

Objective

The Asthma Life Impact Scale (ALIS)¹ is a disease-specific measure used to assess the quality of life of people with Asthma. It was developed in parallel in the UK and US and has proven to be acceptable to patients, to have good psychometric properties and to be unidimensional.

Aim

The objective of this study was to produce and validate Italian and Russian versions of the ALIS.

Methods

Three main stages were involved in the adaptation process:

Translation

- The dual-panel process² was adopted to translate the ALIS. This method produces translations that are more acceptable to patients.
- Two translation panels were conducted consecutively in each country; a "bilingual" panel and a "lay" panel.
- Bilingual panel participants are fluent in both English and the target language.
- Lay panel members have average to low education and check the level of language to ensure its suitability for use with future respondents.

Cognitive debriefing interviews

- Face and content validity of the new versions of the ALIS was assessed by cognitive debriefing interviews with asthma patients in each country.

Validation Survey

- Test-retest surveys (two administrations, two-weeks apart) were conducted in each country to assess the psychometric properties of the new language versions. Assessments included internal consistency, test-retest reliability (reproducibility), convergent validity (with the Nottingham Health Profile (NHP)³) and known groups validity related to self-perceived general health, asthma severity and clinician rating of asthma severity for Russia only.
- Spirometry values of forced expiratory volume (FEV1) and peak expiratory flow (PEF) were available for the Russian adaptation.

Results

Translation

- Bilingual panels in both countries had little difficulty providing conceptually equivalent translations.
- Minor changes in wording were made following the lay panel to improve the register of language.

Cognitive debriefing interviews

- Interviews conducted in Italy (n=15) and Russia (n=9) indicated that the new language versions were easy to complete and had appropriate content.

Validation

Demographic details of the validation survey samples are shown in Table 1.

Table 1: Demographic details for validation survey

Country (n)	Gender	Age (years)	Asthma
			Duration (years)
	Female n (%)	Mean (SD)	Mean (SD)
Italy (61)	34 (55.7)	40.7 (15.4)	16.3 (10.0)
Russia (71)	40 (56.3)	49.5 (14.6)	16.7 (8.6)

- Mean scores (SD) for the Italian and Russian adaptations were 5.8 (5.4) and 8.3 (5.7) respectively (maximum possible = 22, indicating poor QoL).

Internal consistency and test-retest reliability:

- Both new versions had good internal consistency and test-retest reliability (Table 2).

Convergent validity (Figure 1):

- ALIS scores correlated highest with energy level and the NHP-Distress scale.
- ALIS scores correlated -0.35 with %FEV1 and -0.40 with %PEF. These were statistically significant (p<0.01).

Known groups validity (Figures 2-4):

- Scores were significantly (p<.05) related to:
 - Patient-rated asthma severity (both countries),
 - Clinician-rated asthma severity (Russian sample),
 - Patient-rated general health (both countries)
 - Spirometry assessments (Russian sample).

Figure 1: Mean correlation coefficients by NHP scales (Italy)

