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The correlation between asthma control and health status: the GOAL study

Eric D Bateman,[1] Jean Bousquet,[2] Martin L Keech[3], William W Busse,[4] Tim JH Clark,[5] Søren E Pedersen,[6] on behalf of the GOAL Investigators Group[*]

[*]List of investigators supplied separately

[1]University of Cape Town, Cape Town, South Africa; [2]Hôpital Arnaud de Villeneuve, Montpellier, France; [3]GlaxoSmithKline, Greenford, UK; [4]University of Wisconsin Medical School, Madison, WI, USA; [5]Imperial College, London, UK; [6]University of Southern Denmark, Kolding Hospital, Kolding, Denmark

Correspondence to: Professor Eric D Bateman, UCT Lung Institute, PO Box 34560, Groote Schuur 7937, Cape Town, South Africa

Tel: +27 214 066 900; Fax: +27 214 066 902

(E-mail: ebateman@uctgsh1.uct.ac.za)

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Abstract

This study examined the association between guideline-derived asthma control and health-related quality of life (HRQoL), assessed using the Asthma Quality of Life Questionnaire (AQLQ), in patients with uncontrolled asthma whose treatment was directed toward achieving the highest possible level of control.

This randomised, double-blind, parallel-group study compared the efficacy of fluticasone propionate (FP) and salmeterol/fluticasone (SFC) in achieving two composite, guideline-derived measures of control — Total Control (TC) and Well-Controlled (WC) asthma. Not achieving these levels was classed as Not-Well Controlled (NWC). Doses were stepped up until patients achieved TC or reached maximum dose. This dose was maintained for the remainder of the study. AQLQ was assessed at baseline and each clinic visit.

AQLQ scores improved throughout the study, reaching near maximal levels in patients achieving TC and WC, and 52 week mean scores in the three control groups were statistically significantly different ($p<0.0001$). Clinically meaningful improvements (mean change from baseline) were: TC group (SFC 1.9, FP 1.8), WC (SFC 1.5, FP 1.5) and NWC (SFC 1.0, FP 0.9).

Treatment aimed at controlling asthma improves HRQoL to levels approaching normal. The difference in AQLQ scores in TC and WC confirms that patients distinguish between even these high levels of control.

(200 words)

Introduction

Guidelines for the management of asthma issued by the Global Initiative for Asthma (GINA)/National Institutes of Health (NIH) state that the therapeutic aim should be to achieve overall asthma control to minimise the impact of asthma on the individual patient [1,2]. However, it is also increasingly recognised that asthma patients have low expectations of their therapy — leading to an acceptance of a lower level of asthma control than might be achievable [3,4].

Assessment of health-related quality of life (HRQoL) alongside conventional clinical monitoring is increasingly proposed as a means of aligning patient expectations with the clinician's therapeutic goals [5]. However, a number of studies have demonstrated poor correlation between conventional clinical indices and the outcomes of the Asthma Quality of Life Questionnaire (AQLQ) [6–8]. Conversely, studies that have used more comprehensive measures of overall asthma control have found that achieving asthma control translates into significant improvements in AQLQ score [9,10]. Additionally, a study by Katz et al. found that perceived control of asthma was strongly associated with improvements in both asthma-specific and generic health status outcomes [11].

Based on retrospective analyses of results of efficacy trials in asthma, we have previously suggested that, in contrast to conventional endpoints of clinical trials such as forced expiratory volume in 1 second (FEV_1), the use of a composite measure incorporating a range of clinically relevant endpoints provides a more complete view of the overall level of asthma control for the individual patient [12] and is likely to correlate with patient perception of control or freedom from disease [13]. The Gaining Optimal Asthma controL (GOAL) study was designed to investigate prospectively whether, and in what proportion of patients, asthma control measured according to a rigorous composite measure derived from the GINA/NIH guidelines can be achieved, and to compare the efficacy of individualised increasing doses of two recommended controller therapies — fluticasone propionate alone or in combination with the long-acting β_2-agonist salmeterol — in achieving this objective. The primary efficacy results from the GOAL study have been published in detail elsewhere [14]. Some of the results of the AQLQ analysis have previously been presented in abstract form [15]. This analysis of the results examines the extent to which patients distinguish the different levels of clinical asthma control achieved during the study using this disease-specific health status measure.

Methods

Study design

Full details of the GOAL study design and patient population have been reported elsewhere [14] and are summarised here.

