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SHORT REPORT

Comparing Baseline Characteristics of Patients with Chronic Rhinosinusitis with Nasal Polyps with and without Asthma in the AROMA Registry

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Background: Chronic rhinosinusitis with nasal polyps (CRSwNP) is a predominantly type 2 inflammatory disease of the nose and paranasal sinuses. Asthma is a common coexisting condition, associated with more severe sinus disease and reduced quality of life. Treating patients with uncontrolled CRSwNP and coexisting asthma is currently challenging.

Objective: To compare baseline characteristics and disease burden in patients with CRSwNP with and without coexisting asthma in AROMA.

Methods: AROMA is a prospective global registry study recruiting adult patients with severe CRSwNP who initiate dupilumab and follows them for up to 36 months. All patients entering the registry were assessed for baseline demographics and disease characteristics.

Results: As of February 2023, the study had enrolled 303 patients, with 210 (69.3%) patients reporting coexisting asthma. Of the patients with asthma, 11.0% reported ongoing oral/systemic corticosteroid use at baseline, and 29.0% had at least 1 severe asthma exacerbation in the year before screening.

Conclusion: More than two-thirds of adults with CRSwNP who initiated dupilumab in AROMA have coexisting asthma. Of these patients, one-third reported at least 1 severe asthma exacerbation in the past year.

Plain Language Summary: Chronic rhinosinusitis with nasal polyps (CRSwNP) is a condition that causes partial or complete blockage of the nose, making it difficult to breathe. This has a negative effect on many aspects of a person's life, and a person with severe CRSwNP is more likely to be affected by diseases such as asthma. People with asthma and CRSwNP are more likely to have severe forms of both diseases, making both conditions challenging to treat. A drug called dupilumab, which is injected under the skin every other week, has been approved for treating people with both CRSwNP and asthma. This article presents initial findings from a large study called AROMA, which observed people with severe CRSwNP for 3 years after beginning dupilumab treatment. The study also looked at the characteristics of patients with CRSwNP and asthma before they began dupilumab treatment. The initial findings showed that 1 in 3 people with CRSwNP and asthma had at least 1 severe asthma attack in the year before beginning dupilumab treatment. People in the study with CRSwNP and asthma were more likely to take steroids than people with just CRSwNP.

Keywords: asthma, chronic rhinosinusitis with nasal polyps, dupilumab, real-world evidence, type 2 inflammation

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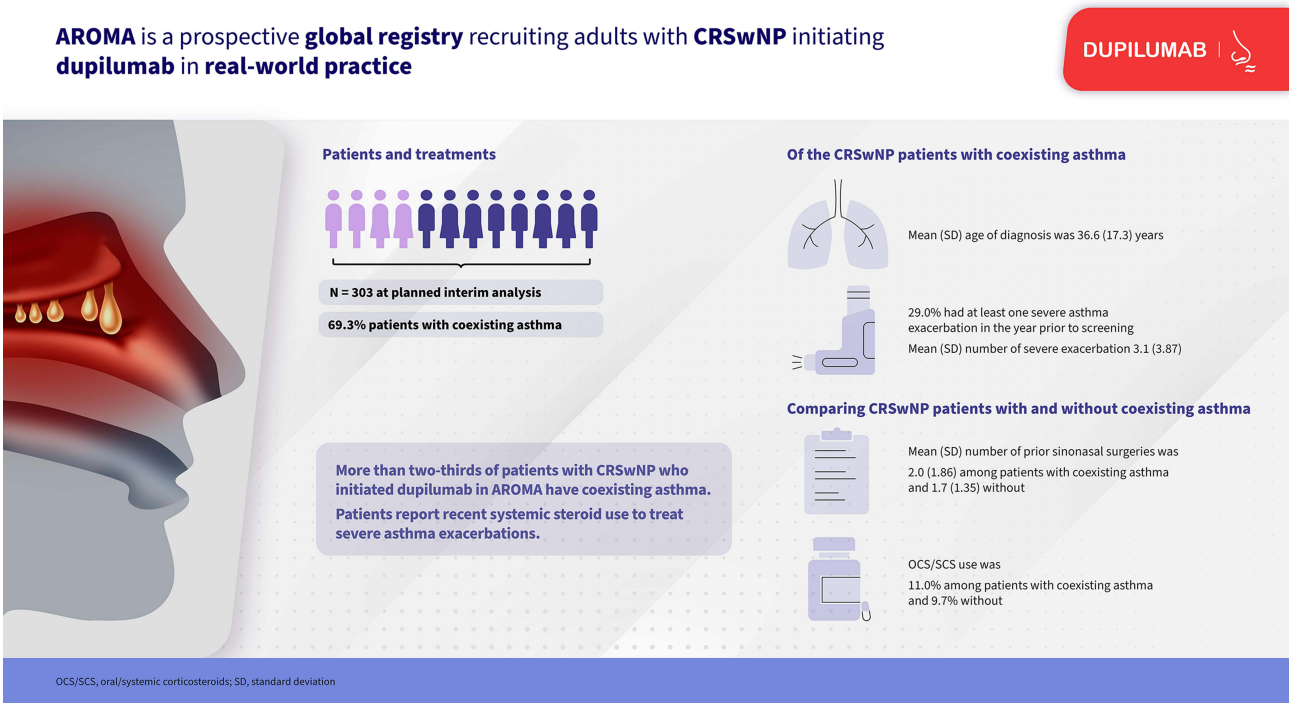
Graphical Abstract