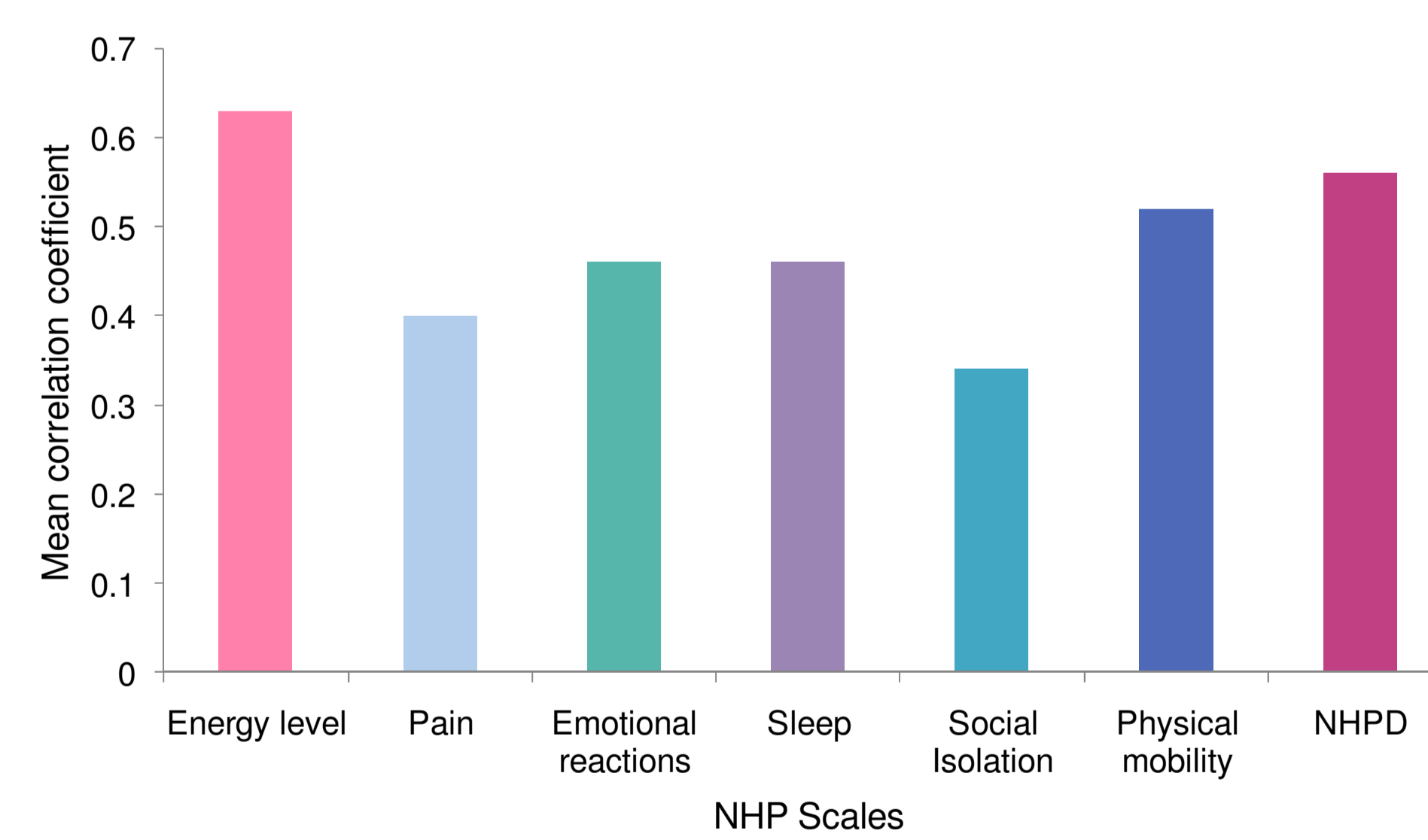


Figure 2: Mean ALIS scores by Asthma severity ratings

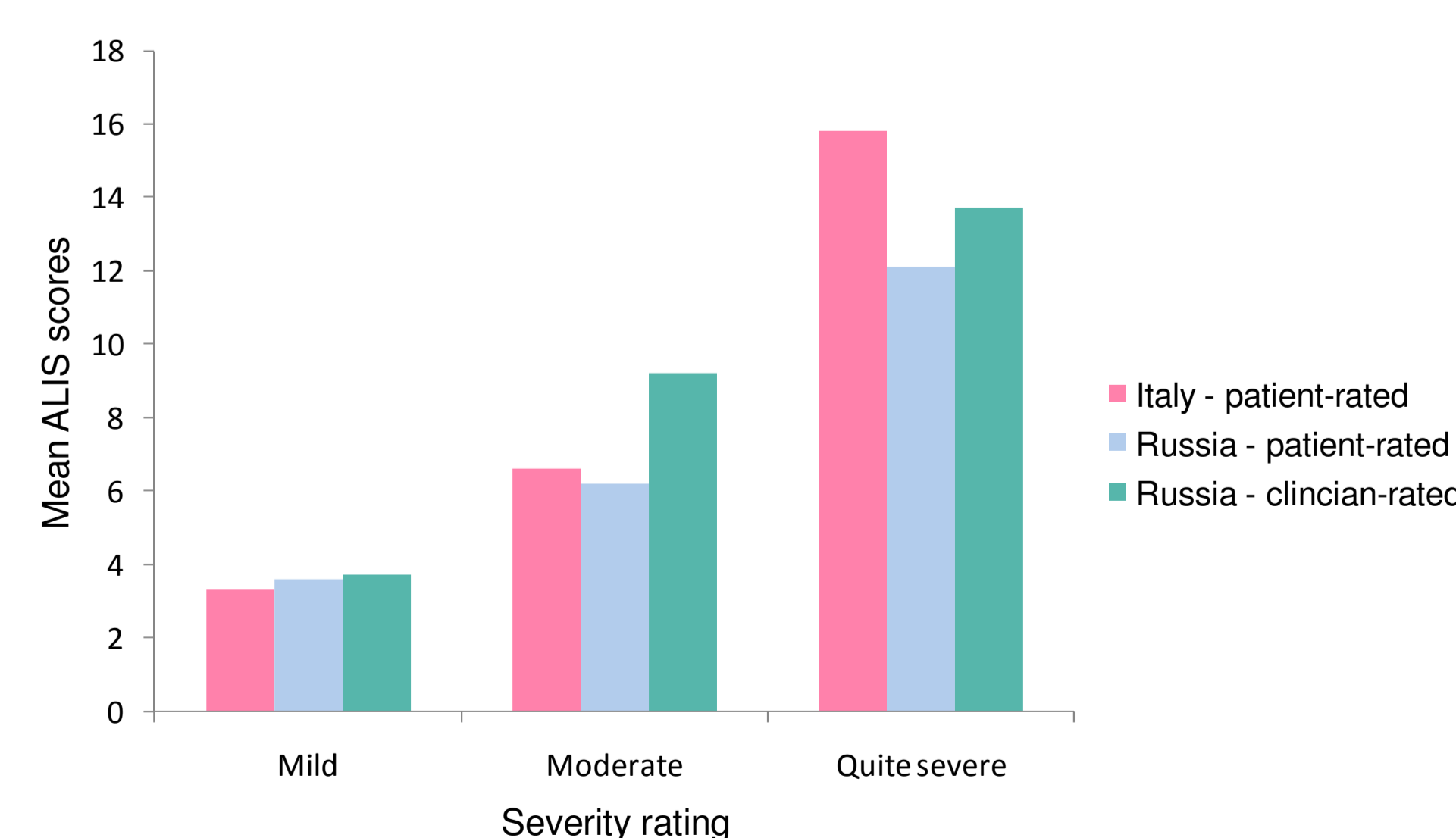


Table 2: Internal consistency and test-retest reliability scores

Country (n)	Internal Consistency	Test-retest reliability
Italy (59)	0.92	0.86
Russia (65)	0.92	0.94