GOAL was a 52-week, randomised, double-blind, multicentre, stratified, parallel-group step-up study designed to compare the level of asthma control achieved in adults and adolescents with salmeterol/fluticasone propionate (SFC; Seretide®/Advair®, GlaxoSmithKline, Middlesex, UK) combination Diskus® (Accuhaler®) dry powder inhaler and fluticasone propionate (FP; Flixotide®/Flovent®, GlaxoSmithKline, Middlesex, UK) alone also via Diskus® (Accuhaler®).

Following a 4-week run-in, eligible patients were allocated to one of three strata based on their dose of inhaled corticosteroid (ICS) during the previous 6 months — Stratum 1: no ICS; Stratum 2: ≤500 μg beclomethasone dipropionate daily or equivalent; or Stratum 3: >500–≤1000 μg beclomethasone dipropionate daily or equivalent. During Phase I of the study, FP or SFC dose was increased in a stepwise manner every 12 weeks until guideline-derived Total Control (see definition below) was achieved, or the maximum dose of study medication dose was reached. Patients were then maintained at the final dose level for the remainder of the study (Phase II). Thus, the duration of the dose titration phase (Phase I) ranged from 12 to 36 weeks and the follow-up phase (Phase II) ranged from 16 to a maximum of 40 weeks.

Rigorous composite measures derived from the treatment goals of the GINA/NIH guidelines [1,2] were used to define asthma control: Total Control or Well-Controlled (the full criteria are reported elsewhere [14]). If neither measure was achieved, then the outcome was defined as Not Well-Controlled.

Patient population

To be eligible for inclusion, patients had to be aged 12 years or older with a clinical history of asthma for at least 6 months, and had to demonstrate an FEV_1 reversibility of ≥15% and ≥200 mL in response to inhalation of a short-acting β_2-agonist. Exclusion criteria included assessment as Well-Controlled for ≥3 weeks of the 4-week run-in period or a smoking history of >10 pack-years.

AQLQ data was available from patients in 16 of the 44 countries involved in the study. Only those countries for which a validated translation in the local language was available were eligible for inclusion. All participants gave written informed consent prior to inclusion. The study was approved by local research ethics committees.

Assessment of quality of life

The AQLQ consists of 32 questions in four domains: Activity Limitation, Symptoms, Emotional Function and Environmental Stimuli. Responses in each domain and an overall score are graded on a 7-point scale, where 1 represents 'total impairment' and 7 represents 'no impairment' [16–18]. The AQLQ was administered at baseline and at clinic visits in Weeks 4, 12, 24, 36, 48 and 52. Investigators administered the questionnaire at the same time during each visit (prior to revealing the results of lung function assessments but after enquiring about adverse events). AQLQ scores were presented as the means of each domain, as well as an overall score. A within-subject change of 0.5 points on either the overall AQLQ score or any of the individual domains is considered the minimum change to be clinically meaningful [16–18].

Statistical analysis

Demographic data for the ITT patients who completed at least one AQLQ questionnaire were summarised. Well and Total control endpoints from the primary analyses [14] are presented. Using the same logistic regression methods as the primary analyses, the proportion of patients achieving control cumulatively in both phases of the study has been assessed.

The changes from baseline in AQLQ scores for each domain and the overall AQLQ score were plotted over the one year treatment period for each stratum. A Chi-square test was used to test the association of treatment with change from baseline in AQLQ score (≥0.5 vs <0.5).

The changes from baseline in overall AQLQ scores at Week 52 were categorised into ≤0, >0-<0.5, ≥0.5-<1, ≥1-<1.5 and ≥1.5. These values are summarised by treatment groups for each strata and overall. This was additionally split by control status in Phase I and at the end of phase II (52 weeks).

An analysis of variance model was fitted to AQLQ scores at 52 weeks, with the sole predictor variable being control status at the end of Phase II (52 weeks). For each

control status, least squares means and 95% confidence intervals were estimated. P-values for all pair-wise differences in control status were calculated. To adjust for all the multiple comparisons, we used the Bonferroni correction method, which increases the p-value to account for the increased risk of incorrectly rejecting the null hypothesis. Unlike predictor variables traditionally used in analysis of variance models, control status is not randomised, and was not measured prior to the AQLQ measurement.

The absolute AQLQ scores at 52 weeks was categorised and a 2-sided Fisher's Exact test was used to test the association of treatment with AQLQ score (<6, ≥6).

All analyses were performed using SAS Software (Version 8.2) in a UNIX environment (SAS is a registered trademark of the SAS Institute, Inc.).

Results

Patient demographics

The total intention to treat (ITT) population for the GOAL study comprised 3416 patients. The baseline demographics and clinical characteristics and primary efficacy results of the overall GOAL population, including AQLQ scores achieved in each stratum, have been described elsewhere [14]. A total of 1994 patients (SFC n=1001; FP n=993) in the ITT population completed the AQLQ at least once during the study. The demographics of the AQLQ population were comparable to those of the overall study population (Table 1).