Introduction

Chronic rhinosinusitis with nasal polyps (CRSwNP) is associated with a high symptom burden and a significant reduction in health-related quality of life (HRQoL), particularly in patients with moderate-to-severe disease.[1,2] CRSwNP is characterized by a predominantly type 2 inflammatory signature in the nose and paranasal sinuses.

Sinonasal mucosal inflammation often coexists with inflammation in the lower airways, and up to 67% of patients with CRSwNP have coexisting asthma.[3] In the "united airway disease" model, upper and lower airway diseases such as CRSwNP and asthma are affected by and influence each other. The presence of coexisting asthma is associated with more severe sinus disease, higher rates of corticosteroid dependence, and lower HRQoL with respect to both diseases.[4,5] This is due to increased airway inflammation, eosinophilia, and poorer lung function in patients with CRSwNP and asthma.[4] Patients with CRSwNP and coexisting asthma are more likely to undergo sinonasal surgery than those without asthma.[6,7] Additionally, asthma in the presence of CRSwNP is more exacerbation prone and difficult to control.[4]

The management of severe, uncontrolled CRSwNP remains a challenge. First-line therapies such as nasal irrigation and topical corticosteroids are often inadequate. Second-line therapies such as oral corticosteroids provide only temporary improvement in HRQoL and reduction in polyp size and are associated with systemic side effects when used long term.[1,8] Given the united airway disease model, and common type 2 inflammatory signatures present in both CRSwNP and asthma, there is a need for treatments that are effective in either and both diseases, improving both the clinical markers of disease and associated HRQoL.

In the Phase 3 SINUS-24 and SINUS-52 trials, dupilumab, a fully human VelocImmune-derived monoclonal antibody that inhibits signaling by interleukin (IL)-4 and IL-13, significantly improved objective and patient-reported outcome measures in patients with severe, uncontrolled CRSwNP.[9] In the Phase 3 LIBERTY ASTHMA QUEST trial, dupilumab reduced the rate of severe asthma exacerbations in patients with moderate-to-severe uncontrolled asthma.[10] Other studies have found dupilumab efficacious in subpopulations of patients with CRSwNP and asthma.[11–14] However, there is an evidence gap between dupilumab efficacy observed over 52 weeks in randomized clinical trials and its long-term real-world effectiveness.

The AROMA study, focusing on real-world evidence, is collecting data on the long-term effectiveness of dupilumab as represented by changes in patient-reported outcomes and HRQoL over time, and to characterize patients who receive dupilumab for CRSwNP in a real-world setting. This manuscript reports the baseline characteristics of patients enrolled in AROMA with CRSwNP and coexisting asthma as part of a planned interim analysis.

