BRIEF REPORT

The impact of a medical food containing gammalinolenic and eicosapentaenoic acids on asthma management and the quality of life of adult asthma patients

Marc E. Surette [a], Dean Stull [b] and Julianne Lindemann [b]

[a]Department of Chemistry and Biochemistry, University of Moncton,
Moncton, NB, Canada

[b]Efficas Inc, Boulder, CO, USA

Address for correspondence: Marc Surette, PhD, Department of Chemistry and Biochemistry, Université de Moncton, Moncton, NB, E1A 3E9, Canada. Tel.: +1 506 858 4293; Fax: +1 506 858 4541; marc.surette@umoncton.ca

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ABSTRACT

Background: Leukotriene synthesis inhibitors and receptor antagonists are efficacious for the treatment of asthma. Diets containing the fatty acids gammalinolenic acid (GLA) and eicosapentaenoic acid (EPA) decrease leukotriene synthesis; however, their impact on asthma management and quality of life (QOL) has not been evaluated in asthmatic subjects.

Objective: To evaluate asthma management and the QOL of asthmatic adult subjects consuming a medical food emulsion containing GLA and EPA.

Research design and methods: Trial 1 was a randomized, prospective, double-blind, placebo-controlled, parallel group trial in atopic subjects with mild-to-moderate asthma ($n = 35$ evaluable) consuming a low dose (0.75 g GLA + 0.5 g EPA), high dose (1.13 g GLA + 0.75 g EPA) or placebo emulsion daily. Subjects were questioned about their asthma management using a non-validated questionnaire after 2 and 4 weeks. Blood leukotrienes were measured at baseline and after 4 weeks.

Trial 2 was an open-label study ($n = 65$ evaluable) where subjects consumed the low-dose medical food emulsion, EFF1009, daily. QOL and asthma management were measured using the validated Mini Asthma Quality of Life (MiniAQLQ) and the Asthma Control (ACQ) questionnaires, respectively, administered at baseline and after 4 weeks.

Results: In Trial 1, leukotriene biosynthesis decreased ($p < 0.05$). Self-reported asthma status and bronchodilator use improved in subjects consuming low- and high-dose emulsion between week 2 and week 4 ($p < 0.01$), but not compared to placebo ($p > 0.1$). In Trial 2, mean ± standard error total MiniAQLQ and ACQ scores improved by 1.5 ± 0.2 and 1.0 ± 0.1, respectively ($p < 0.001$). Subdomain scores from MiniAQLQ improved and rescue bronchodilator use decreased ($p < 0.001$).

Conclusion: The inclusion of the medical food EFF1009 in asthma management regimens can improve patient quality of life and decrease reliance on rescue medication.

Introduction

Leukotrienes (LT) are a potent class of lipid mediators of inflammation derived from the essential fatty acid, arachidonic acid (AA). The initial conversion of AA to leukotrienes is catalyzed by the enzyme 5-lipoxygenase.

The properties of these compounds include potent chemotactic activity toward neutrophils and eosinophils by LTB_4[1] as well as proinflammatory and bronchoconstrictor activities by the cysteinyl-leukotrienes (cys-LT), which include LTC_4, LTD_4 and LTE_4[2,3]. As would be expected from the aforementioned biological activities,

the LTs play a significant role in the pathophysiology of asthma. Because of these potent properties, the biosynthesis as well as the actions of leukotrienes on their specific cellular receptors are therapeutic targets for several inflammatory and allergic disorders including asthma[4–10]. The cys-LT$_1$ receptor blockers zafirlukast and montelukast, as well as the 5-lipoxygenase inhibitor zileuton, have been marketed for the treatment of asthma[4–6], and montelukast was recently approved for the relief of symptoms of perennial and seasonal allergic rhinitis. These receptor blockers are presently under consideration for the treatment of other inflammatory conditions[7–9,11].

Since AA is an essential dietary polyunsaturated fatty acid (PUFA), the biosynthesis of its metabolites, including the leukotrienes, can be modulated by dietary means. Indeed, supplementation of human diets with PUFA such as gammalinolenic acid (GLA), which can be metabolized to compounds that interfere with the capacity for leukotriene biosynthesis[12,13], results in a decreased capacity for leukotriene synthesis[14–16]. More recently, the daily consumption of a dietary emulsion product containing a combination of GLA and the n-3 PUFA eicosapentaenoic acid (EPA) also resulted in significantly decreased leukotriene biosynthesis in both healthy subjects and patients with mild-to-moderate atopic asthma[17–19]. Given that leukocytes from atopic subjects, including atopic subjects with asthma, have a greater capacity to produce leukotrienes than cells from healthy individuals[20–24], dietary interventions with targeted dietary PUFA may help normalize leukotriene production in asthmatic individuals. Such dietary interventions could be administered as medical foods[25] which are intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements exist.