Improvements in quality of life

Significantly more patients treated with SFC than FP in each stratum achieved either Well-Controlled or Total Control status in each phase of the study, ($p \leq 0.039$), including at study end (52 weeks) (Table 2)[14]. At 52 weeks, the majority of patients achieved clinically meaningful improvements in HRQoL from baseline, as demonstrated by a change in AQLQ score of ≥0.5 (81% with SFC and 74% with FP; $p<0.001$). A total of 16% and 18% of patients achieved improvements ≥0.5–<1.0, with 19% and 17% achieving improvements of ≥1.0–<1.5, and 45% and 39% achieving improvements ≥1.5 with SFC and FP, respectively. A non-clinically meaningful improvement (>0–≤0.5) was achieved by 12% and 14% of SFC and FP patients, whilst 8% and 11% achieved no change, or deterioration in QoL indicated by a negative change in AQLQ score. However, the proportions of patients experiencing these different levels of change in AQLQ were similar in the three individual strata (stratum 1 to 3)(Table 3).

In addition, there was a significant association between treatment and the proportion of patients with Week 52 AQLQ scores of ≧6 vs <6. More patients in the SFC group achieved an AQLQ score ≥6 (minimal or no impairment) compared with those receiving FP (p<0.001). Across all strata, the proportions were 61% vs 52% for SFC vs FP, respectively (Figure 1). For individual strata, the proportions achieving an AQLQ score ≥6 were 63% vs 62% (n.s.)(Stratum 1), 65% vs 53% (p< 0.005) (Stratum 2) and 57% vs 45% (p<0.005) (Stratum 3) for SFC vs FP, respectively.

Relationship between level of asthma control and quality of life

Mean values for both the final score and the magnitude of the improvement in AQLQ score were significantly higher in patients achieving Total Control than in those with Well-Controlled asthma (p <0.001), and between those with Well-Controlled asthma and those Not Well-Controlled,(p <0.001, Table 4). The proportions achieving clinically meaningful improvements of ≥0.5 unit change were higher in patients with Total Control (SFC, 89% and FP, 85%) and Well-Controlled status (SFC, 85% and FP, 84%) compared with those Not Well-Controlled (SFC, 67% and FP, 65%) (Figure 2). Even in patients with Not Well-Controlled status, a large proportion achieved improvements in total AQLQ scores ≥1.0 (SFC, 50% and FP, 47%), with 31% in each treatment group achieving changes in AQLQ score ≥1.5 (Figure 2).

Profile of improvements in AQLQ (all strata)

The largest improvement in overall score and in the scores for each domain was observed during the first 4 weeks of the treatment period; however, scores continued to improve throughout the study period, with highest values for each treatment being observed at 52 weeks (Figure 3) Mean AQLQ scores in each of the four domains improved by a similar magnitude in Strata 2 and 3. In Stratum 1, greatest improvement was seen for Symptoms. No clinically meaningful differences between domains were noted with either treatment.

Discussion

The GOAL study is the first prospective study to evaluate the concept of achieving complete clinical control, defined in GOAL as Total Control, based on the goals of treatment described in international treatment guidelines [1,2].

The AQLQ is a disease-specific, self-administered quality of life tool that is available in 36 languages and has been shown to be valid, reliable and reproducible for evaluating the impact of treatment regimens on the quality of life of asthma patients [16–18]. The unique design of the GOAL study permits evaluation of the relationship between asthma control and health status as measured using this AQLQ questionnaire. Total Control is associated with achievement of near maximal levels of HRQoL. The final values for the AQLQ for patients achieving lesser levels of clinical control (i.e. Well-Controlled and Not Well-Controlled status) were lower, but still statistically significant and exceeded the minimal clinically significant difference in a large majority of patients. Furthermore, there was a statistically significant difference in mean total AQLQ score at 52 weeks between Total and Well-controlled patients confirming that patients (assessed using with this instrument) distinguish between even these high levels of control, and this in spite of the probable 'ceiling' effect as large proportions of subjects in both categories score the maximum score of 7 However it should be noted that unlike predictor variables traditionally used in analysis of variance models, control status was not randomised, and was not measured prior to the AQLQ measurement.