Methods

Study Design and Patient Population

AROMA is a Phase 4, prospective, observational, multicenter, global registry study being conducted in the USA, Canada, Germany, Italy, Japan, and the Netherlands. Details of the study design have been reported previously.[15] The study is recruiting adult patients who initiate dupilumab for the treatment of CRSwNP and monitors them for up to 36 months. Patients who previously received dupilumab treatment were excluded from the study. There are no restrictions on dupilumab dosage or concomitant medications during the study. The study duration for each participant is up to 36 months, with study visits at baseline and scheduled every 3 months through month 24, and then every 6 months through to the planned end of the study at month 36. This study protocol was reviewed and approved by Advarra, a commercial Institutional Review Board, Approval No.: Pro00054731. The study conformed to the 1976 Declaration of Helsinki. All patients provided written informed consent before enrollment and any study-related procedure.

Assessments

Baseline assessments included patient demographics, disease characteristics, medical history, and coexisting type 2 inflammatory diseases. The 22-item Sino-Nasal Outcome Test (SNOT-22) and the Work Productivity and Activity Impairment Questionnaire for CRSwNP (WPAI-CRSwNP) were assessed at baseline, every 3 months for the first 2 years, and every 6 months in the last year of the study. Patients with coexisting asthma were requested to complete the Mini Asthma Quality of Life Questionnaire and the 6-item Asthma Control Questionnaire (ACQ-6). Additional measures such as the University of Pennsylvania Smell Identification Test (UPSIT), the Sniffin Stick Test, Lund–Mackay computed tomography (LMK-CT) score, peak nasal inspiratory flow, fractional exhaled nitric oxide (FeNO), and spirometry were collected where available. Total symptom score (TSS), nasal congestion (NC), and loss of smell (LoS) were completed daily after an initial 4-week period from the screening or baseline visit, then daily over 2-week periods commencing at weeks 10, 22, 46, 70, 94, 118, and 142, and at early termination visit.

Statistical Analysis

As this is an observational registry study, the results for symptoms and HRQoL are summarized descriptively. *T*-test p-values are derived from the Satterthwaite method due to unequal variances between the subgroups with and without coexisting asthma.

Results

Baseline Characteristics

As of February 2023, the study had recruited 303 patients, including 210 (69.3%) patients with coexisting asthma. Compared with patients without coexisting asthma, patients with coexisting asthma were slightly older (mean age [standard deviation (SD)] 52.6 [13.2] years versus 46.8 [12.9] years) and less likely to be male (46.2% versus 57.0%) (Table 1). Rates of previous sinonasal surgery were similar between the 2 groups (62.4% versus 60.2%) and the mean (SD) number of prior surgeries was 2.0 (1.9) versus 1.7 (1.4), respectively.

Disease Burden

Among patients with coexisting asthma, the mean (SD) age of asthma diagnosis was 36.6 (17.3) years (Table 2). Sixty-one patients (29.0%) had at least 1 severe asthma exacerbation in the year prior to screening, and the mean (SD) number of severe exacerbations in this timeframe was 3.1 (3.9). Eight patients required hospitalization to treat a severe asthma exacerbation in the year prior to screening, and the mean (SD) number of hospitalization days for these patients was 1.9 (0.6).

Table 1 AROMA Patient Demographics with and without Coexisting Asthma

Characteristic	With Coexisting Asthma (n = 210)	Without Coexisting Asthma (n = 93)	Total (n = 303)
Age, years			
Mean (SD)	52.6 (13.2)	46.8 (12.9)	50.8 (13.4)
Gender, n, %			
Male	97 (46.2)	53 (57.0)	150 (49.5)
Race, n, %			
White	133 (63.3)	66 (71.0)	199 (65.7)
Black or African American	17 (8.1)	9 (9.7)	26 (8.6)
Asian	39 (18.6)	10 (10.8)	49 (16.2)
American Indian or Alaska Native	1 (0.5)	1 (1.1)	1 (0.3)
Multiple	9 (4.3)	4 (4.3)	10 (3.3)
Not reported	10 (4.8)	2 (2.2)	14 (4.6)
Unknown	1 (0.5)	1 (1.1)	3 (1.0)
Weight, kg			
Mean (SD)	79.7 (23.2)	83.8 (19.7)	81.0 (22.2)
BMI, kg/m^2			
Mean (SD)	27.7 (6.8)	28.6 (6.1)	28.0 (6.6)
Previous sinonasal surgery, n, %	131 (62.4)	56 (60.2)	187 (61.7)
Mean (SD)	2.0 (1.9)	1.7 (1.4)	1.9 (1.7)

Abbreviations: BMI, body mass index; SD, standard deviation.

