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# Acupuncture Enhances Quality of Life and Disease Control in Chronic Spontaneous Urticaria Patients on Omalizumab: A Study of 61 Cases

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Data Interpretation D  
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**Background:** Chronic urticaria (CU) is a skin condition causing itchy hives that can significantly impact quality of life. While medications like omalizumab can help, some patients may seek additional relief. This study aimed to investigate the potential benefits of acupuncture, a traditional Chinese medicine practice, as an adjunctive therapy alongside omalizumab for CU patients.

**Material/methods:** We enrolled 31 CU patients who received acupuncture in addition to omalizumab (study group) and 30 CU patients who received omalizumab only (controls). Mean scores of each CU-Quality of life (QoL) and urticaria control test (UCT) scores after acupuncture were compared with the pre-acupuncture scores and with the scores of the controls.


**Results:** There was no significant difference in mean food limitation, symptom embarrassment, cosmetics, and sports scores before and after acupuncture ( $P>0.005$ ). Other CU-QoL scores were significantly lower after acupuncture compared to pre-acupuncture scores ( $P<0.005$ ). Mean total CU-QoL score was significantly lower ( $P<0.001$ ) and mean UCT score was significantly higher ( $P=0.001$ ) after acupuncture compared to pre-acupuncture scores. There was no significant difference in free time, falling asleep, waking up at night, tiredness, concentration, symptom embarrassment, public embarrassment, cosmetics, clothing limitation, and sports scores between the acupuncture and control groups ( $P>0.005$ ). Other CU-QoL scores were significantly lower in the acupuncture group compared to the controls ( $P<0.005$ ). Mean total CU-QoL score was significantly lower ( $P=0.006$ ) and mean UCT score was significantly higher ( $P<0.001$ ) in acupuncture group compared to the controls.

**Conclusions:** Acupuncture is an effective adjunctive therapy for CU patients already receiving omalizumab, and can improve quality of life and disease control in these patients.

**Keywords:** **Acupuncture • Omalizumab • Quality of Life • Urticaria**

**Abbreviations:** **CU** – chronic urticaria; **CU-QoL** – Chronic Urticaria- Quality of Life Questionnaire; **UCT** – urticaria control test

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## Introduction

Chronic urticaria (CU), characterized by persistent itchy wheals and/or angioedema lasting over 6 weeks [1-3], affects approximately 1% of the population, especially females, and it persists for several years in many patients [4,5]. The pathogenesis of CU is not fully elucidated; however, cutaneous mast cells are pivotal in the development of wheals and angioedema. The release of histamine and a plethora of pro-inflammatory mediators from these cells induces vasodilation and increased vascular permeability, leading to the characteristic wheals and flares. Concomitantly, the recruitment of inflammatory cells, such as eosinophils, basophils, and T lymphocytes, perpetuates the inflammatory cascade and contributes to the pruritic nature of the disease [6,7]. CU is a non-life-threatening disease that can significantly impair quality of life. Patients may suffer from persistent fatigue, sleep disturbances, emotional difficulties, and social isolation. Additionally, CU can increase the risk of depression and anxiety, further impacting overall well-being [8-10].

Beyond physical discomfort, CU significantly impacts quality of life due to psychological factors like stress and anxiety [11], itching-induced sleep disturbances [12], and the disease's prolonged nature [13]. Moreover, CU can impose an economic burden and increase healthcare costs for many countries. Currently, there is no well-known treatment that can cure CU. Approved therapies offer symptom relief but do not alter the disease's natural progression [6].

The second-generation antihistamines and leukotriene receptor antagonists are standard therapies, with omalizumab the sole approved biological agent for refractory cases [14]. Prior studies showed that omalizumab was highly effective in treatment of CU, with an average response rate of 67.9% [15].

While current treatment guidelines often advocate a sequential approach to CU, current recommendations often prioritize initiating therapy with second-generation H1-antihistamines. Additional treatments, such as omalizumab and cyclosporin, may be required to achieve optimal symptom control in many patients.

This therapeutic strategy may not be universally effective. A standardized therapeutic approach may not be universally effective in treating chronic urticaria. The heterogeneous nature of the condition, characterized by diverse underlying mechanisms, often necessitates a more individualized therapeutic regimen [16].

