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Eliminating Low-Value Medical Care in Chronic Spontaneous Urticaria

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Chronic spontaneous urticaria (CSU) carries an economic burden for patients due to therapeutic costs, medical evaluations, work absence, and emergency department visits. Laboratory testing represents a substantial, unnecessary contributor to the financial burden of this disease. It is well recognized that the vast majority of cases of chronic urticaria (CU) have no underlying cause and are thus diagnosed as CSU. Current US and international guidelines on the evaluation of CSU acknowledge that no testing may be necessary, yet allow for the performance of limited testing at the discretion of the provider. Consequentially, this can lead to variability in the evaluation of CSU between clinicians, with many ordering tests that are unlikely to impact treatment or lead to improved patient outcomes.

In the current issue of the *Journal of Allergy and Clinical Immunology: In Practice*, Shaker et al¹ use decision modeling to reevaluate the need for the performance of screening labs to care for patients with CSU. This builds upon previous work that has demonstrated the frequency and futility of ordering screening tests for CU. In 2011, Tarbox et al² published a retrospective analysis of laboratory test results in 356 patients with CU and angioedema. They reported that 17% of the results for 1872 tests ordered were abnormal, only 1.60% of patients underwent further evaluation, and a change in management was made in only 1 patient on the basis of abnormal test result findings. Similarly, Carrillo-Martin et al³ analyzed the electronic records of 725 patients with urticaria to evaluate the frequency at which specific tests were ordered, the costs of testing, and the resulting changes in management and outcome in patients who underwent at least 1 test. They found that 543 (74.8%) had at least 1 test performed, with normal results in more than 90% of patients. Only 8 patients were given a different diagnosis as a result of testing, and 5 patients had a change in outcome. Together, these studies suggest that screening tests for CU are unlikely to lead to improved care and increase health costs.

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In this issue, Shaker et al provide evidence that our approach to evaluating patients with CSU needs to change as a community. The authors sought to evaluate the cost-effectiveness of laboratory screening tests for patients with CSU. Specifically, they created a Markov model that incorporated cohort analysis and patient-level simulations for adult patients over a 10-year time period who were randomized to undergo either baseline screening laboratory testing or no testing based on the findings by Tarbox et al.² Costs were obtained from published values in 2019 with a projected 3% annual increase.

Using decision modeling, Shaker et al evaluated several scenarios on the basis of disease severity (eg, infrequent symptoms or daily symptoms) and treatment required (eg, cetirizine, ranitidine, omalizumab, or cyclosporine). The effectiveness of laboratory testing was determined by the percentage of patients with an improved outcome (ie, CSU remission). The cost-effectiveness of ordering laboratory tests was evaluated using a willingness-to-pay threshold of \$100,000/quality-adjusted life-year using an incremental cost-effectiveness ratio in patients with untreated CSU, and patients treated with antihistamines, cyclosporine, or omalizumab. Although they did not seek to evaluate the cost-effectiveness of therapies, they did include costs of therapies in their model as well.

Notably, Shaker et al found in their modeling that only $0.16\% \pm 3.99\%$ of tests resulted in an improved outcome, and the average cost per simulated patient with a laboratory-associated improved outcome was $\$572.97 \pm \41.11 . The authors ran an analysis to identify the minimum screening cost that would be cost-effective and determined that \$67 was the threshold for cost-effective screening in patients not receiving therapy. This sum exceeds the costs of tests proposed as an option for limited screening in the Joint Task Force on Practice Parameters (JTFPP).⁴ Furthermore, this value would have needed to be less than \$200 in the omalizumab-treated group or result in resolution of CSU in 0.73% of patients in this subgroup. Thus, laboratory testing was not cost-effective, and would rarely result in an improved outcome. Disturbingly, they also found that the estimated total cost of screen tests could well exceed \$900 million.

The limitations of this study involve the methodology and model design. This model was dependent on the laboratory tests and respective costs set by the authors. Despite an extensive testing panel, some of the tests ordered by clinicians were not included in the model, such as the CU index, stool analysis for ova and parasites, and complement studies. Also not clear is the source or method of the population costs that were calculated. Setting the measure of effectiveness of laboratory testing as remission for an analysis of the cost-effectiveness of testing is debatable, because the reason for ordering tests may not be to induce remission, and substantially improving symptoms rather than inducing remission may be the goal of treatment.

The most recent JTFPP update on the diagnosis and management of acute and chronic urticaria states that “after a thorough history and physical examination, no further diagnostic testing might be appropriate for patients with CU; however, limited routine laboratory testing can be performed to exclude underlying causes.” These tests might include a complete blood count with differential, sedimentation rate and/or C-reactive protein, liver enzymes, and thyroid-stimulating hormone level.⁴ Although the JTFPP generally does

not consider cost when formulating practice parameter recommendations, it notes that “extensive routine testing is not favorable from a cost-benefit standpoint and does not lead to improved patient care outcomes” in CU patients.”⁴ The article by Shaker et al is among a growing list of reports that have clearly demonstrated that routine screening tests are not cost-effective in CSU. Screening tests will continue to be ordered routinely by clinicians as long as the guidelines do not take a definitive stand on testing, and patient /provider education is not improved. Although there has been some progress in advising against performing certain tests in CSU, the guidelines do not make a decisive statement against general screening.

Based on Shaker et al and other studies, it is time to revisit the recommendations and consider new, updated guidelines that recommend against testing in CSU given the lack of cost-effectiveness. This would eliminate care that has no benefit to the patient and reduce a tremendous cost burden on our health care system. Furthermore, achieving a unified approach among allergists could reduce doctor shopping by patients who believe an allergic etiology for their CSU needs investigation. Guideline revision may also prompt further development of resources that would improve the knowledge of patients and providers regarding the evaluation of CU, particularly with regard to testing. This could include an adjustment of the 2016 Choosing Wisely initiative of the American Board of Internal Medicine Foundation patient handout, which currently acknowledges that screening tests may be performed for CU.⁵ Other ideas include research into developing a triage tool for urticaria similar to the rapid triage tool that is available for hereditary angioedema and has 98% success rate.⁶ A CSU tool could be made available to identify the rare instances where testing may lead to a change in the management for CU, and avoid testing that is not beneficial.

Routine laboratory testing adds to the economic burden already faced by patients with CSU without providing benefit. Although it may be difficult to get specialists outside of our community to stop ordering these tests, allergists should take the lead and eliminate the practice of routine testing for CSU.

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