Table 2 Baseline Asthma Disease Burden

Characteristic	Total (n = 303)
Age at diagnosis of asthma, years	
n	201
Mean (SD)	36.6 (17.3)
Number of severe asthma exacerbations during the past 1 year prior to screening visit	
n	61
Mean (SD)	3.1 (3.9)
Total number of treatment days of systemic corticosteroids used to treat severe asthma exacerbation in the past 1 year prior to screening visit	
n[a]	40
Mean (SD)	15.5 (17.3)
Total number of days of hospitalization (any type of unit) to treat severe asthma exacerbation in the past 1 year prior to screening visit	
n[a]	8
Mean (SD)	1.9 (0.6)

Note: [a]Some data are missing or not recorded.
Abbreviation: SD, standard deviation.

Among all screened patients with asthma (n = 168), the baseline mean (SD) ACQ-6 score was 1.4 (1.2), with 40.5% of patients having poorly controlled asthma (ACQ-6 ≥1.5) (Table 3). The mean (SD) FeNO (n = 51) was 53.3 (63.8) parts per billion (ppb), the mean percent predicted forced expiratory volume in 1 second (FEV_1) was 88.8%, and the percentage of patients with moderate-to-severe reduction (FEV_1 < 60%) in lung function was 7.1%.

Table 3 AROMA Population Baseline Respiratory Characteristics

Characteristic	Total (n = 303)
Highest PNIF, L/min	
n, %	48 (15.8)
Mean (SD)	79.3 (33.2)
Predicted pre-bronchodilator FEV_1, L	
n, %	70 (23.1)
Mean (SD)	2.9 (0.7)
Best pre-bronchodilator FEV_1, L	
n, %	70 (23.1)
Mean (SD)	2.7 (0.8)
Percent predicted pre-bronchodilator FEV_1, %	
n, %	70 (23.1)
Mean (SD)	88.8 (18.8)
<60, n, %	5 (7.1)
≥60 to <80, n, %	15 (21.4)
≥80, n, %	50 (71.4)
Predicted FVC, L	
n, %	69 (22.8)
Mean (SD)	3.6 (0.8)
Percent predicted FVC, %	
n, %	70 (23.1)
Mean (SD)	98.5 (16.9)
PEF, L/s	
n, %	68 (22.4)
Mean (SD)	6.6 (7.1)
Baseline FeNO level, ppb	
n, %	51 (16.8)
Mean (SD)	53.3 (63.8)
Baseline ACQ-6 score	
n, %	168 (55.4)
Mean (SD)	1.4 (1.2)
≥1.5, n, %	68 (40.5)
Mini-AQLQ score	
Symptoms	
n, %	168 (55.4)
Mean (SD)	5.0 (1.5)
Activity limitation	
n, %	168 (55.4)
Mean (SD)	5.6 (1.3)
Emotional function	
n, %	168 (55.4)
Mean (SD)	5.2 (1.5)

(*Continued*)

Table 3 (Continued).

Characteristic	Total (n = 303)
Environmental stimuli	
n, %	168 (55.4)
Mean (SD)	5.0 (1.6)

Abbreviations: ACQ-6, 6-item Asthma Control Questionnaire; FeNO, fractional exhaled nitric oxide; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; mini-AQLQ, Mini Asthma Quality of Life Questionnaire; PEF, peak expiratory flow; PNIF, peak nasal inspiratory flow; ppb, parts per billion; SD, standard deviation.

Patient-Reported Outcomes

TSS and LoS were slightly numerically higher in patients with coexisting asthma than in patients without (mean [SD] TSS: 5.5 [2.1] versus 5.3 [2.6]; LoS: 2.3 [1.0] versus 2.0 [1.2], respectively) (Table 4). NC scores were similar in both groups (mean [SD] 1.8 [0.9] versus 1.8 [0.9]). SNOT-22, LMK-CT, and UPSIT scores were slightly lower in the coexisting asthma group. WPAI-CRSwNP scores across all domains were numerically lower in patients with coexisting asthma compared with those without. There were no statistically significant differences between patient groups in patient-reported outcomes.