Since chronic urticaria greatly reduces quality of life, more and more patients world-wide are seeking alternative treatment options. Particularly in China, acupuncture and similar

treatments are widely used to manage CU [5]. Acupuncture is widely used in dermatologic diseases, including acne, atopic dermatitis, psoriasis, anogenital warts, and leg ulcers [17]. There are many reported cases of total recovery and considerable improvement in the disease process achieved by acupuncture therapy [17], showing the potential of acupuncture therapy as an alternative treatment option for dermatologic diseases, including CU.

To assess disease activity, the urticaria control test (UCT) is frequently used. Additionally, the Chronic Urticaria-Quality of Life Questionnaire (CU-QoL) is used to determine the daily effects of CU on physical and psychosocial life in the last 2 weeks [18].

The goal of this clinical study was to investigate the efficacy of acupuncture treatment on CU patients receiving omalizumab therapy, using UCT and CU-QoL scales. The study compared the UCT and CU-QoL scale scores before and after acupuncture treatment and compared these results to a control group receiving omalizumab therapy without acupuncture.

## Material and Methods

### Study Procedures

All procedures performed in this study were in accordance with the ethics standards of the local ethics committee of Balikesir University (IRB Number: 2021/177). Informed consent was obtained from all participants.

A total of 61 patients diagnosed with chronic CU were enrolled. All patients included in this study were diagnosed with chronic urticaria by a dermatologist and had a history of urticarial symptoms for at least 6 weeks. The CU-QoL and UCT were administered to all participants beforehand. The CU-QoL scores and UCT scores of the control group and study group (before and after acupuncture) were compiled from their medical records and noted. Thirty-one adult patients with a known history of chronic urticaria and receiving acupuncture therapy in addition to omalizumab were enrolled in the study group. The control group consisted of 30 adult patients with chronic urticaria receiving omalizumab treatment at our outpatient clinic and received no acupuncture therapy. We excluded patients with a history of malignancy, other inflammatory or autoimmune diseases, or history of acupuncture therapy for any other reason.

To evaluate the effects of acupuncture therapy in patients with CU receiving omalizumab treatment, the mean scores of every question of CU-QoL, the total scores of CU-QoL, and UCT scores before and after acupuncture were compared. Additionally, the mean scores of every question of CU-QoL, the total scores of

CU-QoL, and UCT scores of the study group after acupuncture therapy were compared with the control group.

### Omalizumab Treatment

All participants received the standard urticaria dose of omalizumab 300 mg by subcutaneous injection every 4 weeks. All patients receiving omalizumab were monitored for at least 2 hours after each injection.

### Acupuncture Therapy

In our center of traditional medicine, the acupuncture treatment protocol for CU patients consisted of 2 separate methods – body and ear applications. In acupuncture treatment, specific points on meridians, often named after internal organs, are targeted for needle insertion. A total of 23 needles were used in this particular treatment. These points were as follows: The first point was between the 1<sup>st</sup> and 2<sup>nd</sup> toes, proximal to the margin of the interdigital web (liver-2 point). The second point was 11.14 cm above the center of the umbilicus and 14.86 cm lateral to the anterior midline, on the mammillary line (spleen-16 point). The third point was in the depression between the highest prominence of the medial malleolus and the Achilles tendon (kidney-3 point). The fourth point was 7.43 cm proximal to kidney-3 point, at the anterior border of the Achilles tendon (kidney-7 point). The fifth point was 7.43 cm lateral to the umbilicus (stomach-25 point). The sixth point was 11.14 cm distal to lateral eye of the knee and fingerbreadth lateral to the anterior crest of the tibia, on the tibialis anterior muscle (stomach- 36 point). The seventh point was on the radial aspect of the hand, between the 1<sup>st</sup> and 2<sup>nd</sup> metacarpal bones, closer to the 2<sup>nd</sup> metacarpal bone and approximately at its midpoint (large intestine -4 point). The eighth point was with the elbow flexed, on the lateral end of the elbow crease, in a depression between the end of the crease and the lateral epicondyle of the humerus, on the extensor carpi radialis longus muscle (large intestine -11 point). The ninth point was 14.86 cm proximal to the dorsal wrist joint space, between the radius and the ulna, radial to the tendon of the extensor digitorum communis muscle (the triple burner-8 point). The tenth point was in the center of the eyebrow, with the eyes looking straight ahead, directly above the pupil (extra points: head and neck -4 point). The eleventh point was on the temple, in a depression approximately 3.715 cm lateral to the midpoint of a line connecting the lateral extremity of the eyebrow and the other canthus of eye (extra points: head and neck-5 point). Needles were placed on the body bilaterally at all points described so far. The twelfth point was on the anterior midline, between the eyebrows (extra points: head and neck-3 point). The number of needles inserted from the twelfth point was one. Patients rested for 40 minutes and then the whole-body needles were removed. Next, the second

stage of the treatment auricular acupuncture was applied. A total of 8 permanent ear acupuncture needles (4 in each ear) were placed in association with CU. This treatment protocol applied to the body and ears was applied once a week for a total of 8 weeks. Permanent ear needles were replaced with new ones every week.