Figure 3: Mean ALIS scores by general health ratings

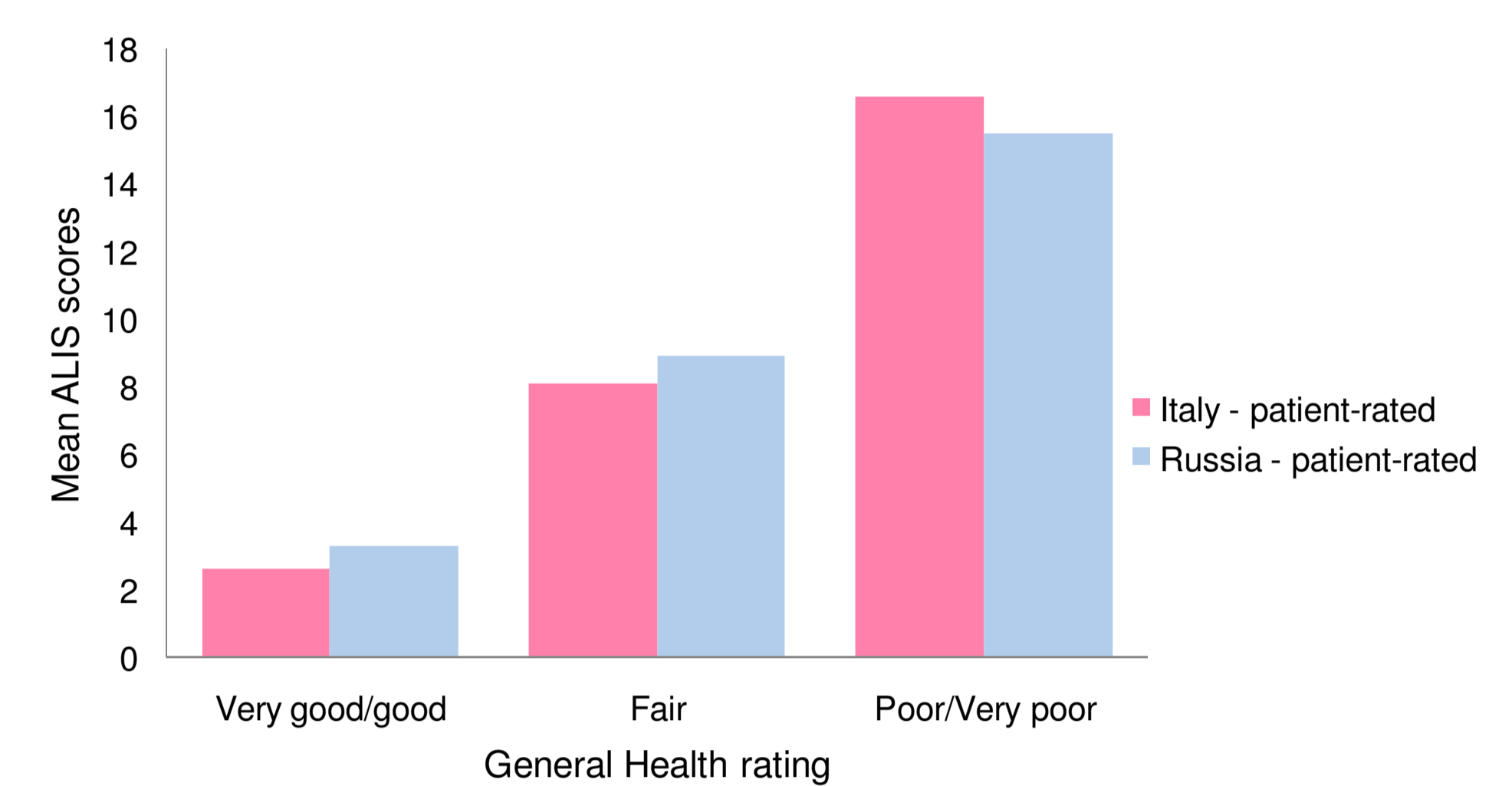
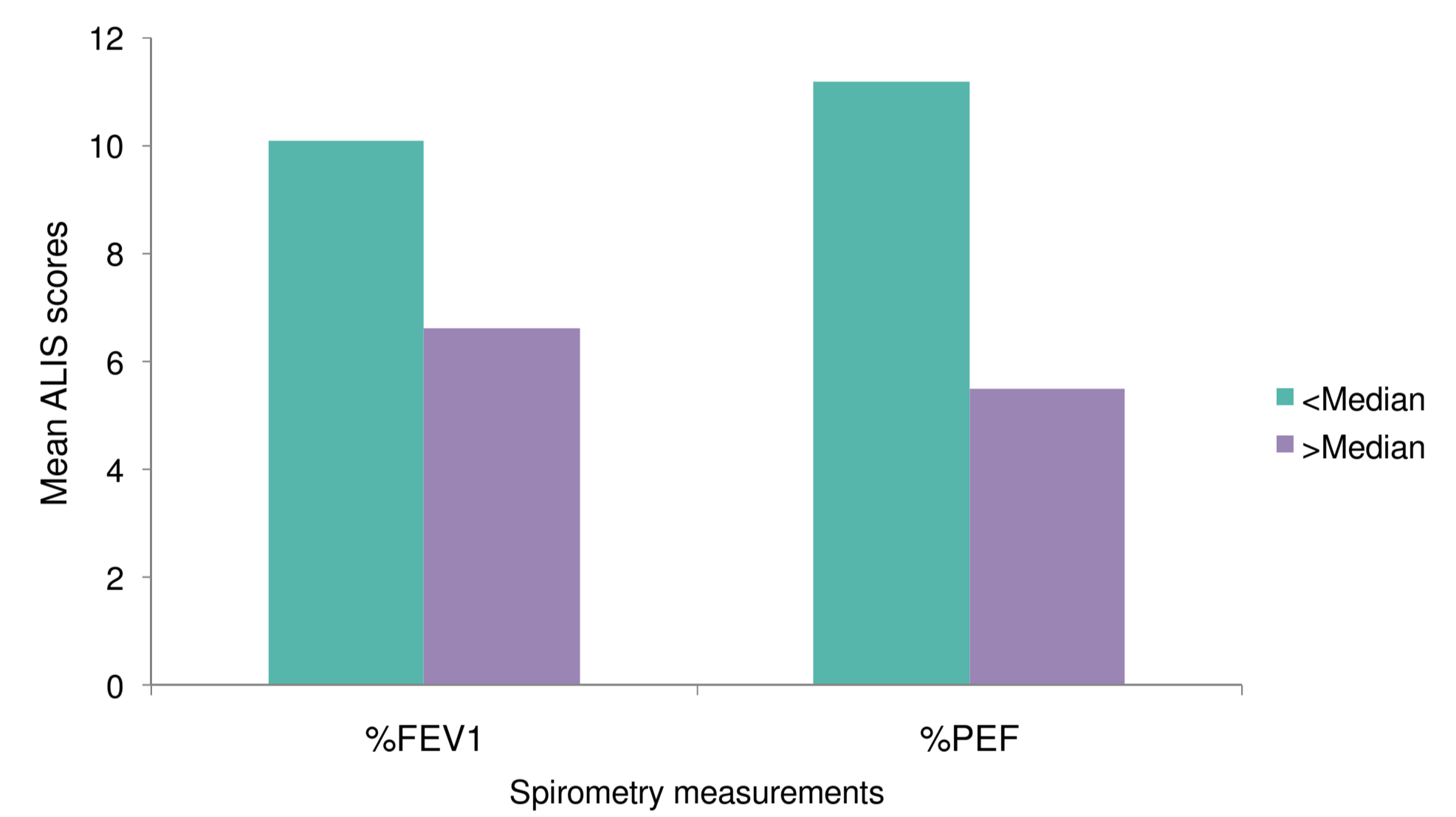