Corticosteroid and Biologic Use

Ongoing leukotriene receptor antagonist use at baseline was higher among patients with coexisting asthma than without (41.0% versus 16.1%) (Table 5). Ongoing oral/systemic corticosteroid (OCS/SCS) use at baseline for either CRSwNP or asthma was similar among patients with coexisting asthma and those without (11.0% versus 9.7%). Intranasal corticosteroid (INCS) use was slightly lower among patients with coexisting asthma than without (34.3% versus 36.6%).

Discussion

Asthma frequently coexists with CRSwNP, and the coexistence is often correlated with more severe sinus disease. In addition, it is hypothesized that asthma is frequently undiagnosed in patients with CRSwNP, or that a subpopulation of patients with

Table 4 Patient Baseline CRSwNP Disease Burden

	With Coexisting Asthma (n = 210)		Without Coexisting Asthma (n = 93)		p-value
	n	Mean (SD)	n	Mean (SD)	
Total symptom score[a] (scale 0–9)	185	5.5 (2.1)	83	5.3 (2.6)	0.6076
Loss of smell[a] (scale 0–3)	185	2.3 (1.0)	83	2.0 (1.2)	0.0597
Nasal congestion[a] (scale 0–3)	185	1.8 (0.9)	83	1.8 (0.9)	0.9174
SNOT-22 total score[a] (scale 0–110)	166	44.7 (21.1)	78	46.9 (24.5)	0.5074
UPSIT[a] (scale 0–40)	24	14.2 (12.4)	23	15.7 (13.1)	0.6825
LMK-CT[a] (scale 0–24)	47	15.6 (5.9)	19	16.0 (6.1)	0.7876
WPAI-CRSwNP (0–100%)					
Work time missed	119	5.8 (15.4)	64	6.0 (15.7)	0.9235
Work impairment	119	31.5 (25.1)	64	40.6 (26.3)	0.0248
Overall impairment	119	34.5 (27.1)	64	43.2 (28.1)	0.0447
Activity impairment	165	39.9 (28.3)	78	42.8 (28.0)	0.4564

Note: [a]Higher scores indicate greater disease severity, except for UPSIT, for which lower scores indicate greater disease severity.
Abbreviations: CRSwNP, chronic rhinosinusitis with nasal polyps; LMK-CT, Lund–Mackay computed tomography; SD, standard deviation; SNOT-22, 22-item Sino-Nasal Outcome Test; UPSIT, University of Pennsylvania Smell Identification Test; WPAI-CRSwNP, Work Productivity and Activity Impairment Questionnaire for CRSwNP.

Table 5 Ongoing Medications at Baseline in Patients with and without Coexisting Asthma

n, %	With Coexisting Asthma (n = 210)	Without Coexisting Asthma (n = 93)
Oral/systemic corticosteroids	23 (11.0)	9 (9.7)
Prednisone	6 (2.9)	3 (3.2)
Betamethasone dipropionate	5 (2.4)	1 (1.1)
Methylprednisolone	2 (1.0)	0
Prednisolone	2 (1.0)	0
Budesonide	1 (0.5)	0
Mometasone	1 (0.5)	0
Betamethasone; dexchlorpheniramine maleate	0	1 (1.1)
Uncoded	6 (2.9)	4 (4.3)
Intranasal corticosteroids	72 (34.3)	34 (36.6)
Azelastine hydrochloride; fluticasone propionate	1 (0.5)	0
Budesonide	19 (9.0)	12 (12.9)
Fluticasone	1 (0.5)	0
Fluticasone furoate	3 (1.4)	1 (1.1)
Fluticasone propionate	17 (8.1)	14 (15.1)
Mometasone	19 (9.0)	2 (2.2)
Mometasone furoate	16 (7.6)	7 (7.5)
Mometasone furoate monohydrate	1 (0.5)	0
Leukotriene receptor antagonists	86 (41.0)	15 (16.1)
Montelukast	46 (21.9)	7 (7.5)
Montelukast sodium	38 (18.1)	8 (8.6)
Pranlukast hydrate	2 (1.0)	0
Biologics	4 (1.9)	0
Benralizumab	2 (1.0)	0
Fremanezumab-vfrm	1 (0.5)	0
Vedolizumab	1 (0.5)	0

CRSwNP has no asthma diagnosis despite indicators of lower airway dysfunction, eg, elevated FeNO.[16,17] The high (>50 ppb) average FeNO levels at baseline in AROMA suggest that the patients' coexistent asthma has a type 2 phenotype.

