Author’s response to reviews

Title: Use of the Italian version of the Pediatric Asthma Quality of Life Questionnaire in the daily practice: results of a prospective study.

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Author’s response to reviews: see over
Dear Editor,

Thank you for considering our manuscript. The corrections that we made to our manuscript are in red colour in order to make it easier to identify them. Here are our replies to the reviewers’ comments, I hope you will be satisfied with our answers.

First reviewer:

Major comments

First of all the presentation of the results of the PAQLQ should be given for the total score and then by domains but not by questions. (tables 3 are useless).

I agree with you on the matter that table 3 is redundant. We changed it with a new table that includes PAQLQ total score and the score of each domain.

PAQLQ although not perfectly normally distributed is usually analysed as a continuous variable.

Even if psychometric scores are often treated as continuous variables, in this paper some other measures were not normally distributed. This is the reason why we liked it better to analyze those data by non parametric tests. At time 0, FVC measures distribution had Skewness=-.4885548 and Kurtosis=3.509792, FEV1 had Skewness=-.9348208 and Kurt.=3.771807, FEV1/FVC had Skewness=-1.132227 and Kurt.=3.877487, FEF25-75 had Skewness=.0074148 and Kurt.=3.128955, QOL had Skewness=-1.484483 and Kurt.=4.673699. At time 1, FVC had Skewness=-.0915008 and Kurtosis=3.949216, FEV1 had Skewness=-.2045159 and Kurtosis=2.558802, FEV1/FVC had Skewness=-.6682507 and Kurtosis=2.548404, FEF25-75 had Skewness=-.0626528 and Kurtosis=2.121785 and QOL had Skewness=-2.367228 and Kurtosis=11.35312

If one wants to examine the interest of such an evaluation of HRQL, the analysis should be separate in 2 steps:

- first of all to understand the construct validity of the PAQLQ by studying the relationships between the questionnaire, its different domains (and not each question) and different items such as asthma severity, asthma control, seasonal or perennial asthma and respiratory function. This should be based on correlation analysis. Because the authors have data twice for each child included in the study, the analysis could be based on the entire data set, but with specific analysis taking into account the dependence between observations from the same patients, for example by regression mixed models, with generalized estimation equations. Therefore results from both tables 4 would be shown on only one analysis.
Performing a factorial analysis with our data, we did not identify the same factors that usually are released by some other authors in German or Anglosaxon children. So we preferred to avoid the presentation of data of classical domains of this questionnaire at any rate their means or medians did not change from time0 to time1 as you can see in table 3 (we are carrying out further investigation to understand if this is a phenomenon due to the small sample or if it is due to some cultural differences)

We didn’t expose data of regression mixed models with generalized estimation equations both because they were not s.s. and because of the limited power of this study (n=52)

- Secondly to study the responsiveness of the PAQLQ between the 2 evaluations. This should be done by comparing the evolution of the PAQLQ scores and changes in asthma severity, asthma control and respiratory function on paired data. This analysis has not been performed formally by the authors. In this respect, it would be useful to know in details what medications changes have been prescribed between the 2 visits.

A paragraph concerning the evolution of the PAQLQ score and changes in the other parameters was added in the “Results” section, as well as an explanation of the medications used.

Regarding the clinical outcomes used to compare the PAQLQ, the authors assessed asthma severity according to the 2006 GINA guidelines. These recommendations should be applied to children who do not use long term treatment. However it seems that this classification has been used for all children even those already treated.

We were actually inaccurate about this point: asthma severity was assessed according to the 2005 GINA guidelines, where a classification is proposed of asthma severity according to the daily medication regimen (page 76).

Page 9, second paragraph: “HRQL improves when pulmonary function is better” should be modified because this relates to a cross sectional analysis: HRQL is better when the respiratory function is higher.

The sentence has been corrected as suggested.

I do not agree with the conclusion of the authors regarding the different relationships between FEV1 and PAQLQ scores in the 2 surveys: this has probably nothing to do with better completion of
the questionnaire.

The relationship might actually have nothing to do with better completion of the questionnaire so we preferred to eliminate the sentences about this point.

The results of the correlations between PAQLQ scores and asthma control are not well shown in the results section: PAQLQ scores of the controlled and not controlled population should be given.

Two figures have been added (called 1a and 1b) that show the relationship between PAQLQ score and asthma control.

Besides, we added a figure (fig. 2) that shows the relationship between asthma severity and the PAQLQ score. We have also analyzed the relationship between lung function and HRQL in function of stable and unstable asthma severity. This part was added in the “Results” section.

Level of interest: An article of limited interest

Quality of written English: Needs some language corrections before being published

The revised version of the article was corrected by an native English-speaking person before submission.

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
'I declare that I have no competing interests'

Second reviewer

Reviewer’s report:

1/ No major compulsory revisions
2/ No minor essential revisions
3/ Discretionary revisions

5th page, last paragraph: According to GINA 2006 the control of asthma means that the patient has not more than two asthmatic complaints and not more beta agonist need than twice during one week. The authors speak about two weeks. Of course the patients having less complaints than the GINA guideline allows,
this means a good control of the disease.

We preferred to consider asthma control over 2 weeks even if the GINA guidelines only consider one week.

Table 1. and 6th page, 4th paragraph: If the children's age is 6-17 years, than the question arises: Six year old children can not read and can not write - how is it possible to fill out themselves the questionnaire.

For the younger patients, there was a longer explanation and some kind of assistance by a doctor or nurse, but no help by the parents in the replies. There was actually only one child aged 6 years (already going to school) and three children aged 7, all the others were older. These considerations were added in the text in the section “Results – Understanding of the PAQLQ”.

8th page 3rd and 4th paragraph, 9th page, 1st paragraph: The difference between the first and second examination (6 months) may be in connection with the pollen season. It would be nice to give the data about pollen sensitivity, and seasonal correlation to clear the contradiction.

The pollen season might explain part of the measured differences identified between the 1st and 2nd visit, however the two groups (seasonal and non-seasonal asthma) were too small to analyze the role of allergies in this study. By the way, this is an interesting point that we are willing to analyze by collecting more data.

9th page, 3rd paragraph: Several versions of the questionnaire exist.... What kind of recent versions are used in the questionnaires found in Italy.

This unclear sentence was corrected in the text, in fact only one Italian version exists as far as we know, whereas the PAQLQ was translated in several languages.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests
**Ethics:**

This study was only observational and did not interfere with the clinical management of the patients, so we did not submit it to our ethical committee for approval. However, both the parents and the patients were informed that the questionnaire was proposed in an experimental manner; they were given the questionnaire only after signing a consent for both the study and the treatment of personal data for the privacy.

**Abstract:**

The abstract was re-structured according to your indications.

Looking forward to hearing for your reply,

Kindest regards

Giampaolo Ricci

On behalf of the other authors