Although dietary supplementation with sufficient quantities of GLA and EPA can reduce the capacity for LT biosynthesis in patients with asthma, the impact of such supplementation on disease activity has not been assessed. An effective evaluation of impact on disease can be achieved with the use of quality of life (QOL) measurements. In fact, such measurements are recommended for the evaluation of benefit in those disease states not entirely amenable to objective evaluation, such as asthma[26]. QOL questionnaires have been developed and validated for the measurement of asthma control and these methodologies have proven very useful in evaluating the effectiveness of interventions on disease control[27–30].

In the present studies, we conducted a post-hoc analysis of asthma management questionnaires administered during a placebo-controlled trial investigating the efficacy of a medical food product containing GLA and EPA on LT biosynthesis. This was followed by an open-label trial evaluating the efficacy of the medical food product, EFF1009, using the Mini Asthma Quality of Life Questionnaire (MiniAQLQ)[28] and the Asthma Control Questionnaire (ACQ)[29,31]. Overall, the results demonstrate that supplementation of the diet with the medical food product EFF1009 significantly improved asthma management and the QOL of subjects with asthma.

Patients and methods

Trial 1

Study design

In this report we present unpublished asthma management results from a previously reported clinical trial in atopic subjects with asthma[19]. Briefly, this was a randomized, double-blind, prospective, placebo-controlled, parallel group trial in subjects with mild-to-moderate asthma performed at Wake Forest University Medical Center. This study sought to determine the optimal intake of dietary GLA and EPA required to safely reduce leukotriene biosynthesis in atopic asthma patients. The protocol was approved by internal and external (Western IRB) institutional review boards, and each patient gave written informed consent before entering the study. All subjects had a diagnosis of asthma for at least 1 year, a positive methacholine challenge test (PC20) < 8 mg/ml, their symptoms were controlled solely with beta agonists and/or theophylline, and had an FEV$_1$ > 70% of predicted. No subject had taken inhaled or systemic steroids for at least 4 weeks prior to study enrollment. Inhaled, intranasal and systemic corticosteroids and systemic antihistamines were forbidden during the study period, but intranasal antihistamines were permitted.

Subjects were randomly assigned into one of three groups: a low-dose group consumed 10 g of a medical food emulsion delivering 0.75 g GLA + 0.5 g EPA, a high-dose group consumed 15 g of emulsion delivering 1.13 g GLA + 0.75 g EPA and a placebo group consumed a placebo emulsion once daily for 4 weeks. The placebo contained olive oil with no EPA or GLA. Randomization was structured to assign two times as many subjects to each of the treatment groups as the placebo group. The detailed composition of the emulsion and placebo formulations were previously described[18]. Vital signs as well as hematology and clinical chemistry tests were performed both at baseline and at the end of the study period. Stimulated whole blood leukotriene synthesis was measured at baseline and after 4 weeks of daily supplementation as previously described[18].

Asthma questionnaire

Subjects were queried about their asthma on an exploratory basis after 2 weeks and 4 weeks of daily use of the medical food using two non-validated questions, and the responses were analyzed *post hoc*. One question related to global asthma status (Is your asthma better, worse or the same compared to the baseline visit?) and the other question related to rescue inhaler use (Has your use of your 'rescue' inhaler increased, decreased, or remained the same compared to the baseline visit?). Responses were assigned nominal values of 1 (asthma is not better; or inhaler use has not decreased) or 2 (asthma is better; or inhaler use has decreased) to allow comparisons of responses to question after 2 weeks and 4 weeks of supplementation.

Trial 2
Study design

This was an open-label investigation of the medical food EFF1009, an emulsion that contains 0.5 g of EPA from fish oil and 0.75 g of GLA from borage oil per daily serving, which is equivalent to the low-dose group in Trial 1. Subjects were recruited from a pool of consumers who had previously participated in a quantitative marketing study. Subjects were recruited from throughout the United States via the internet and were screened by filling out detailed questionnaires, including a medical history with a focus on allergy and asthma symptoms. Subjects were then invited to participate in the trial in writing (by email).

