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*Published in:*  
Annals of Allergy, Asthma and Immunology

*DOI:*  
[10.1016/j.anai.2017.12.026](https://doi.org/10.1016/j.anai.2017.12.026)

*Publication date:*  
2018

*Licence:*  
CC BY-NC-ND

*Document Version*  
Peer reviewed version

[Link to publication in Discovery Research Portal](#)

*Citation for published version (APA):*  
Jabbal, S., & Lipworth, B. (2018). Does the asthma visual analogue scale relate to the asthma control questionnaire? *Annals of Allergy, Asthma and Immunology*, 120(5), 533-535.  
<https://doi.org/10.1016/j.anai.2017.12.026>

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Elsevier Editorial System(tm) for Annals of  
Allergy, Asthma & Immunology  
Manuscript Draft

Manuscript Number: 17-11-0589R2

Title: Does the asthma visual analogue scale relate to the asthma control questionnaire?

Article Type: Letters

Keywords: Asthma; VAS; Visual Analogue Scale; ACQ; Asthma Control Questionnaire

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Order of Authors: Sunny Jabbal, Mb ChB; Brian J Lipworth, MD

Suggested Reviewers:

Opposed Reviewers:

Response to Reviewers: We thank you for the final review of our manuscript. We have duly acknowledged the last suggestion and changed the manuscript accordingly.

**Does the asthma visual analogue scale relate to the asthma control questionnaire?**

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**Declaration of funding:** Existing departmental funds

**Word count:** 1066

Both authors have made substantial contributions to the acquisition, analysis and interpretation of data, drafting the article, and give final approval of the version to be submitted.

1 Control based asthma management, comprising a continuous cycle of assessment,  
2 adjustment, and review of treatment response, is recommended by the Global Initiative for  
3 Asthma (GINA) guidelines (1). Objective measurement and documentation of asthma control  
4 in UK clinical practice is often poor. In the National Review of Asthma Deaths (UK), of the  
5 69% of patients who had an asthma review before their death, only 27% had any formal  
6 assessment of asthma control (2). Therefore, having a simple, but effective tool to detect  
7 changing severity of asthma is important.

8 The Asthma Control Questionnaire (ACQ-6), is a widely used and well validated non-binary  
9 metric which strongly predicts future exacerbations(3). It demarcates between controlled (C),  
10 partially controlled (P), and uncontrolled (U), based on cut point scores of  $<0.75$ ,  $\geq 0.75 < 1.5$ ,  
11 and  $\geq 1.5$  respectively (4). The asthma visual analogue scale (VAS) is a 10cm continuum  
12 indicating the overall symptom burden (5), and can be patient or physician administered. It  
13 has been demonstrated, in a large Japanese population to discriminate between GINA defined  
14 categories of C, P and U as  $<1.5\text{cm}$ ,  $\geq 1.5 < 7.19\text{cm}$ , and  $\geq 7.19\text{cm}$  respectively (5). VAS has  
15 also been shown to be effective in adolescents at detecting changes in asthma symptoms  
16 reflecting more detailed multi-item asthma diaries (6). We have evaluated for the first time  
17 whether VAS correlates to ACQ-6, and if the predefined GINA cut points relates to ACQ-6  
18 defined levels of control.

19 We retrospectively analysed  $n=84$  patients who volunteered for asthma screening into clinical  
20 trials at the Scottish Centre for Respiratory Research. All patients gave written informed  
21 consent for their anonymised screening data to be used. Patients had to have a physician  
22 based asthma diagnosis for at least three months before attending screening, and be free from  
23 an asthma exacerbation requiring steroids for 3 months prior to screening. Patients completed  
24 basic spirometry (Micromedical, Chatham, U.K.), exhaled nitric oxide (FeNO, NIOX MINO,  
25 Circassia Ltd, UK) had their medical history and concomitant medications recorded, and

26 completed both ACQ-6 (Qoltech Ltd), and VAS questionnaires. As per Ohta et al. patients  
27 were asked to perform the VAS, and ~~As per Ohta et al. patients were asked to~~ “pPut a mark  
28 on the line below to indicate how much your symptoms bother you?”, with a 0-10cm line  
29 presented to the patient, 0cm= “not at all bothersome”, and 10cm= “extremely bothersome”  
30 (5).

31 The average age of patients was 52 years, and 90% of patients were receiving inhaled  
32 corticosteroids (ICS) with a mean beclometasone dipropionate (BDP) equivalent dose of  
33 675µg/day. Of those on ICS 80% received a long acting beta-2 agonist (LABA) as a  
34 combination inhaler (ICS/LABA), 42% of those receiving ICS also received concomitant  
35 leukotriene receptor antagonist (LTRA), mean FeNO was 45ppb, mean forced expiratory  
36 volume in 1 second (FEV1) was 89% predicted; 63% of patients had a positive skin prick  
37 test, with the mean number of positive skin prick tests being 2.