A high proportion of patients (69.3%) with CRSwNP who initiated dupilumab in AROMA have coexisting asthma, and almost one-third reported at least 1 severe asthma exacerbation in the year prior to screening. The mean age of asthma onset in AROMA (36.6 years) was similar to that in SINUS-24/-52 Phase 3 studies (combined 34.8 years intent-to-treat population)[9] and slightly higher than in LIBERTY ASTHMA QUEST (27.0 years intent-to-treat population).[10] As in other studies, patients with CRSwNP and coexisting asthma were more likely to be female and report prior OCS use than patients without asthma.[11] Although rates of prior sinonasal surgery were similar, patients with coexisting asthma had a slightly higher mean number of prior surgeries than those without (2.0 versus 1.7).

Patient-reported outcomes and assessments of disease severity showed mixed results, with some scoring systems indicating greater disease severity in the coexisting asthma group (TSS, LoS, UPSIT), and some systems showing less (SNOT-22, LMK-CT). However, none of the differences achieved statistical significance, due to relatively small sample sizes and missing data collection. AROMA patients with coexisting asthma did not appear to have significantly higher OCS/SCS burden than patients without coexisting asthma, though the study did not record the full duration of OCS/SCS and INCS use prior to enrollment.

Regardless of asthma status, the patients enrolled in AROMA demonstrate disease heterogeneity, highlighting the importance of an interdisciplinary approach to the treatment of CRSwNP and its associated type 2 comorbidities.[18,19]

The limitations of this interim AROMA analysis include the relatively small patient sample size, which makes it difficult to draw statistically significant conclusions about disease severity in the 2 subgroups. Additionally, inhaled

corticosteroid and asthma-only medication data were not collected. Future analyses will address some of these data gaps about the prevalence of CRSwNP with coexisting asthma and the physiologic connections between the 2 diseases.

Conclusion

In conclusion, more than two-thirds of adult patients with CRSwNP who initiate dupilumab in AROMA have coexisting asthma. Of these patients, one-third report at least 1 severe asthma exacerbation in the past year. The elevated FeNO levels at baseline, while not in the majority of patients, indicate a high level of airway dysfunction in the AROMA population, supporting the need for a multidisciplinary approach to the treatment of CRSwNP.

Abbreviations

ACQ-6, 6-item Asthma Control Questionnaire; BMI, body mass index; CRSwNP, chronic rhinosinusitis with nasal polyps; FeNO, fractional exhaled nitric oxide; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; HRQoL, health-related quality of life; IL, interleukin; INCS, intranasal corticosteroid; LMK-CT, Lund–Mackay computed tomography; LoS, loss of smell; mini-AQLQ, Mini Asthma Quality of Life Questionnaire; NC, nasal congestion; OCS, oral corticosteroid; PEF, peak expiratory flow; PNIF, peak nasal inspiratory flow; ppb, parts per billion; SCS, systemic corticosteroid; SD, standard deviation; SNOT-22, 22-item Sino-Nasal Outcome Test; TSS, total symptom score; UPSIT, University of Pennsylvania Smell Identification Test; WPAI-CRSwNP, Work Productivity and Activity Impairment Questionnaire for CRSwNP.

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethics Approval and Informed Consent

This study protocol was reviewed and approved by Advarra, a commercial Institutional Review Board, Approval No.: Pro00054731. All patients provided written informed consent.

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Author Contributions

All authors made a significant contribution to the work reported, through the conception, study design, execution, acquisition of data, analysis, and/or interpretation; took part in drafting, revising, and/or critically reviewing the article; gave final approval of the version to be published; agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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