

**TABLE I.** Characteristics of participants before treatment with omalizumab

ID	Age (y)	Sex	Urticaria type	Duration	Comorbidities	Previous medication	Total IgE (kU/L)	BHR test
1	47	M	DPU, HCU	3 y	ANA, DA		107	0
2	64	M	CSU	20 y	A, DM, DA, HT	MTX	NA	0
3	37	F	DPU	4 y	H, HT	AZA	928	NA
4	36	F	CSU	15 y		LTRA	75.2	0
5	65	F	CSU	4 y		AZA	83.1	0
6	43	F	CSU, UF	5 y		LTRA, CS, AZA	63.4	0
7	16	F	CSU	7 mo		LTRA, CS	141	0
8	23	F	CSU	3 y	ANA	LTRA	82.2	0
9	39	F	CSU, DPU	NA		CS, CsA, AZA	32.1	0
10	14	F	CSU	2 y	A	LTRA, CS	448	0
11	37	M	CSU	4 y		CS, AZA	59.7	0
12	10	M	CSU	1 y		LTRA, CS	94.5	0
13	53	M	CSU	8 y		LTRA, CS, CsA, D	169	0
14	65	F	CSU	18 y	A	AZA	51.4	0
15	12	F	CSU, DPU, UF	3 y			19.4	0
16	24	F	CSU	1 y	DA		450	0
17	19	F	CSU, DPU, HCU	4 y	AR, D, DA	LTRA, AZA, UVB	1824	0
18	52	F	CCU, CU	3 y			97.4	0
19	36	F	CSU	3 y		CS, AZA	131	0
20	47	F	CSU, CU	20 y	D, DA, DM		454	NA
21	14	F	CSU	4 y	DM	LTRA	NA	0
22	32	M	CSU	14 y	AR		NA	NA
23	43	M	CSU	1 y	A	LTRA, CS, AZA	34	0
24	19	F	CCU	3 y	AR, D	LTRA	138	0
25	20	F	CSU, UF	1 y	A, D	LTRA	35.1	NA
26	47	F	CSU, DPU	3 y	AR, H	LTRA, CS, CsA, MTX, D, MMF	118	0
27	12	M	CSU	7 y	AR, H		8.4	1

A, Asthma; AD, atopic dermatitis; ANA, anaphylaxis; AR, allergic rhinitis; AZA, azathioprine; BHR, basophil histamine release; CCU, cold contact urticaria; CS, corticosteroid; CsA, cyclosporine A; CSU, chronic spontaneous urticaria; CU, contact urticaria; D, dapsona; D, depression; DA, drug allergy; DM, diabetes mellitus; DPU, delayed pressure urticaria; F, female; FA, food allergy; H, hypothyroidism; HCU, heat contact urticaria; HT, hypertension; LTRA, leukotriene receptor antagonist; M, male; MMF, mycophenolate mofetil; MTX, methotrexate; NA, not assessed; UF, urticaria factitia; UVB, ultraviolet B light.

responding to conventional treatment should be treated with omalizumab in an individualized regimen as described above. For economic reasons, treatment should, however, be restricted to recalcitrant cases where systemic treatment with fourth-line drugs such as cyclosporine, methotrexate, dapsona, or mycophenolate has proven ineffective or not feasible.

Pinar Uysal, MD  
Esben Eller, MSc, PhD  
Charlotte G. Mortz, MD, PhD  
Carsten Bindslev-Jensen, MD, PhD, DMSci

From the Department of Dermatology and Allergy Centre, Odense Research Center for Anaphylaxis, Odense University Hospital, University of Southern Denmark, DK-5000 Odense C, Denmark. E-mail: carsten.bindslev-jensen@rsyd.dk.

Disclosure of potential conflict of interest: The Allergy Center, Odense University Hospital, is participating in the Asterial project (Q4881g) on treatment with omalizumab. E. Eller has received one or more payments for lecturing from or is on the speakers' bureau for Thermo Fisher. C. Bindslev-Jensen is a board member for Novartis; has consultancy arrangements with Novartis and MSD; and has received one or more payments for lecturing from or is on the speakers' bureau for Novartis, MSD, and Thermo Fisher. The rest of the authors declare that they have no relevant conflicts of interest. These data were presented at the European Academy of Allergy and Clinical Immunology Congress 2012 as a poster with abstract number 1747.