Included in the trial were males and females aged 22–55 years with a history of asthma. Evaluable subjects had a physician diagnosis of their asthma and were using medication to manage their symptoms. Subjects with liver disease, who were pregnant or nursing, or with a history of hypersensitivity or allergy to fish, shellfish or soy were excluded from the trial.

The medical food test article was sent by mail to the subjects. On day 1 subjects who met the inclusion and exclusion criteria were sent an email that directed them to a website where the day 1 allergy history, medication use, MiniAQLQ[28] and ACQ[29] questionnaires were posted. Subjects filled out the questionnaires on-line and submitted them electronically to the data management site. Subjects were instructed to begin consuming the product after they submitted the day 1 questionnaires.

The EFF1009 medical food was a flavored emulsion packaged as single serving tear-open pouches that were ingested once daily for 28 days. The daily serving contained 12 g of emulsion delivering 0.75 g of GLA and 0.5 g of EPA. There were no dietary restrictions during the test period. Participants were given a toll-free telephone number to report adverse events. Participants were also advised to keep daily or periodic notes of their experience with the product during the trial so that their responses at the end of the study would be as accurate as possible.

On day 28, subjects were sent an email that directed them to a website where the day 28 medication use, MiniAQLQ, ACQ and global status questionnaires were posted. Those subjects who filled out the questionnaires on-line and submitted them electronically to the data management site within 10 days were included in the analysis. Key fatty acids in the emulsion accumulate in cells and tissues over a period of approximately 2 weeks with daily use, remain elevated with continued use, and then fall during several weeks if use is discontinued. Thus, 10 days was determined to be the longest time period allowed for completing the day 28 questionnaires before an impact on perceived benefit would be expected.

Quality of life and asthma management assessments

QOL and asthma management were measured using two self-administered validated instruments, the MiniAQLQ[28] and the ACQ[29,31], respectively. The MiniAQLQ instrument is comprised of 15 questions in four domains: Symptoms, Activities, Emotions and Environment. In all cases the questions refer to how the subject was feeling during the previous 2 weeks due to their asthma. The scale for each question is from 1 ('all of the time' or 'totally limited') to 7 ('none of the time' or 'not at all limited'). For each question low scores indicate poor asthma-related quality of life compared to higher scores. The total score is computed as the mean of responses to all 15 questions and each domain score is computed as the mean of the responses with the domain[28].

The ACQ instrument is comprised of seven questions, with a focus on symptom frequency and severity, and the need for rescue medication (short-acting bronchodilator) during the previous week. Subjects were not required to answer the ACQ question 7 on FEV_1 since a typical peak flow meter prescribed to asthma patients cannot measure FEV_1. The validity and the measurement properties of the ACQ at the group level are not affected in the absence of FEV_1 measurement[32]. The scale for each question is from 0, indicating good asthma control, to 6, indicating poor asthma control. The total score is computed as the mean of all six responses. The ACQ does not have domains, however the frequency of bronchodilator use, sleep disturbance, activity limitation, and the severity of some key symptoms were evaluated individually due to the interest of the investigators to compare responses

to these questions between the ACQ and the similar MiniAQLQ domains.

On day 28, subjects were also asked to make a global assessment of their asthma (a nonvalidated question), and indicate whether or not their asthma had become less severe, more severe or was unchanged after 4 weeks' use of the medical food.

Participants completed these questionnaires at baseline and after 4 weeks of daily use of the medical food. Subjects were deemed evaluable for efficacy if they submitted a fully completed MiniAQLQ questionnaire and completed ACQ questions 1–6 at both timepoints.

Statistical analyses

In Trial 1, differences in the proportion of subjects in the different groups responding that their asthma was better or that their inhaler use had decreased was determined using a Fisher's exact test. The difference in the responses within each group between week 2 and week 4 were compared using McNemar's test for correlated proportions.

In Trial 2, the data from all subjects who fully completed both the day 1 and the day 28 questionnaires within the permitted time frame were analyzed by comparing changes from day 1 scores, including individual domain score analyses, by paired t-test. The entire cohort was evaluated for both the MiniAQLQ and the ACQ analyses. In addition, a 'mild-to-moderate' MiniAQLQ subgroup, predefined as those participants whose total MiniAQLQ score at baseline fell within the middle two quartiles of possible scores, was also evaluated since this subgroup was deemed

comparable to the majority of asthma patients likely to use a medical food as part of their management regimen.

