Chronic Spontaneous Urticaria: Backgrounder

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What is chronic spontaneous urticaria (CSU)?

Chronic spontaneous urticaria (CSU), also known as chronic idiopathic urticaria (CIU) in the US, is a distressing skin condition that causes red, swollen, itchy and sometimes painful hives or "wheals" on the skin^{1,2}. At any given time, the worldwide prevalence of CSU is 0.5% to $1\%^3$. A patient is diagnosed when hives spontaneously present and reoccur for at least six weeks³. Women are twice as likely as men to be diagnosed with the disease and most people first develop symptoms between the ages of 20 and 40^3 .

CSU has negative effects on quality of life, which frequently include sleep deprivation and psychological comorbidities such as depression and anxiety³. Research indicates this negative impact on quality of life is similar to patients with ischemic heart disease, with patients feeling a similar lack of energy, social isolation and emotional upset^{4,5}. The frequent failure to identify a specific underlying cause of CSU, its unpredictable symptoms and a high disease burden lead to frustration among patients and their doctors³.

What are the symptoms of CSU?

Symptoms of CSU include the appearance of flare-type skin reactions and itchy welts, often described as hives or wheals³. The itch is often persistent, even at night-time, and is not relieved with an approved dose of anti-histamine. Between 40 and 50% of CSU patients also experience angioedema, a swelling in the deep layers of the skin⁶.

What may trigger a person to develop CSU?

In CSU symptoms appear spontaneously and there is no specific external trigger for the individual hives or swelling that develop^{3,7}. Research into the underlying cause of the disease has uncovered the role of the autoimmune system in many patients, and other aggravating factors may include stress, fatigue and infection⁸.

How is CSU diagnosed and treated?

CSU is difficult to diagnose and manage because the trigger is unknown or, in the case of factors like the autoimmune system, cannot be easily changed. If a person presents with symptoms, he or she should be evaluated by a healthcare professional who may ask the patient to record any potential triggers e.g., cold, heat, exercise pressure or other physical triggers, and the area and frequency of the hives for a period of one to two weeks. This aids the diagnosis to exclude obvious underlying causes and/or eliciting triggers for the condition ⁹. Further CSU testing may include evaluations of the skin, blood and urine¹⁰.

Antihistamines are currently the mainstay of therapy for CSU; however, more than 50% of patients on approved doses do not achieve symptom relief³. Medical guidelines allow for increased doses of antihistamines, up to four times the approved dose, to increase symptom control in some patients³. However, there remains a critical need for new treatment options as up to 40% of CSU patients fail on these increased antihistamine doses⁶.

References

- 1 Asthma and Allergy Foundation of America (AAFA) website. "Chronic Urticaria (Hives)." Accessed November 14, 2012. Available at: <u>http://www.aafa.org/display.cfm?id=9&sub=23&cont=328</u>.
- 2 American Academy of Allergy Asthma & Immunology (AAAAI) website. "Skin Allergy Overview." Accessed November 14, 2012. Available at: <u>http://www.aaaai.org/conditions-and-treatments/allergies/skin-allergy.aspx</u>.
- 3 Maurer M, Weller K, Bindslev-Jensen C, et al. Unmet clinical needs in chronic spontaneous urticaria: A GA(2)LEN task force report. *Allergy*. 2011;66:317–330.
- 4 Maurer M, Rosén K, Hsieh HJ, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. *NEJM* 2013; DOI: 10.1056/NEJMoa1215372
- 5 O'Donnell BF, Lawlor F, Simpson J, et al. The impact of chronic urticaria on the quality of life. *Br J Dermatol* 1997;136:197-201.
- 6 Sánchez-Borges M, Asero R, Ansotegui IJ, et al. Diagnosis and treatment of urticaria and angioedema: a worldwide perspective (position paper). *World Allergy Organization Journal.* 2012; 5:125–147.
- 7 Zuberbier T, Asero R, Bindslev-Jensen C, et al. EAACI/GA2LEN/EDF/WAO guideline: definition, classification and diagnosis of urticarial. *Allergy*. 2019;64:1417–1426.
- 8 Maurer M, Bindslev-Jensen C, Gimenez-Arnau A, et al. Chronic Idiopathic Urticaria (CIU) is no longer idiopathic: time for an update. *Br J Dermatol.* 2013 Feb;168(2):455-456.
- 9 Zuberbier T, et al. Guideline: definition, classification and diagnosis of urticaria. Allergy 2009;64:1417–26
- 10 American College of Allergy, Asthma & Immunology (ACAAI) website. "Hives (Urticaria)." http://www.acaai.org/allergist/allergies/Types/skin-allergies/hives/Pages/default.aspx. Accessed November 14, 2012.



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