Figure 4: Mean ALIS scores by %FEV1 and %PEF (Russia)



Conclusions

The adaptation and validation of the ALIS into both Italian and Russian was successfully accomplished.

Both the Italian and Russian adaptations demonstrated good reproducibility and construct validity.

The new adaptations represent valid and reliable tools for measuring QoL in international clinical trials and for use in routine clinical practice.

They join a growing list of language versions available for use in multi-national clinical trials (see Table 3).

Table 3: ALIS Language Availability

UK (English)	Germany (German)*
USA (English)	Italy (Italian)
Belgium (Flemish)*	Netherlands (Dutch)*
Belgium (French)*	Russia (Russian)
Canada (English)*	Spain (Spanish)*
Canada (French)*	Sweden (Swedish)*
Denmark (Danish)*	Turkey (Turkish)*
France (French)*	USA (Spanish)*

*If you are interested in further validating these versions please contact Galen Research Ltd using the details below.

References

- [1] Meads DM, McKenna SP, Doward LC, Pokrzywinski R, Revicki D, Hunter C, Glendenning GA. Development and Validation of the Asthma Life Impact Scale (ALIS). *Respir Med* 2010; 104: 633-43. [2] Hunt SM, Alonso J, Buquet D, Niero M, Wiklund I, McKenna SP. Cross-cultural adaptation of health measures. *Health Policy*. 1991; 19: 33-44. [3] Hunt SM, McEwen J, McKenna SP. Measuring health status: a new tool for clinicians and epidemiologists. *J R Coll Gen Pract* 1985; 35:185-8.

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Sponsorship

This project was supported by Novartis AG.