Results

Tolerability

The medical food product appeared to be well tolerated by most subjects in both studies. In Trial 1, there were no significant between-group differences in adverse events or mean clinical chemistry values. In Trial 2, two subjects reported gastrointestinal upset. No serious adverse events occurred during either trial.

Trial 1

The demographics of the subjects who completed Trial 1 are shown in Table 1. A total of 43 subjects were enrolled in the trial and eight dropped out voluntarily. Eight subjects consuming placebo, 12 subjects consuming the low dose and 15 subjects consuming the high dose completed the study and were available for analysis. One subject in the low-dose group did not answer the asthma questionnaire.

Stimulated LTB_4 biosynthesis was previously reported to be significantly decreased between baseline and week 4 in both the 10 g/day and 15 g/day treatment groups compared to the placebo group[19]. When subjects were questioned about their rescue medication use and their asthma status after 2 weeks, 19% of subjects in the treatment arms (low dose and high dose combined) reported improved asthma status and 23% reported reduced use of rescue

Table 1. Demographic characteristics of subjects who completed Trial 1 and Trial 2

	Trial 1			Trial 2
	Placebo	Low dose	High dose	
Age (years)	29 ± 9	30 ± 12	29 ± 10	40 ± 12
Weight	168 ± 47	166 ± 52	161 ± 50	ND
Number of subjects	8	12	15	65
Race, no. (%)				
White	7 (88%)	11 (92%)	12 (80%)	44 (68%)
Black	1 (12%)	1 (8%)	3 (20%)	4 (6%)
Other*	0	0	0	4 (6%)
Declined to say	–	–	–	13 (20%)
Sex, no. (%)				
Male	2 (25%)	4 (33%)	3 (20%)	23 (35%)
Female	6 (75%)	8 (67%)	12 (80%)	42 (65%)

Values represent means ± SD
ND = not determined
*Other includes Latino/Hispanic, Native American and Asian/Pacific Islander

inhaler which was similar to that of the placebo group (37.5% of subjects for each question) ($p > 0.1$ for each comparison, Fisher's test). There was no further change in the number of subjects reporting improved asthma status or reduced rescue inhaler use in the placebo group during the subsequent 2-week period. The percentage of subjects reporting improved asthma status (53% low dose, 55% high dose) or decreased inhaler use (64% low dose, 47% high dose) in the treatment groups was not different from placebo at week 4 ($p > 0.1$ for each comparison, Fisher's test). However, the medical food groups showed improvement at week 4 compared to week 2 with 54% of subjects reporting improved asthma status and 54% of subjects reporting reduced use of rescue inhaler ($p = 0.004$ and $p = 0.008$, respectively, compared to week 2 result; McNemar test). Given that this *post hoc* analysis utilizing a non-validated instrument resulted in a positive result with such a small sample size, a second trial (Trial 2) evaluating asthma status and quality of life parameters using validated instruments was conducted.

Trial 2

A total of 101 subjects were enrolled in Trial 2 and submitted day 1 questionnaires. Ninety-five subjects answered the global assessment question at day 28, but only 65 participants fully completed both the day 1 and day 28 MiniAQLQ and ACQ within the designated time frames, and were thus included in the statistical analyses. Thus, 95% of the subjects completed the study but only 64% were evaluable for efficacy. The demographics of the evaluable subjects who completed Trial 2 are shown in Table 1.

The MiniAQLQ evaluation

The MiniAQLQ scale is from 1 to 7, with higher numbers indicating a higher quality of life. A significant improvement ($p < 0.001$) in the Total of Quality of Life score of 1.5 ± 0.2 (mean ± standard error), equivalent to 25% of the MiniAQLQ Scale, was reported by the participants during the study (Table 2)[29]. Significant improvements ($p < 0.001$) were also obtained within each of the four domains of the MiniAQLQ (Table 2). Additionally, improved responses ($p < 0.001$) were observed in all domains regardless of whether subjects indicated that their asthma was triggered by exercise, animal exposure or smoke exposure, or whether disease symptoms were year-round or not (not shown). Similarly, the mild-to-moderate subgroup of subjects also reported significant improvements ($p < 0.001$), indicating that the effect was not limited to large changes in mild or severe asthmatics. Indeed, Figure 1A shows that the improvements in total QOL scores for evaluable individuals did not appear to be dependent on self-evaluated asthma severity. Frequency plots of the distribution of individual scores further illustrate the shift in the range of reported scores between day 1 and day 28 (Figure 1B).

