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Diagnostic And Therapeutic Yield Of Routine Laboratory Testing In Adults With Chronic Urticaria: A Cross-Sectional Study

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Abstract
Background: *Chronic urticaria (CU) is a common, mast cell–driven skin disease that is frequently subjected to extensive laboratory investigation, even though most cases are spontaneous and autoimmune in origin and international guidelines advocate a limited, history-directed workup. Real-world data on the value of routine testing from resource-limited settings remain scarce.*
Objective: *To determine the diagnostic and therapeutic yield of routine laboratory investigations in adults with chronic urticaria, and to characterise the frequency, nature, and clinical relevance of abnormal findings.*
Methods: *This single-centre cross-sectional study was conducted during 2023 at a tertiary allergy and respiratory centre in Baghdad, Iraq. Sixty consecutive adults with chronic urticaria underwent a standard panel of routine investigations. Abnormal results were assessed for clinical relevance and for their effect on disease outcome, defined a priori as complete remission or significant improvement of urticaria after treatment of an identified abnormality. Proportions are reported with exact (Clopper–Pearson) binomial 95% confidence intervals (CIs).*
Results: *Chronic spontaneous urticaria was present in 52 patients (86.7%; 95% CI 75.4–94.1) and chronic inducible urticaria in 8 (13.3%; 95% CI 5.9–24.6). Abnormal laboratory findings were detected in 19 patients (31.7%; 95% CI 20.3–45.0), most commonly autoimmune thyroid disease (n=6), Helicobacter pylori infection (n=5), urinary tract infection (n=4), chronic viral hepatitis (n=2), parasitic infection (n=1), and systemic lupus erythematosus (n=1). The majority of abnormalities were previously known or incidental and unrelated to urticaria activity. Only 2 patients (3.3%; 95% CI 0.4–11.5) achieved complete remission after treatment of a detected abnormality, and no statistically significant association was observed between abnormal findings and clinical improvement.*
Conclusion: *Routine extensive laboratory testing in chronic urticaria carried a very low diagnostic and therapeutic yield. A targeted approach guided by clinical history and examination is more appropriate, less costly, and aligned with international guidelines—particularly in resource-limited settings.*
Keywords: *chronic urticaria; chronic spontaneous urticaria; laboratory testing; diagnostic yield; overdiagnosis; cross-sectional study.*

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I. Introduction

Chronic urticaria (CU) is defined as the recurrence of wheals, angioedema, or both for more than six weeks.[1] It is a frequent, mast cell–driven disorder; a systematic review with meta-analysis estimated the point prevalence of chronic urticaria at approximately 0.5–1% of the general population, with a higher pooled estimate of about 1.4% in Asian populations and evidence of an increasing trend over time.[2] The condition imposes a substantial burden through its protracted course, sleep disturbance, psychological distress, and impaired performance at work and school; a large real-world study reported clinically meaningful quality-of-life impairment comparable to that of other chronic inflammatory skin diseases.[3,4]

Chronic urticaria is conventionally divided into chronic spontaneous urticaria (CSU), in which no consistent external trigger is identified, and chronic inducible urticaria (CIndU), in which wheals are reproducibly elicited by a defined physical stimulus.[1] Contemporary evidence indicates that CSU is predominantly an autoimmune or autoallergic, mast cell–driven disease rather than a classic allergen-driven one. Two principal endotypes are recognised: type I (autoallergic) CSU, mediated by IgE autoantibodies directed against self-antigens such as thyroid peroxidase, and type IIb (autoimmune) CSU, mediated by IgG autoantibodies that activate mast cells via the high-affinity IgE receptor (FcεRI) or IgE itself; estimates of the prevalence of each endotype vary with the diagnostic criteria applied.[3,5,6] These internal immunological mechanisms help explain why most patients remain symptomatic despite negative allergen and infection screening.

Notwithstanding the low probability of identifying a reversible external cause, broad laboratory panels are still routinely ordered in everyday practice.[7,8] Such indiscriminate testing increases healthcare costs, prolongs the diagnostic pathway, and frequently generates incidental or false-positive results that do not alter management but may provoke patient anxiety and unwarranted dietary or lifestyle restriction.[3,7] Accordingly, the international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline recommends a limited first-line evaluation—principally a differential blood count and inflammatory markers—with any further investigation directed by the clinical history and examination.[1,11]

Although several studies from high-income settings have reported a low yield of routine testing in chronic urticaria,[7,8,9] comparable real-world data from resource-limited healthcare systems remain limited. The present study was therefore undertaken to evaluate the diagnostic and therapeutic value of routine laboratory testing in adults with chronic urticaria managed at a tertiary allergy centre, and to quantify how often abnormal findings actually influenced disease outcome.