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Available online December 18, 2013.  
<http://dx.doi.org/10.1016/j.jaci.2013.10.015>

**Characterization of factors associated with systemic corticosteroid use in severe asthma: Data from the Severe Asthma Research Program**

*To the Editor:*

Inhaled corticosteroids remain gold standard asthma therapy; however, some patients appear to require chronic systemic

**TABLE 1.** Selected covariates for subjects with SA with and without SCS therapy at enrollment\*

	No SCS	SCS requirement	P value	Model covariate odds ratio (P value)
Age at enrollment (y), mean $\pm$ SD	43.10 $\pm$ 12.77 n = 222	43.76 $\pm$ 11.39 n = 97	.662	NA
Sex, n (%)			.600	
Male	80 (36.0)	32 (33.0)		
Female	142 (64.0)	65 (67.0)		1.32 (.257)
Race, n (%)			.047	
European White	141 (63.5)	72 (74.2)		
Black or African American	68 (30.6)	17 (17.5)		0.61 (.088)
Other	13 (5.9)	8 (8.2)		0.75 (.540)
Body mass index			.124	
<30	111 (50.0)	39 (40.6)		
$\geq$ 30	111 (50.0)	57 (59.4)		1.59 (.049)
Ever have recurrent bronchitis, n (%)			.009	
No	129 (59.7)	39 (43.3)		1.78 (.019)
Yes	87 (43)	51 (56.7)		
Ever have acute or recurrent sinusitis, n (%)			.091	
No	108 (49.8)	37 (39.4)		
Yes	109 (50.2)	57 (60.6)		1.38 (.183)
Any positive skin reaction to allergen, n (%)			.091	
No	29 (15.5)	20 (24.1)		
Yes	158 (84.5)	63 (75.9)		0.62 (.114)
Baseline FEV <sub>1</sub> (% predicted), n (%)			<.001	
>80%	56 (25.2)	14 (14.4)		
60% to 80%	76 (34.2)	20 (20.6)		1.12 (.759)
<60%	90 (40.5)	63 (64.9)		2.23 (.058)
Baseline FVC (% predicted), mean $\pm$ SD	79.09 $\pm$ 18.00	70.95 $\pm$ 19.03	<.001	0.99 (.202)
Log <sub>10</sub> exhaled nitric oxide, mean Log <sub>10</sub> FENO $\pm$ SD	1.43 $\pm$ 0.36	1.59 $\pm$ 0.41	.001	2.71 (.009)

NA, Not applicable/available.

\*The last column exhibits calculated odds ratio for each model covariate and the associated P value.

corticosteroids (SCSs) for optimal control. Although no previous studies have addressed factors predisposing a patient with severe asthma (SA) to require SCSs, obesity, persistent inflammation, and airway obstruction have all been associated with higher inhaled and SCS use.<sup>1,2</sup> The study's purpose was to identify factors that could increase the likelihood for chronic SCS use in adults with SA from the Severe Asthma Research Program (SARP) to help identify high-risk patients. Biologic and clinical factors were compared between rigorously defined participants with SA who used SCSs regularly versus those who did not. Logistic regression analysis identified the most predictive factors.

Cross-sectional data from participants with SA ( $\geq$ 18 years) in the multicenter SARP population were used as previously defined.<sup>3</sup> Participants with SA met 1 of 2 major criteria and at least 2 of 7 minor criteria as per the American Thoracic Society 2000 definition.<sup>3</sup> Initial analysis included categories of demographic characteristics, smoking status, medical history, blood/sputum analysis, fractional exhaled nitric oxide (FENO), pulmonary function, medication use, atopy, and family history. Variables were chosen on the basis of their potential as a pathophysiologic cause and clinical utility.

Chronic SCS use was defined as a "yes" answer to the following question: "Do you take systemic corticosteroids (pills or shots but not bursts) on a regular basis (more than 6 of the last 12 months)?" Race was self-reported as European White, African American, or other (European White as the reference), and obesity was defined as a body mass index of 30 or more. Variables related to smoking included ever smoked, exposed to second-hand smoke, and pack-year history. Atopy was defined as 1 or more positive allergen skin prick tests with a wheal diameter of

more than 3 mm and greater than control (yes/no). FEV<sub>1</sub> percent predicted (FEV<sub>1</sub>%pred) was categorized into more than 80, 60 to 80, and less than 60 (>80 as the reference). Forced vital capacity percent predicted (FVC%pred) was represented as a mean value. Only participants with FENO data and fewer than 10 pack years of smoking were eligible for this study (to reduce the need to impute biological and clinical data).

Statistical analysis was conducted by using SAS JMP, SAS 9.2 (SAS, Cary, NC), STATA (College Station, Tex), and SPSS (Armonk, NY). After univariate analysis and collapsing significant variables for categories, logistic regression was performed by using demographic characteristics (age at enrollment, sex, race, obesity), medical history (physician-diagnosed recurrent bronchitis and acute or recurrent sinusitis), pulmonary function (FEV<sub>1</sub>%pred and FVC%pred), FENO (transformed to Log<sub>10</sub>FENO), and atopic status. Significant variables not considered included elements of disease impact (eg, quality-of-life scores, health care utilization, and medication use), nonsignificant associations (eg, smoking, family history, and IgE), and pathobiologic factors known to be regulated by SCSs (eg, blood neutrophils and eosinophils).

Stepwise logistic regression started with demographic, then clinical, pulmonary function, and laboratory variables (ie, FENO and atopy). Multiple imputation was used for missing data (eg, missing data included atopy [15.4% imputed], recurrent bronchitis [4.1% imputed], and acute or recurrent sinusitis [2.2% imputed]).

Chronic SCS use was reported in 97 (30.4%) of the 319 participants with SA, most of whom were on high-dose inhaled corticosteroids (91.6%). Participants reporting chronic SCS use

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