The ACQ evaluation

The ACQ scale is from 0 to 6, with lower numbers indicating greater asthma control. The total scores reported in the ACQ showed a significant overall improvement ($p < 0.001$) in asthma control with a mean change of 1.0 ± 0.1 (Table 3). As with the MiniAQLQ results, the reported improvements did not seem to be dependent on self-evaluated asthma severity (Figure 2A). The shift in the distribution the
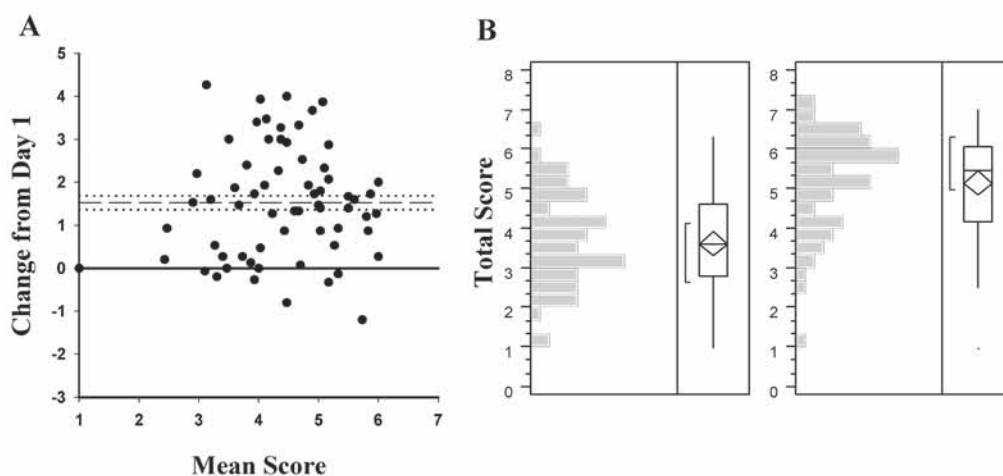

Figure 1. (A) Distribution of total scores from the MiniAQLQ for individual subjects enrolled in Trial 2. Mean score represents the average of day 1 and day 28 scores. The hatched line represents the mean change, the dotted lines show the standard error. (B) Frequency distribution of total scores on day 1 (left panel) and day 28 (right panel) from the MiniAQLQ for subjects enrolled in Trial 2

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total ACQ scores from days 1 to 28 is illustrated with frequency plots in Figure 2B.

Responses to the ACQ encompass questions relating to symptoms, disease control, activity limitation and inhaler use. When the disease or QOL indicators deemed most important to physicians (sleep disturbance and activity limitation)[29] and to patients (symptoms control)[33] were evaluated individually,

Table 2. *Asthma quality of life scores from the MiniAQLQ in subjects (*n = 65) from Trial 2 consuming EFF1009 daily for 28 days*

Measurement	Day 1 Mean ± SE	Day 28 Mean ± SE	Mean change Mean ± SE
Total score	3.6 ± 0.1	5.2* ± 0.2	1.5 ± 0.2
Activity limitation	4.2 ± 0.2	5.6* ± 0.2	1.4 ± 0.2
Symptoms	3.7 ± 0.2	5.2* ± 0.2	1.5 ± 0.2
Emotional function	3.2 ± 0.2	5.1* ± 0.2	1.8 ± 0.2
Environmental stimuli	3.2 ± 0.2	4.7* ± 0.2	1.5 ± 0.2
Mild/moderate subset	4.0 ± 0.1	5.4* ± 0.2	1.4 ± 0.2

In the MiniAQLQ an increased score is indicative of an improvement in asthma status. The mean change may not be the same as the difference between the means due to rounding of the values
*Significantly different from day 1, $p < 0.001$, paired t-test

Table 3. *Asthma quality of life scores from the Asthma Control Questionnaire (ACQ) in subjects (*n = 65) from Trial 2 consuming EFF1009 daily for 28 days*