II. Objectives

Primary objective

- To determine the diagnostic and therapeutic yield of routine laboratory investigations in adults with chronic urticaria.

Secondary objectives

- To determine the frequency and pattern of abnormal laboratory findings.
- To assess the proportion of abnormalities that influenced clinical outcome.
- To estimate the proportion of incidental versus clinically relevant findings.

III. Materials And Methods

Study design and setting

This single-centre, cross-sectional observational study was conducted during 2023 at the Al-Zahraa Specialized Center for Allergy and Respiratory Diseases, Baghdad, Iraq, a tertiary referral centre.

Participants

Sixty consecutive adults with a clinical diagnosis of chronic urticaria were enrolled.
Inclusion criterion. Recurrent wheals and/or angioedema for more than six weeks.
Exclusion criteria. Urticarial vasculitis; drug-induced urticaria with a clear causal relationship; and incomplete clinical or laboratory data.

Clinical evaluation

All participants underwent a structured history and physical examination, with particular attention to systemic symptoms, autoimmune disease, infections, current medications, and physical triggers.

Laboratory evaluation

The routine panel applied to all participants comprised:

- Complete blood count;
- Thyroid function tests and thyroid antibodies;
- Antinuclear antibody;
- Stool examination for parasites;
- Helicobacter pylori testing;
- Urinalysis and culture;
- Hepatitis B and C screening.

Outcome definition

A clinically meaningful diagnostic yield was defined a priori as complete resolution, or significant improvement, of urticaria following treatment directed at an identified laboratory abnormality.

Statistical analysis

Data were summarised using descriptive statistics. Categorical variables are expressed as frequencies and percentages. Diagnostic and therapeutic yields, and the proportions of clinical subtypes and abnormal findings, are reported with exact (Clopper–Pearson) binomial 95% confidence intervals. The association between the presence of an abnormal laboratory finding and clinical improvement was examined using the chi-square test; given the small number of outcome events, this analysis should be regarded as exploratory and underpowered (see Limitations).

Ethics

The study was conducted in accordance with the principles of the Declaration of Helsinki. Institutional ethical approval and the method of obtaining informed consent should be stated explicitly here *[to be completed by the author]*.

IV. Results

Clinical subtypes

Sixty patients were included. Chronic spontaneous urticaria was present in 52 patients (86.7%; 95% CI 75.4–94.1) and chronic inducible urticaria in 8 patients (13.3%; 95% CI 5.9–24.6) (Figure 1).

Figure 1. Clinical subtypes of chronic urticaria (n = 60)

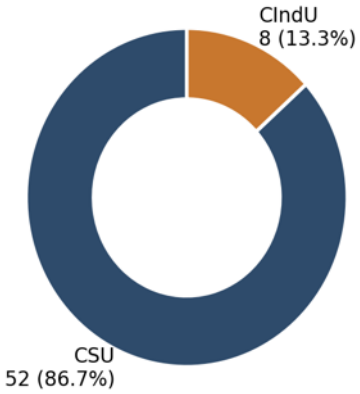

Figure 1. Distribution of chronic urticaria subtypes among the 60 study participants (CSU, chronic spontaneous urticaria; CIndU, chronic inducible urticaria).

Frequency and pattern of abnormal findings

Abnormal laboratory findings were detected in 19 patients (31.7%; 95% CI 20.3–45.0). The distribution of abnormalities is shown in Table 1 and Figure 2. The most frequent were autoimmune thyroid disease (n=6), Helicobacter pylori infection (n=5), urinary tract infection (n=4), chronic viral hepatitis (n=2), parasitic infection (n=1), and systemic lupus erythematosus (n=1).