The difference between patients designated controlled and Not Well-Controlled by the definitions used in this study has recently been used by Juniper et al to define cut-points for the Asthma Control Questionnaire for distinguishing 'well-controlled' and 'not well controlled' asthma.[19] Although in their analysis the definition of Total Control was not used, but grouped under 'well-controlled', a cut-point of 1.5 was associated with a probability of having 'well-controlled' asthma of only 66%, but a score of 0.75 (the ACQ score is inverse of the level of control) increased the likelihood of control to 85%, suggesting that highest levels of control can distinguished by control measures.

A further important conclusion of the current study is that, even when the desired levels of control were not achieved, a great majority of patients benefited from the treatment approach, with most achieving clinically significant improvements in AQLQ. Indeed, many patients not achieving Total Control or Well-Controlled status achieved

high scores on the AQLQ, regardless of baseline values and treatment received. At the end of the 52-week randomised period, virtually all patients from all strata had achieved at least moderate improvements in HRQoL, as defined by an increase in AQLQ score of ≥1.0 [16–18]. In nearly half of all patients, the improvement exceeded the threshold for a large improvement (defined by an AQLQ score increase of ≥1.5) [16–18] and came close to reaching the maximum achievable score. The clinical implications of these findings are that when treatment is individualised and directed towards achieving Total Control, it offers the vast majority of asthma patients (regardless of severity of asthma) the prospect of achieving quality of life scores approaching the maximum — i.e. with little or no impact of asthma on patients' daily lives.

Throughout the study, the values for SFC were higher than for FP, except for the suggestion of a ceiling effect as values approached maximal levels.

Comparisons between studies of different design should be performed with care; however, the magnitude of the increase and end of study values in our study were high, comparing favourably with values in the Formoterol And Corticosteroids Establishing Therapy (FACET) study [6] which was of similar duration. This is to be expected since the individualised treatment was increased in GOAL with the purpose of achieving the best possible level of control, whereas the FACET study employed only a single fixed dose of treatment and a 'step-down' study design. The GOAL results confirm the findings of the earlier retrospective analysis by Bateman et al, that guideline-derived control is associated with attainment of near-normal AQLQ scores [13].

The main improvements were seen during the initial dose-titrating phase of the study, particularly in the first 4 weeks of treatment. However, further improvement in AQLQ score was observed throughout the remainder of the 52-week study, beyond the point at which patients received no further dose increase in controller treatment. The plateauing of the values towards the end of the study may reflect the absence of further dose increases, the fact that no further benefit was being achieved (the limits of efficacy) or a ceiling effect [6] as more and more patients approached maximum scores. By contrast, in the FACET study an initial large increase in AQLQ score was followed by a gradual decline over the remainder of the 1-year study period, suggesting gradual loss of control [6].

In the GOAL study, all three strata showed similar improvements in each of the four AQLQ domains. The exception was the greater improvement in the Symptoms domain in Stratum 1. It is reasonable to assume that the greatest impact of achieving control, as per the composite measure employed in the GOAL study, might have been in the Symptoms domain because the parameters within the composite measure tend to be symptom-based. However, it is important to note that, in all strata, comparable improvement occurred in all AQLQ domains — even those not represented in the composite measure. This supports the view that the composite measure of control used in the GOAL study provides a simple measure that reflects a patient-reported outcome such as the AQLQ.

The absence of a placebo group is a potential limitation in the design of the GOAL study with respect to HRQoL that may restrict its validity in a wider patient population. For ethical reasons, it was not acceptable to include a placebo arm in a study of patients with uncontrolled asthma, of whom the majority in Strata 2 and 3 had severe asthma. It seems improbable that spontaneous improvements could account for the high AQLQ scores at the end of the study. Other potential limitations are that no record was made of overall patient satisfaction with treatment and the treatment approach, due to the current lack of validated and approved satisfaction instruments; in addition, AQLQ measurements were dependent on patient recall of the 2 weeks prior to the clinic visit.

Since improving HRQoL is a slow process and changes may be subtle, there is a risk of perceived lack of progress and under-reporting of improvements — especially if patients have low expectations of their asthma treatments to begin with [3,4]. However, the clear, consistent and biologically plausible trends and correlations suggest that the results are reliable.