Measurement	Day 1 Mean ± SE	Day 28 Mean ± SE	Mean change Mean ± SE
Total score	3.2 ± 0.1	2.2* ± 0.1	1.0 ± 0.1
Sleep disturbance	2.9 ± 0.1	2.1* ± 0.1	0.9 ± 0.1
Activity limitation	3.2 ± 0.1	2.1* ± 0.1	1.1 ± 0.1
Shortness of breath	3.8 ± 0.2	2.6* ± 0.1	1.2 ± 0.2
Wheeze	3.4 ± 0.1	2.4* ± 0.1	1.1 ± 0.1
Inhaler use	2.7 ± 0.1	1.9* ± 0.1	0.8 ± 0.1

In the ACQ a decreased score is indicative of an improvement in asthma status. The mean change may not be the same as the difference between the means due to rounding of the values
*Significantly different from day 1, $p < 0.001$, paired t-test
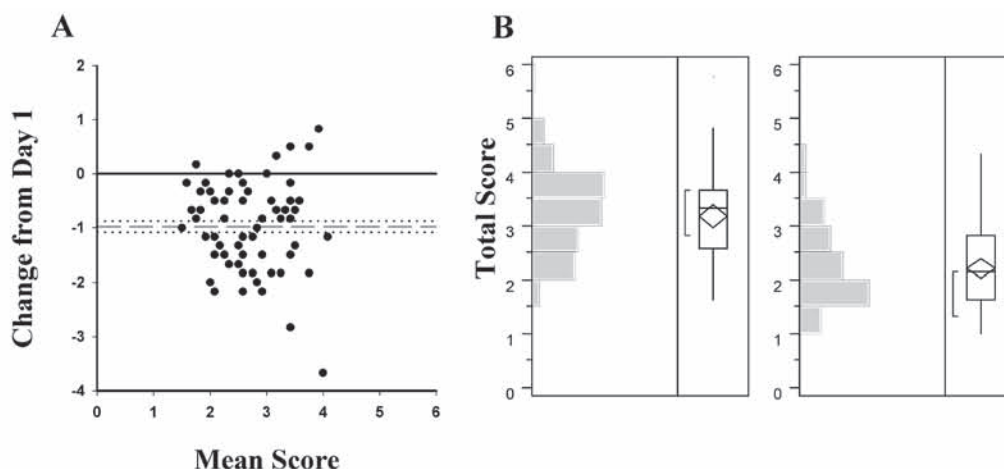

Figure 2. *(A) Distribution of individual total scores from the ACQ for individual subjects enrolled in Trial 2. Mean score represents the average of day 1 and day 28 scores. The hatched line indicated the mean change, the dotted lines are the standard error. (B) The frequency distribution of total scores from the ACQ on day 1 (left panel) and day 28 (right panel) for subjects enrolled in Trial 2*

significant improvements were obtained for each category (Table 3). Similarly, a significant decrease in rescue inhaler use ($p < 0.001$) was also reported (Table 3), from a mean of approximately 5–8 puffs per day on day 1 to 3–4 puffs per day by day 28. Taken as a whole, results from the ACQ are consistent with those from the MiniAQLQ as well as from the asthma status question results obtained in Trial 1.

Global assessment question

Seventy percent and 74% of subjects who answered the global assessment question ($n = 95$) and the efficacy evaluable population ($n = 65$), respectively, indicated that their asthma became less severe after 4 weeks of consuming the medical food. This indicates that those who were evaluable for efficacy ($n = 65$) were representative of the larger population who completed Trial 2. While specific information was not collected about why certain subjects did not fully complete the validated questionnaires at day 28, this group apparently was not disproportionately comprised of participants who perceived no benefit from the product.

Discussion

The modulation of leukotriene biosynthesis or action is an effective target for the management of asthma. This is achieved pharmacologically by modulating leukotriene biosynthesis with 5-lipoxygenase inhibitors such as zileuton or by controlling leukotriene activity using cys-LT receptor antagonists such as montelukast or zafirlukast. The supplementation of diets with oils containing the PUFAs GLA and EPA is also an effective means of modulating leukotriene biosynthetic capacity, however, the impact of such dietary supplementation on asthma severity, reliance on medication or quality of life has not been evaluated. In the present study, we report two separate clinical trials where dietary supplementation with the medical food emulsion EFF1009, containing GLA and EPA, impacts positively on asthma management and on the quality of life of asthma patients.