Abnormal finding	n	% of 60	95% CI (%)
Autoimmune thyroid disease	6	10.0	3.8–20.5
Helicobacter pylori infection	5	8.3	2.8–18.4
Urinary tract infection	4	6.7	1.8–16.2
Chronic viral hepatitis	2	3.3	0.4–11.5
Parasitic infection	1	1.7	0.0–8.9
Systemic lupus erythematosus	1	1.7	0.0–8.9
Any abnormal finding	**19**	**31.7**	**20.3–45.0**

Table 1. Abnormal laboratory findings with exact (Clopper–Pearson) binomial 95% confidence intervals. Percentages are calculated over the full sample (n=60); the count of findings sums to 19 patients.

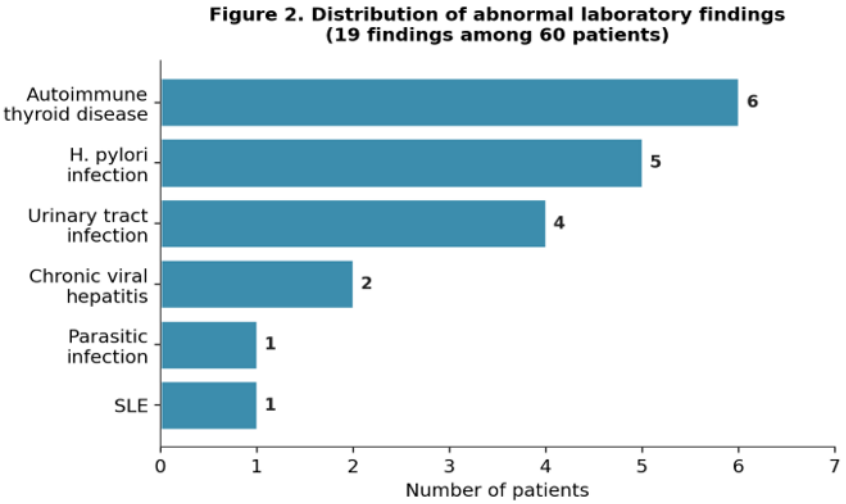

Figure 2. Distribution of abnormal laboratory findings among the 60 participants.

Clinical relevance and therapeutic yield

Most abnormalities were either previously known or clinically suspected from the history and examination, and the majority were judged incidental or unrelated to urticaria activity. Only 2 patients (3.3%; 95% CI 0.4–11.5) achieved complete remission after treatment directed at the detected condition (Figure 3). The chi-square analysis showed no statistically significant association between the presence of an abnormal laboratory finding and clinical improvement ($\chi^2 = 0.84$, $p = 0.36$, as reported); however, with only two remission events this comparison is statistically underpowered and should be interpreted cautiously. Overall, the great majority of patients showed no change in disease activity despite treatment of laboratory abnormalities, indicating a low therapeutic impact of routine screening.

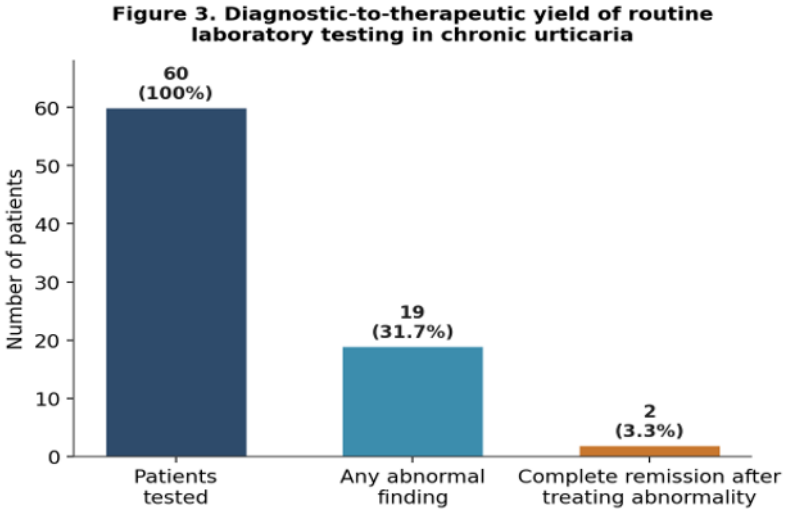

Figure 3. Attrition from the number of patients tested, to those with any abnormal finding, to those achieving complete remission after treatment of an abnormality.

