent	127 (23.7)
Moderate persistent	151 (28.2)
Severe persistent	142 (26.5)
Comorbidites (N, %):	
Rhinitis	223 (41.6)
Atopy(*)	245 (45.7)
Lung function (N, %):	
> 80%	244 (45.5)
Between 60–80%	146 (27.2)
<60%	115 (21.5)
Unknown	31 (5.8)
Asthma diurnal symptoms (N, %):	
<Once a week	130 (24.2%)
>Once a week and <once a day	143 (26.7%)
Daily; exacerbations may affect activity and sleep	146 (27.2%)
Daily; frequent exacerbations	117 (21.8%)
Asthma nocturnal symptoms (N, %):	
<Twice a month	169 (32.9%)
>Twice a month	118 (23.0%)
>Once a week	116 (22.6%)
Frequent	110 (21.4%)
Pulmonary function (N, %):	
FEV_1 or PEF ≥ 80% predicted, PEF or FEV_1 variability < 20%	146 (27.4%)
FEV_1 or PEF ≥ 80% predicted, PEF or FEV_1 variability 20–30%	118 (22.1%)
FEV_1 or PEF 60–80% predicted, PEF or FEV_1 variability > 30%	141 (26.4%)
FEV_1 or PEF ≤ 60% predicted, PEF or FEV_1 variability > 30%	128 (24.0%)

PEF, peak expiratory flow; FEV_1, forced expiratory volume in the first second; (*) Definition: patient with rhinitis and/or conjunctivitis and/or eczema/atopic dermatitis.

Asthma control information

Approximately 81% of the patients acknowledged to have received information regarding asthma control, being the most common source of information their assigned physician (general practitioner or pneumologist). Only 15% of the patients had participated in asthma control educational programs (ranging from 10% in intermittent asthma patients to 24% in severe asthma patients, $p = 0.005$). Most of the educational seminars took place in hospitals (84%). Approximately 56% of the patients had a written plan for asthma self management (from 46% in intermittent asthma to 67% in severe asthma, $p = 0.006$). General practitioners were the most common source for the asthma plan (82.0%) (Table 3).

Table 3 Patient information about asthma.

Information about asthma control (N, %):	
Yes	433 (80.8)
No	102 (19.0)
Unknown	1 (0.2)
Sources of information (n = 433):	
Media	10 (2.3)
Friends and family	3 (0.7)
General practitioner	382 (88.2)
Non-longitudinal physician	12 (2.8)
Internet	1 (0.2)
Associations	3 (0.7)
Others	22 (5.1)
Participation in an asthma educational programme:	
Yes	81 (15.1)
No	454 (84.7)
Unknown	1 (0.2)
Places (n = 81):	
Hospital	68 (84.0)
Tertiary care center	7 (8.6)
Primary care center	3 (3.7)
Associations	2 (2.5)
Others	1 (1.2)
Asthma self-management plan:	
Yes	300 (56.0)
No	235 (43.8)
Unknown	1 (0.2)
Source (n = 300):	
General practitioner	246 (82.0)
Educational program	20 (6.7)
Non-longitudinal physician	4 (1.3)
Others	27 (9.0)
Unknown	3 (1.0)

QoL measurements

The results of the three QoL questionnaires are summarized in Table 4.

Self-estimated health status: The percentage of patients that declared to have a bad status (from slightly bad to very bad) ranged from 1.7% in those with intermittent disease to 23.3% in those with severe persistent disease ($p < 0.001$).
EQ-5D: The mean VAS score ranged from 74.7 (mild persistent score) to 59.4 (severe persistent disease) ($p < 0.001$). As shown in Fig. 1, that summarizes the influence of the disease on patients' daily life, statistically significant differences were observed in all EQ-5D dimensions according to disease severity ($p \leq 0.003$).
Mini AQLQ: The mean global score ranged from 5.43 (mild persistent disease) to 4.26 (severe persistent disease), $p < 0.001$.

Table 4 Self-estimated health status and Mini-AQLQ questionnaire according to asthma severity.