Subjects with atopic asthma consuming EFF1009 for up to 4 weeks show a significant decrease in stimulated whole blood leukotriene biosynthesis compared to placebo[19], consistent with results reported in previous studies where leukotriene biosynthetic capacity decreases after a minimum of 2 weeks of supplementation with GLA and EPA[17,18]. Although no difference compared to placebo was measured in self-reported asthma status and inhaler use, the reported difference in responses between week 2 and week 4 of supplementation are consistent with the mechanism of action of the medical food since the decrease in leukotriene biosynthesis is only measurable after 2 weeks of treatment[18].

Since Trial 1 was performed on a small number of subjects and the instruments measuring disease status were not validated, a more comprehensive evaluation of QOL utilizing the validated MiniAQLQ and ACQ instruments (Trial 2) was conducted and significant improvements in QOL were also measured in subjects consuming EFF1009 daily. Importantly, the magnitude of the improvement in the total quality of life score using the MiniAQLQ was 1.5 ± 0.2, equivalent to 25% of the instrument's scale. A minimum clinically important difference (MID) for the more comprehensive asthma QOL instrument, AQLQ, is 0.5, while differences of 1.0 are considered moderate and differences greater than 1.5 are considered large changes[27]. While no MID has been specifically determined for the MiniAQLQ, the magnitude of change for the MiniAQLQ and AQLQ are very comparable[29,34] and the MID are considered to be equivalent for both questionnaires[30]. Therefore, in this study the mean change of 1.5 suggests that the medical food produced a clinically significant improvement that was of moderate-to-large size. This result compares very favorably with AQLQ scores obtained in mild asthmatics treated with montelukast or zafirlukast where median QOL scores were improved by 0.8 and 0.9, respectively[35].

Responses to the ACQ questionnaire were similar to those obtained using the MiniAQLQ. As with the MiniAQLQ, the mean change in total QOL score of 1.0 ± 0.2 obtained using the ACQ was well above the MID of 0.5 for this instrument[32,36]. In fact, responses to both the MiniAQLQ and ACQ instruments indicated that a generalized improvement in asthma was recorded since all subdomain scores were similarly impacted, including those identified by physicians (sleep disturbance and activity limitation)[29] and patients (symptoms control)[33] to be the most important. In this study both the MiniAQLQ and the ACQ questionnaires were administered via the internet and were thus completed in an unsupervised fashion. However, previous studies have demonstrated excellent concordance of results obtained by unsupervised postal distribution of questionnaires with those obtained by means of supervised administration for both the MiniAQLQ and the ACQ[30,37]. Accordingly, the MiniAQLQ has been determined to be a reliable instrument for measuring health-related QOL in asthma patients participating in online interventions[38].

The effect of the medical food on QOL appeared to be unrelated to self-reported asthma severity since the mild-to-moderate asthma subgroup in the MiniAQLQ evaluation reported results that were similar to the group as a whole. This is also reflected

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in the shift in the distribution of individual scores illustrated in Figures 1 and 2 for the MiniAQLQ and ACQ responses, respectively. Furthermore, improved quality of life responses were measured regardless of the subjects' asthma trigger or whether the disease was seasonal or not. These results suggest that this medical food may have a general anti-inflammatory effect, as would be expected based on its mechanism of action targeting mediators of inflammation, resulting in reduced symptoms and decreased reliance on rescue medication.

Unlike pharmaceutical products, many healthcare providers may not be familiar with the regulatory category of products termed medical foods. In the United States, the statutory definition of a medical food is a food administered under medical supervision and intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements exist[25]. The US Food and Drug Administration (FDA) has included this statutory definition into the agency's regulations governing medical foods. Stimulated leukocytes from asthmatic subjects as well as from other atopic individuals produce more leukotrienes than cells from healthy individuals[20–24], and it is generally accepted that asthmatics produce elevated concentrations of leukotrienes. These mediators of inflammation play a significant role in the pathophysiology of asthma[39,40] and have been targets for both pharmaceutical interventions and dietary management strategies. The consumption of medical food products which provide dietary PUFA not easily obtained in the diet that help normalize leukotriene production can address unique nutritional needs of patients with asthma.

Conclusions

This study suggests that the daily consumption of a medical food containing GLA and EPA can improve the quality of life of asthma patients and decrease their reliance on rescue medication. These results indicate that a randomized, placebo-controlled trial investigating the effect of this medical food on the quality of life in asthma patients is warranted.

Acknowledgments

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