V. Discussion

This study demonstrates that routine, broad laboratory testing in adults with chronic urticaria has a low clinical value. Although abnormal findings were present in approximately one-third of patients, the overwhelming majority were incidental or reflected pre-existing conditions unrelated to urticaria activity, and only 3.3% of patients achieved remission after treatment directed at a detected abnormality.

These results are consistent with a body of prior evidence. In a retrospective analysis of 356 adults with chronic urticaria/angioedema, Tarbox and colleagues found that of 1,872 tests ordered, 17% were abnormal yet only a single patient (0.28%) experienced a management change that improved outcome.[7] In a prospective comparison of diagnostic strategies, Kozel and colleagues showed that detailed history-taking with limited testing identified a cause in 45.9% of patients, scarcely fewer than the 52.7% identified by adding an extensive screening

programme, and that routine screening did not contribute substantially to diagnosis.[8] Similarly, in 339 patients, Buss and colleagues concluded that individually tailored evaluation—rather than broad initial panels—was the more rational strategy.[9] Our therapeutic yield of 3.3% sits within the low range reported by these studies and reinforces their central message.

The mechanistic rationale for this low yield is now well established. Because CSU is predominantly a mast cell–driven, autoimmune or autoallergic disorder rather than an allergen- or infection-driven one, screening for external causes is unlikely to alter management in most patients.[3,5,6] This explains why patients commonly remain symptomatic despite negative food, infection, and autoimmune panels, and why effective control is generally achieved through symptomatic, guideline-based pharmacotherapy rather than through the pursuit of an elusive underlying "cause."[1,11]

The infections detected in our cohort illustrate the difficulty of inferring causality. Helicobacter pylori infection was identified in five patients, but eradication rarely produced urticaria resolution. The relationship between H. pylori and CSU remains contentious: a meta-analysis of 22 studies found that remission was associated with the administration of antibiotic therapy irrespective of whether eradication was achieved, suggesting that any benefit may not be attributable to clearance of the organism itself.[10] Such findings caution against interpreting a positive infection screen as the cause of urticaria in the absence of supportive clinical evidence.

Autoimmune thyroid disease was the single most common abnormality (n=6). Thyroid autoimmunity is a recognised comorbidity of CSU and is associated with the type I autoallergic endotype; however, its detection generally reflects a shared autoimmune predisposition rather than a reversible driver of urticaria, and identifying it seldom alters urticaria management.[3,5] This distinction—between an associated finding and an actionable cause—is central to interpreting laboratory results in this disease.

Beyond their limited yield, unnecessary investigations carry real costs. Broad panels increase expenditure, prolong the diagnostic process, and generate incidental or false-positive results that may precipitate further testing, unwarranted dietary restriction, and patient anxiety, while delaying effective symptomatic treatment.[3,7] These considerations are amplified in resource-limited settings, where laboratory capacity and out-of-pocket costs are pressing concerns. Our findings therefore support international guideline recommendations for a limited, history-directed evaluation—typically a differential blood count and inflammatory markers, with additional tests reserved for specific clinical indications or red flags.[1,11]

VI. Limitations

Several limitations should be acknowledged. First, this was a single-centre study with a relatively small sample (n=60), which limits precision and generalisability, as reflected in the width of the reported confidence intervals. Second, recruitment at a tertiary referral centre may introduce selection bias toward more refractory disease. Third, the cross-sectional design and absence of long-term follow-up preclude conclusions about causality and about delayed treatment effects. Fourth, no formal cost-effectiveness analysis was undertaken, so statements about cost savings remain inferential. Fifth, the test of association between abnormal findings and clinical improvement was based on very few outcome events and is underpowered; an exact method (e.g., Fisher's exact test) would be more appropriate than the chi-square test, and the reported test statistic should be verified against the underlying contingency table. Finally, demographic characteristics (age, sex, disease duration) and disease-activity measures were not available for this analysis and should be incorporated in future work. Larger, multicentre studies with prospective follow-up and economic evaluation are needed to confirm these findings.

VII. Conclusion

Routine extensive laboratory testing in chronic urticaria carried very low diagnostic and therapeutic value in this cohort. Investigations should be selective and directed by the clinical history and examination, and management should focus primarily on guideline-based symptom control rather than broad etiological screening. A targeted strategy is likely to be more cost-effective and patient-centred, particularly in resource-limited settings.

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