Quality of life instruments such as the AQLQ reflect patients' real experiences and perceptions of living with asthma. Despite 'control' being described as the goal of asthma treatment, current surveys confirm that the majority of patients do not achieve control, and are consequently condemned to impaired quality of life [3,4]. The strong correlation between AQLQ scores and guideline-derived asthma control seen in the GOAL study supports the case for attempting to achieve and maintain asthma control at a higher level than is generally the case at present, and confirms that patients are able to distinguish between and appreciate the benefits of this approach. The GOAL study confirms that impaired quality of life is an unnecessary hardship and can be avoided by aiming for Total Control (a composite measure

derived from guideline goals) through individualised treatment escalated, if necessary, in accordance with accepted treatment steps. It further confirms that, with sustained dosing, gains are maintained and further improvements may occur. Since the GOAL study protocol made no provision for stepping down treatment in patients achieving control, further studies are required to examine whether it is possible to maintain the high levels of quality of life achieved in GOAL when controller treatment is reduced. Nevertheless, these results confirm that near-normal HRQoL can be achieved when treatment aims for Total Control of asthma, and that results with SFC are superior to FP alone. This should serve to increase the expectations of patients and their caregivers regarding what can be achieved for all people with asthma.

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Table 1 Baseline characteristics of patients who completed the AQLQ

Characteristics	Stratum 1		Stratum 2		Stratum 3	
	SFC	**FP**	**SFC**	**FP**	**SFC**	**FP**
No. of patients * (total ITT population)	291 (548)	290 (550)	351 (585)	343 (578)	359 (576)	360 (579)
Mean age; years ± SD (total ITT population)	37.3 ± 14.8 (36.1)	37.0 ± 14.6 (36.4)	40.8 ± 16.1 (40.4)	41.0 ± 16.3 (40.3)	42.4 ± 16.0 (44.1)	41.3 ± 15.9 (42.7)
Sex; % female (total ITT population)	59 (57)	54 (57)	57 (58)	58 (60)	58 (57)	61 (59)
Mean AQLQ score (score ± SD)						
Overall score	4.4 ± 1.01	4.5 ± 1.00	4.7 ± 1.07	4.5 ± 1.03	4.5 ± 1.05	4.5 ± 1.05
Activity Limitation domain	4.6 ± 1.07	4.6 ± 1.05	4.7 ± 1.10	4.5 ± 1.08	4.5 ± 1.11	4.5 ± 1.13
Symptoms domain	4.2 ± 1.10	4.4 ± 1.07	4.6 ± 1.11	4.5 ± 1.10	4.5 ± 1.09	4.5 ± 1.09
Emotional Function domain	4.4 ± 1.36	4.6 ± 1.42	4.8 ± 1.47	4.6 ± 1.37	4.6 ± 1.44	4.7 ± 1.45
Environmental Stimuli domain	4.4 ± 1.32	4.4 ± 1.35	4.6 ± 1.40	4.4 ± 1.38	4.4 ± 1.41	4.4 ± 1.45

* Number of patients who completed at least one AQLQ questionnaire at any time during the study

AQLQ = Asthma Quality of Life Questionnaire; FP = fluticasone propionate; ITT = intention to treat; SD = standard deviation; SFC = salmeterol/fluticasone propionate combination.

Table 2 Summary of efficacy results from the Gaining Optimal Asthma controL (GOAL) study [14]

Characteristics	Stratum 1			Stratum 2			Stratum 3		
	SFC	**FP**	**p-value**	**SFC**	**FP**	**p-value**	**SFC**	**FP**	**p-value**
No. of patients — ITT	548	550		585	578		576	579	
Patients achieving Well-Controlled status (Phase I) [No. of patients (%)]*	383 (71)	356 (65)	0.039	400 (69)	302 (52)	<0.001	288 (51)	188 (33)	<0.001
Patients achieving Total Control status (Phase I) [No. of patients (%)]*	225 (42)	169 (31)	≤0.001	189 (32)	114 (20)	<0.001	106 (19)	43 (8)	<0.001
Patients achieving Well-Controlled status (Phase I + end of Phase II) [Cumulative No. of patients (%)]*	418 (78)	380 (70)	0.003	436 (75)	344 (60)	<0.001	350 (62)	264 (47)	<0.001
Patients achieving Total Control status (Phase I + end of Phase II) [Cumulative No. of patients (%)]*	270 (50)	217 (40)	<0.001	257 (44)	163 (28)	<0.001	163 (29)	88 (16)	<0.001

FEV_1 = Fixed expiratory volume in one second; FP = fluticasone propionate; ITT = intention to treat; SFC = salmeterol/fluticasone propionate combination.

*All subjects excluding those with missing baseline FEV_1.

Table 3 Degree of change from baseline in overall AQLQ scores at 52 weeks in patients receiving SFC and FP, presented by individual strata and overall.