	Intermittent ($n = 116$)	Mild persistent ($n = 129$)	Moderate persistent ($n = 150$)	Severe persistent ($n = 142$)	p-Value
Self-estimated health status (N, %)					<0.001
Very good	28 (24.1)	14 (10.9)	22 (14.7)	6 (4.2)	
Pretty good	59 (50.9)	64 (49.6)	42 (28)	34 (23.9)	
Slightly good	16 (13.8)	26 (20.2)	38 (25.3)	26 (18.3)	
Regular	11 (9.5)	21 (16.3)	33 (22)	43 (30.3)	
Slightly bad	0 (0)	2 (1.6)	9 (6)	16 (11.3)	
Pretty bad	2 (1.7)	1 (0.8)	6 (4)	14 (9.9)	
Very bad	0 (0)	1 (0.8)	0 (0)	3 (2.1)	
EQ-5D questionnaire (mean, SD):					<0.001
VAS	77.6 (17.2)	74.7 (14.9)	69.9 (16.8)	59.4 (20.0)	
Mini-AQLQ questionnaire (mean, SD):					<0.001
Global score	5.75 (0.96)	5.43 (0.97)	4.89 (1.17)	4.26 (1.29)	
Symptoms	5.75 (1.11)	5.37 (1.12)	4.90 (1.45)	4.31 (1.43)	
Environmental stimuli	5.12 (1.47)	4.92 (1.29)	4.48 (1.39)	3.83 (1.60)	
Emotional function	5.96 (1.34)	5.56 (1.37)	4.91 (1.62)	4.37 (1.77)	
Activity limitation	6.07 (1.06)	5.80 (1.02)	5.16 (1.27)	4.45 (1.41)	

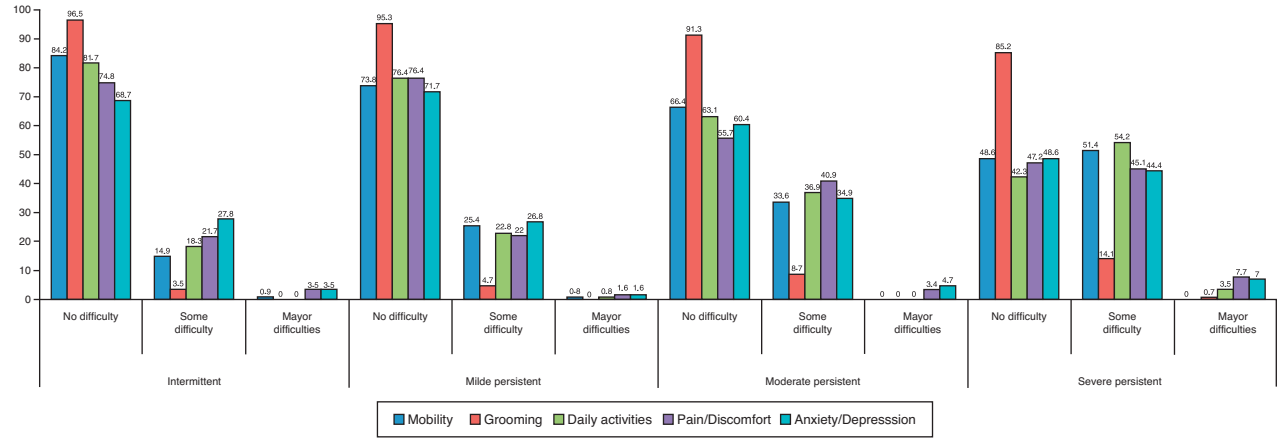

Figure 1 EQ-5D: Influence of the disease on patients' daily life.

Factors affecting QoL in asthma patients

Table 5 summarizes the variables with a significant effect on QoL of asthma patients (bivariate analysis). Those variables included geographical area and location, BMI, job status, educational level, information regarding asthma control, disease severity, including diurnal and nocturnal symptoms and finally pulmonary function. Patients with information about asthma presented a better QoL, quantified in the Mini-AQLQ total score, when compared with patients who had not received asthma education ($p = 0.012$). Significant differences in 'Symptoms' ($p = 0.001$) and 'Activities' ($p = 0.037$) domains were also reported.