### Assessment of Quality of Life and Disease Control

The physician who recorded the scores of the CU-QoL and UCT was blinded to the study and control group assignment.

CU-QoL: The validated Turkish version of this 23-item questionnaire was used to assess patients' quality of life across 6 dimensions [19]. The CU-QoL is a 23-item questionnaire measuring 6 dimensions using a Likert-type scale (5 points): pruritus-2 items, swelling- 2 items, impact on life activities-6 items, sleep problems-5 items, limits-3 items, and appearance-5 items [18]. The scores of the scale are calculated by using linear transformations of raw scores; the possible score is between 0 and 100.

UCT [14]: This 4-question tool evaluated physical symptoms, quality of life, treatment sufficiency, and subjective disease control level. Scores were recorded by a physician based on patient responses. The minimum score of UCT was 0 and the maximum score was 16. The scores over 11 was evaluated as well-controlled disease.

### Statistical Analysis

Results of the study are presented as mean±standard deviation. Due to the limited sample size (n=30), non-parametric tests were used for comparisons. Wilcoxon signed-rank test: compared the scores within the study group before and after acupuncture, because the data of before and after acupuncture included dependent variables of the patients from the study group.

The Mann-Whitney U test compared the age and the scores between the study group (post-acupuncture) and the control group, because the data of the study and control groups included independent variables. The chi-square test compared the gender distribution of the groups. SPSS software (SPSS, Inc., Chicago, IL) was used for statistical analysis, with a *P* value <0.05 considered statistically significant (with a confidence interval of 95%).

## Results

In total, 61 patients with CU were included in the study (Table 1). The study group consisted of 31 patients with CU

**Table 1.** Demographics of the groups.

|              | Acupuncture group | Control group | P value |
|--------------|-------------------|---------------|---------|
| Age          | 45±13 years       | 46±11         | 0.66    |
| Gender (F/M) | 22/9              | 21/9          | 0.34    |

**Table 2.** Comparison of the CU-QoL scores and the UCT score of study group before and after acupuncture therapy.

|                         | Before acupuncture | After acupuncture | P value |
|-------------------------|--------------------|-------------------|---------|
| Pruritis                | 3.17±0.86          | 2.05±1.09         | <0.001  |
| Wheals                  | 2.81±0.89          | 1.74±0.93         | <0.001  |
| Eyes swelling           | 1.6±1.01           | 1.12±0.72         | 0.003   |
| Lip swelling            | 1.43±0.89          | 1.01±0.55         | 0.003   |
| Work                    | 2.16±1             | 1.51±0.87         | 0.006   |
| Physical activities     | 2.33±1.09          | 1.57±0.94         | 0.003   |
| Sleep                   | 2.36±1.01          | 1.54±0.94         | <0.001  |
| Free time               | 2.27±1.02          | 1.57±0.99         | 0.012   |
| Social relationships    | 2.38±1.08          | 1.4±0.77          | <0.001  |
| Eating                  | 2.24±1.07          | 1.54±0.92         | 0.01    |
| Falling asleep          | 2.16±1.14          | 1.68±1.03         | 0.019   |
| Waking up at night      | 2.13±0.84          | 1.8±0.9           | 0.019   |
| Tiredness               | 2.55±0.98          | 1.91±1.01         | 0.001   |
| Concentration           | 2.41±0.94          | 1.68±0.92         | 0.002   |
| Nervousness             | 2.58±0.82          | 1.68±0.9          | 0.001   |
| Bad mood                | 2.44±1.01          | 1.68±1.05         | 0.003   |
| Limits foods            | 2.08±1.02          | 1.68±0.92         | 0.063   |
| Embarrassed by signs    | 1.99±1.1           | 1.6±0.93          | 0.056   |
| Embarrassed in public   | 1.63±0.86          | 1.32±0.71         | 0.011   |
| Cosmetics               | 1.88±1.03          | 1.6±1.12          | 0.067   |
| Limits clothes          | 1.82±1.01          | 1.4±0.83          | 0.012   |
| Sports                  | 1.68±1.01          | 1.49±0.75         | 0.386   |
| Medication side effects | 1.94±1.22          | 1.4±0.86          | 0.019   |
| Total score             | 50.04±12.35        | 35.99±14.5        | <0.001  |
| UCT                     | 6.03±2.61          | 10.9±3.84         | 0.001   |

received omalizumab and additionally completed acupuncture therapy (22 females and 9 males, mean age: 45 ±13 years). The control group consisted of 30 patients with CU who received only omalizumab (21 females and 9 males, mean age: 46±11 years). The groups were age and gender-matched ( $P=0.66$  and  $P=0.34$ , respectively).