	Stratum 1		**Stratum 2**		**Stratum 3**		**Overall**	
Change in AQLQ score n, (%)	SFC (218)	FP (216)	SFC (301)	FP (280)	SFC (291)	FP (277)	SFC (810)	FP (773)
≥1.5	122 (56)	106 (49)	120 (40)	109 (39)	121 (42)	89 (32)	363 (45)	304 (39)
≥1.0 – <1.5	35 (16)	38 (18)	67 (22)	50 (18)	52 (18)	47 (17)	154 (19)	135 (17)
≥0.5 – <1.0	24 (11)	36 (17)	58 (19)	40 (14)	51 (18)	63 (23)	133 (16)	139 (18)
>0 – <0.5	25 (11)	20 (9)	37 (12)	44 (16)	34 (12)	46 (17)	96 (12)	110 (14)
≤0	12 (6)	16 (7)	19 (6)	37 (13)	33 (11)	32 (12)	64 (8)	85 (11)

AQLQ = Asthma Quality of Life Questionnaire; FP = fluticasone propionate; SFC = salmeterol/fluticasone propionate combination.

Table 4 Mean AQLQ scores at 52 weeks and mean change from baseline within each strata split by level of asthma control at the end of Phase II

		Stratum 1		**Stratum 2**		**Stratum 3**		**Overall**	
	Mean ± SD	**SFC**	**FP**	**SFC**	**FP**	**SFC**	**FP**	**SFC**	**FP**
Total Control	Score at 52 weeks Mean change (No. of patients)	6.5 ± 0.78 2.0 ± 1.09 (77)	6.6 ± 0.47 2.1 ± 1.08 (57)	6.6 ± 0.55 1.8 ± 1.07 (110)	6.5 ± 0.64 1.7 ± 1.21 (50)	6.6 ± 0.54 1.9 ± 0.84 (66)	6.5 ± 0.47 1.7 ± 1.03 (37)	6.5 ± 0.63 1.9 ± 1.02 (253)	6.6 ± 0.53 1.8 ± 1.12 (144)
Well-Controlled	Score at 52 weeks Mean change (No. of patients)	6.2 ± 0.67 1.8 ± 1.17 (73)	6.2 ± 0.77 1.6 ± 0.90 (67)	6.1 ± 0.80 1.4 ± 0.92 (101)	6.1 ± 0.74 1.5 ± 1.12 (88)	6.2 ± 0.78 1.5 ± 1.10 (96)	6.1 ± 0.86 1.3 ± 0.84 (90)	6.2 ± 0.76 1.5 ± 1.06 (270)	6.1 ± 0.79 1.5 ± 0.97 (245)
Not Well-Controlled	Score at 52 weeks Mean change (No. of patients)	5.4 ± 1.12 1.2 ± 1.25 (68)	5.5 ± 1.05 1.1 ± 1.13 (92)	5.4 ±1.20 0.9 ± 1.08 (90)	5.4 ±1.18 0.9 ± 1.09 (142)	5.2 ± 1.19 0.9 ± 1.02 (129)	5.1 ± 1.09 0.8 ± 1.04 (150)	5.3 ± 1.18 1.0 ± 1.10 (287)	5.3 ± 1.12 0.9 ±1.09 (384)

AQLQ = Asthma Quality of Life Questionnaire; FP = fluticasone propionate; SFC = salmeterol/fluticasone propionate combination