38 VAS correlated with ACQ-6, overall Spearman’s correlation was 0.62,  $P < 0.001$ . Mean VAS  
39 levels for ACQ were: C ( $< 0.75$ ): 2.2cm (95% CI 1.35-3.06), P ( $\geq 0.75 < 1.5$ ): 2.56cm (95% CI  
40 2.61-4.50), U ( $\geq 1.5$ ): 5.27cm (95% CI 4.46-6.08) (Figure 1). VAS did not correlate ( $r_s = 0.08$ ,  
41  $p = \text{NS}$ ) with FeNO, or FEV<sub>1</sub> % predicted ( $r = -0.18$ ,  $p = \text{NS}$ ).

42 Between group differences for mean values comparing GINA defined VAS categories of C  
43 ( $n = 22$ ) vs P/U ( $n = 62$ ) showed a significant difference for ACQ: 0.57 vs 1.73 ( $p < 0.0005$ ), but  
44 not FEV1: 89% vs 89%, or FeNO: 32ppb vs 30ppb.

45 Between group differences for mean values comparing ACQ defined categories of C ( $n = 27$ )  
46 vs P/U ( $n = 57$ ) showed no significant difference for: FEV1: 91% vs 88% or FeNO 29ppb vs  
47 36ppb. ACQ score also did not correlate to FeNO ( $r = -0.06$ ,  $p = \text{NS}$ ).

48 Receiver operator curve analysis, using ACQ to compare C vs U/P revealed an optimal cut  
49 point for VAS of 1.95cm (AUC 0.8, sensitivity 88%, specificity 68%), comparing C vs U

50 revealed a VAS cut point of 3.5cm (AUC 0.7, sensitivity 66%, specificity 61%). Furthermore  
51 the GINA defined cut point of  $\geq 7.19$ cm was associated with a sensitivity of 26% and  
52 specificity of 91%.

53 Our data showed that VAS correlated with the overall ACQ-6 score, however the VAS cut  
54 points used to determine GINA defined control were not tailored to ACQ. The mean VAS of  
55 5.27 (95% CI 4.46-6.08) for patients with an  $ACQ \geq 1.5$  was not only lower than the 7.19cm  
56 GINA cut point, but also the ROC suggested that a much lower VAS value ( $\geq 3.5$ cm) would  
57 optimally identify such patients. The corollary is that patients with a  $VAS \geq 3.5$ cm, should  
58 warrant further enquiry into their asthma control (e.g. using ACQ), and that VAS may only  
59 be considered a quick screening tool in a busy clinic. Furthermore VAS is sensitive to  
60 bronchodilation (7) and can be repeated daily (6). The benefit of a daily symptom score such  
61 as VAS is that it may obviate recollection errors from retrospective questionnaires (8),  
62 furthermore, in adolescents, asthma VAS has been evidenced as predictive of future asthma  
63 control at 6 months (6).

64 The failure of VAS to correlate with  $FEV_1$  % predicted corresponds with data from primary  
65 care, where VAS did not correlate to peak expiratory flow (9), suggesting that a proportion of  
66 asthmatics do not reliably detect changes in their lung function. This has been evidenced  
67 previously in the context of acute bronchoconstriction (10).

68 We acknowledge our study has limitations. Firstly, the sample size is small, and from a single  
69 site, therefore it may not represent the general asthma population. Secondly this was a  
70 retrospective analysis, which found that VAS cut points correlating to GINA defined asthma  
71 control were not the most suitable for ACQ defined asthma control. The VAS cut points  
72 assessed in our study, were from a large cross sectional Japanese population. However, it  
73 cannot be assumed that these cut points are generalizable to other regions. A prospective

74 study with a larger sample size, using the lower cut points derived from our ROC analysis  
75 would further clarify how sensitive VAS is at detecting levels of ACQ asthma control of C, P,  
76 U. Finally, the VAS is a snapshot of current control, whereas the ACQ is reflective of the  
77 previous week.

78 We conclude that the GINA defined VAS cut off ( $\geq 7.19$ cm) is a poor predictor of control in  
79 relation to an  $ACQ \geq 1.5$ . Hence, further evaluation is required to define the VAS threshold in  
80 relation to control defined by ACQ rather than GINA, and also whether a decline in VAS  
81 correlates to a decline in ACQ, as change in control is arguably more important as current  
82 level.

83

84

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Figure 1.

Distribution of ACQ control categories relative to VAS levels. Vertical lines represent GINA defined cut points of control (1.5cm) and uncontrolled (7.19cm) asthma.

Figure 1  
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