Multivariate analysis

As per the final multivariate model (Table 6), with MiniAQLQ total score as dependent variable and after adjusting for all significant variables in the bivariate analysis, reported QoL was better for patients from Northern and Central Spain as compared with those from the South and the East ($p < 0.001$), students and employed patients as compared with housewives and unemployed ($p < 0.01$), for those who had received information about the disease compared with those who did not ($p < 0.01$), for those with milder daytime symptoms ($p < 0.01$) and for patients with higher education ($p < 0.05$). Regional location was a statistically significant factor related with all the domains of the Mini AQLQ. In addition, job status, information about asthma and diurnal symptoms were related with at least two domains of the instrument.

Discussion

Measuring quality of life has become an increasingly important dimension in assessing patient well-being as well as drug efficacy. Such measurement has gained popularity as a clinical outcome, reaching beyond measurement of physical health or functional status.[30] Quality of life studies are used to assess the impact experienced by patients in their daily lives due to their disease. In order to assess the global impact it is required to evaluate the disease impact on patients' life in general as well as the deterioration that is more related to their disease. Thus, the use of both generic (EQ-5D and self estimated health status) and disease-specific questionnaires (mini AQLQ) allows the assessment of the specific effect of a particular disease and also to compare it with other pathologies.

Although it cannot be assumed that all questionnaires measure the same thing, the results of the present study have shown a clear correlation between the results obtained with the more asthma-specific questionnaire when compared with two more generic questionnaires. In addition, the Mini-AQLQ questionnaire was able to discriminate QoL between asthma severity levels. As severity of symptoms is theoretically related to QoL, it is an indicator of construct validity of the instrument.

With regards to the factors affecting quality of life of asthmatic patients it has been shown that the place of residence (North Central better than South), more active life (students and employed persons vs. house wives and unemployed), better asthma control (milder daytime symptoms) and knowledge about the disease (those who had received information vs. those who had not) improves the quality of life of asthma patients. According to our observations, a recent prospective study concludes that increased lifestyle physical activity was associated with improved in asthma quality of life.[31] Likewise, obesity contributes to a deterioration in quality of life and a recent research shows that the Mediterranean diet can help improve the quality of life of asthmatics.[32]

It is clear that the only two factors that can be easily modified are the management of the disease as well as patient education. With regards to disease control, the goal of asthma treatment, as stated in GINA guidelines, and regardless of patient's asthma severity, should lead to achievement of complete disease control without, or with minimal, symptoms, both during day and night, without limitation of activities (including physical activities), with little or no need for rescue medication, lung function to near normal and no exacerbations.[24,33]

The second factor includes educational interventions. It has been demonstrated that educational and psychological counselling improves the quality of life and enhances patient's understanding of this chronic disease.[8] However, such strategy has not been successful in other chronic

Table 5 Variables influencing QoL (Mini-AQLQ questionnaire) of asthma patients.

Variables	*N*	Mean	SD	*p*-Value
Body mass index (BMI, kg/m²)				
Normal weight	167	5.30	1.20	
Overweight	222	5.00	1.22	0.004
Obese	139	4.84	1.30	
Job status				
Employee	207	5.31	1.19	
Retired	165	4.89	1.15	
Unemployed	10	4.39	1.64	<0.005
Student	20	5.41	1.00	
Housewife	134	4.81	1.36	
Educational level				
Primary	309	4.82	1.27	
Secondary	144	5.26	1.11	<0.005
Higher education	71	5.50	1.17	
Geographic situation				
Coast	207	4.83	1.35	0.003
Inland	326	5.17	1.16	
Area				
North	141	5.56	1.02	
East	198	4.91	1.27	<0.005
Central	100	5.04	1.16	
South	97	4.56	1.33	
Information about Asthma control				
No	102	4.76	1.20	0.012
Yes	433	5.11	1.25	
Disease severity				
Intermittent	116	5.75	0.96	
Mild persistent	127	5.43	0.97	<0.005
Moderate persistent	151	4.89	1.17	
Severe persistent	142	4.26	1.29	
Diurnal symptoms				
Intermittent	130	5.74	0.95	
Mild persistent	141	5.37	0.96	<0.005
Moderate persistent	147	4.80	1.18	
Severe persistent	117	4.16	1.34	
Nocturnal symptom				
Intermittent	169	5.55	1.04	
Mild persistent	116	5.33	0.94	<0.005
Moderate persistent	117	4.85	1.19	
Severe persistent	110	4.12	1.34	
Pulmonary function				
Intermittent	146	5.60	1.04	
Mild persistent	116	5.37	1.00	<0.005
Moderate persistent	142	4.89	1.18	
Severe persistent	128	4.28	1.30	