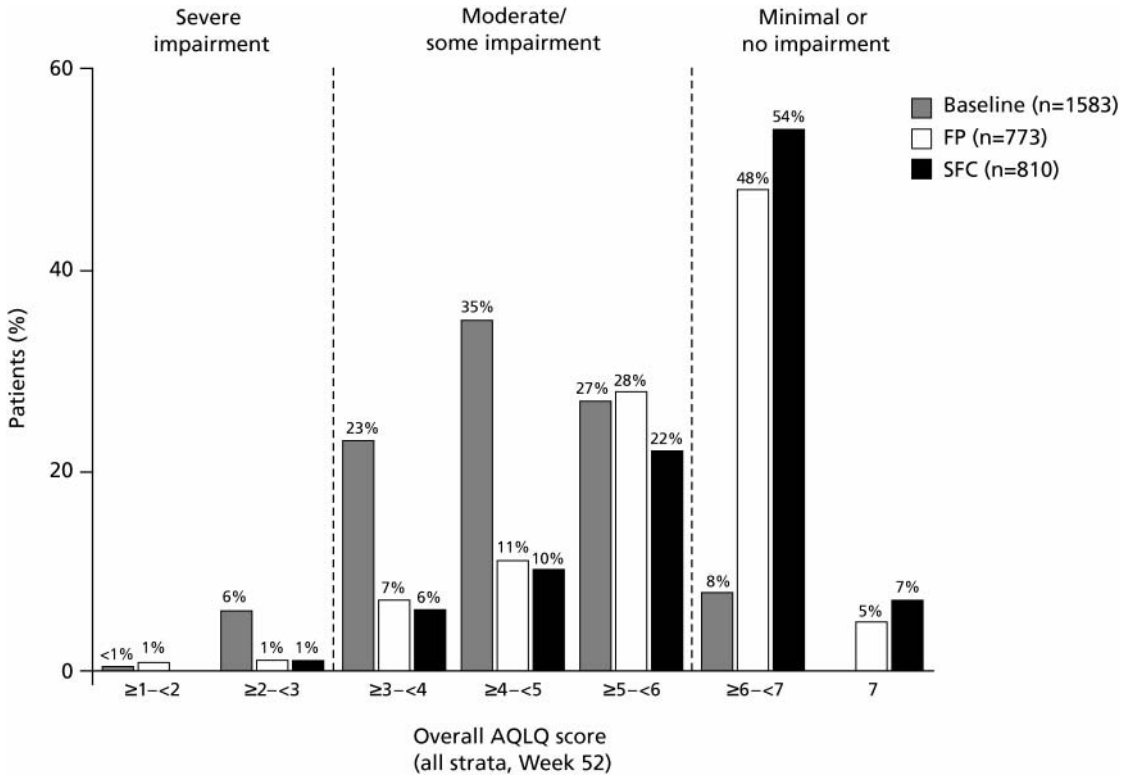

Figure 1. Association of achieving mean overall AQLQ score of ≥6 vs <6 at Week 52 with SFC and FP: p<0.001, in patients who completed the AQLQ at baseline and Week 52 (n=1583). AQLQ = Asthma Quality of Life Questionnaire; FP = fluticasone propionate; SFC = salmeterol/fluticasone propionate.

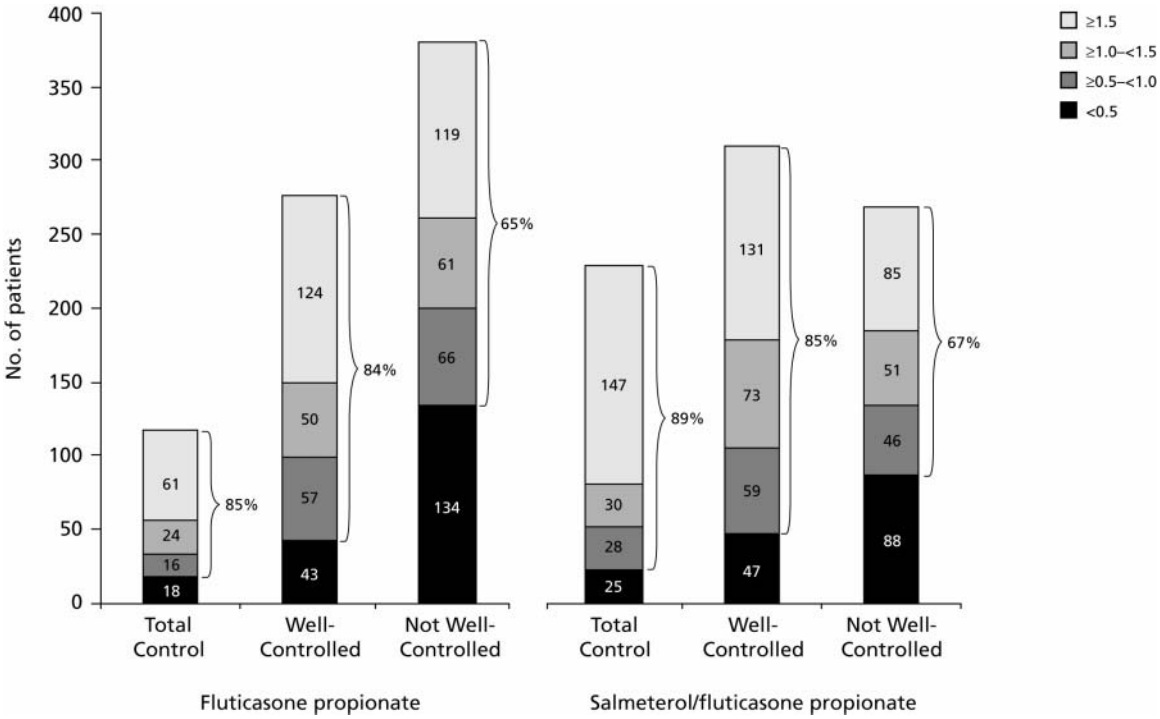

Figure 2. The number and proportion of patients achieving improvements in overall AQLQ score at 52 weeks (according to level of control and treatment group (patients who completed the AQLQ at baseline and Week 52; n=1583). AQLQ = Asthma Quality of Life Questionnaire; NWC = Not Well-Controlled; TC = Total Control; WC = Well-Controlled. Although proportions achieving clinically meaningful improvement (≥0.5) was similar with SFC and FP, more patients achieved control with SFC