pulmonary pathologies such as chronic obstructive pulmonary disease. Thus, the study by Gallefos et al., that examined the influence of an educational program on QoL after 12 months of follow up in patients with COPD and asthma showed an improvement in QoL and FEV_1 only in asthmatic patients measured by the St George's Respiratory Questionnaire, as well as an associated increase in FEV_1.[22] Recently Saito et al.,[34] show that asthma education may be useful to achieve stable control. Despite all this evidence, our article also highlights the few people who follow asthma education plans in Spain and should plan strategies in this respect is.

Table 6 Multivariate analysis. Regression coefficients on Mini-AQLQ scores.

Mini AQLQ	Total		Symptoms		Environment		Emotions		Activities	
	β	*p*	β	*p*	β	*p*	β	*p*	β	*p*
Zone	0.19	**0.000**	0.22	**0.000**	0.13	**0.011**	0.25	**0.000**	0.12	**0.000**
Age	−0.08	0.205	−0.02	0.733	−0.10	0.369			−0.18	**0.006**
Gender									0.13	**0.002**
BMI	0.005	0.917	0.02	0.669					−0.02	0.636
Coast/inland	0.02	0.525	0.02	0.479	0.04	0.532	0.03	0.428	0.07	0.093
Job status	0.09	**0.002**	0.10	**0.000**	0.12	**0.004**			0.05	0.223
Education level	0.09	0.056	0.11	**0.006**	−0.04	0.728			0.08	0.120
Smoking status					0.16	**0.036**				
Information about asthma	0.11	**0.005**	0.14	**0.001**					0.08	**0.041**
Asthma self-management plan					0.04	0.483				
Diurnal symptoms	−0.31	**0.001**	−0.29	**0.000**	−0.08	0.769	−0.25	**0.016**	−0.36	**0.000**
Nocturnal symptoms	−0.18	0.221	−0.22	**0.014**	−0.12	0.847	−0.12	0.443	−0.18	0.243
Pulmonari function	−0.02	0.818	0.08	0.487	−0.12	0.506	−0.03	0.817	0.06	0.613
Multiple *R*	0.56		0.52		0.41		0.45		0.56	
R squared	0.31		0.27		0.16		0.20		0.32	
Adjusted *R* squared	0.29		0.24		0.08		0.19		0.29	
DF	17		19		18		9		19	
Significance	**0.000**		**0.000**		**0.008**		**0.000**		**0.000**	

With regards to the limitations of the study, it is important to note the method used for patient selection. First, a probabilistic method was not used for patient inclusion, but rather the first patients who came to the consultation and met the inclusion criteria were selected. Second, due to the sampling technique used, stratified sampling, to be able to determine the variables with heavier effect on QoL, it is not possible to analyze the clinical characteristics of the general Spanish population of asthmatic patients.

In conclusion, only some factors that have a significant effect on patients' QoL, such as symptom control and patient education on asthma control, are modifiable and therefore great effort should be tailored to improve such factors when managing asthma patients.[35,36]

Ethical disclosures

Protection of human subjects and animals in research. The authors declare that no experiments were performed on humans or animals for this investigation.

Confidentiality of data. The authors declare that they have followed the protocols of their work centre on the publication of patient data and that all the patients included in the study have received sufficient information and have given their informed consent in writing to participate in that study.

Right to privacy and informed consent. The authors declare that no patient data appears in this article.

Conflict of interest

The authors have declared no conflicts of interest.

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Appendix A. List of researchers participating in the ASMACOST Study Group

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