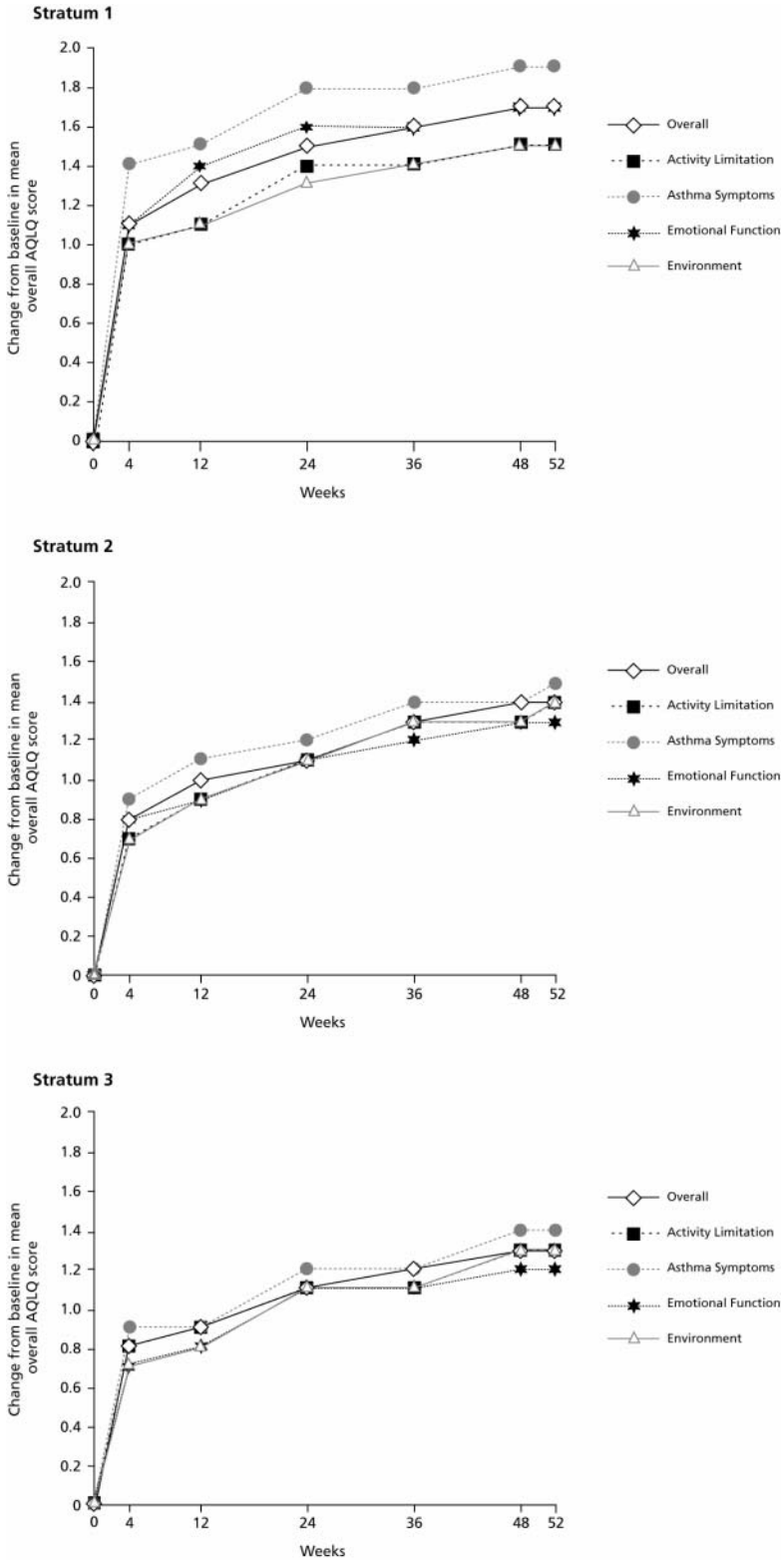

Figure 3. Changes from baseline in mean overall AQLQ scores and in the individual domain scores for patients receiving salmeterol fluticasone combination in each of the three strata. The profile of improvements in mean overall AQLQ scores and for the individual domain scores for patients treated with fluticasone propionate, although numerically lower, were similar (not shown). AQLQ = Asthma Quality of Life Questionnaire.