**Table 2** shows comparison of the CU-QoL score of every question separately, total score, and the UCT score of the study

group before and after acupuncture therapy. According to the Wilcoxon test, the mean food limiting scores, the mean scores of embarrassing by signs of the disease (urticarial plaques vs), the mean scores of cosmetics and the mean scores of sports did not significantly differ before and after acupuncture therapy ( $P=0.063$ ,  $P=0.056$ ,  $P=0.067$ , and  $P=0.386$ , respectively). However, all other scores of the CU-QoL questionnaire (pruritis, wheals, eyes swelling, lip swelling, work, physical activities, sleep, free time, social relationship, eating, falling asleep,

**Table 3.** Comparison of the CU-QoL scores and the UCT score of study group (after acupuncture therapy) with the control group.

|                         | Acupuncture group | Control group | P value |
|-------------------------|-------------------|---------------|---------|
| Pruritis                | 2.05±1.09         | 2.9±0.8       | 0.001   |
| Wheals                  | 1.74±0.93         | 2.67±0.91     | <0.001  |
| Eye swelling            | 1.12±0.72         | 1.48±0.95     | 0.027   |
| Lip swelling            | 1.01±0.55         | 1.45±0.98     | 0.006   |
| Work                    | 1.51±0.87         | 2.23±1.2      | 0.013   |
| Physical activities     | 1.57±0.94         | 2.17±1.14     | 0.025   |
| Sleep                   | 1.54±0.94         | 2.29±0.93     | 0.001   |
| Free time               | 1.57±0.99         | 1.86±0.93     | 0.118   |
| Social relationships    | 1.4±0.77          | 2.03±1.05     | 0.011   |
| Eating                  | 1.54±0.92         | 2.26±1.09     | 0.006   |
| Falling asleep          | 1.68±1.03         | 1.97±0.99     | 0.158   |
| Waking up at night      | 1.8±0.9           | 2.09±0.9      | 0.157   |
| Tiredness               | 1.91±1.01         | 2.17±0.93     | 0.232   |
| Concentration           | 1.68±0.92         | 2.09±2.09     | 0.109   |
| Nervousness             | 1.68±0.9          | 2.41±1.11     | 0.009   |
| Bad mood                | 1.68±1.05         | 2.38±1.12     | 0.011   |
| Limits foods            | 1.68±0.92         | 2.09±0.98     | 0.095   |
| Embarrassed by signs    | 1.6±0.93          | 1.48±0.89     | 0.612   |
| Embarrassed in public   | 1.32±0.71         | 1.74±1.12     | 0.132   |
| Cosmetics               | 1.6±1.12          | 1.48±0.95     | 0.79    |
| Limits clothes          | 1.4±0.83          | 1.59±1.12     | 0.705   |
| Sports                  | 1.49±0.75         | 1.51±0.99     | 0.677   |
| Medication side effects | 1.4±0.86          | 1.88±1.05     | 0.042   |
| Total score             | 35.99±14.5        | 46.20±15.05   | 0.006   |
| UCT                     | 10.9±3.84         | 6.77±2.91     | <0.001  |

waking up at night, tiredness, concentration, nervousness, bad mood, embarrassing in public, limiting clothes (whether had any restriction on clothing choices), and medication adverse effects) were significantly lower after acupuncture therapy compared to the scores before acupuncture therapy ( $P<0.001$ ,  $P=0.003$ ,  $P=0.006$ ,  $P=0.012$ ,  $P=0.01$ ,  $P=0.019$ ,  $P=0.001$ ,  $P=0.002$ ,  $P=0.003$ ,  $P=0.011$ , and  $P=0.012$ , respectively). Additionally, the mean total CU-QoL score was significantly lower ( $P<0.001$ ) and the mean UCT score was significantly higher ( $P=0.001$ ) after acupuncture therapy compared to the scores before acupuncture therapy.

The comparison of the CU-QoL score of every question separately, total score, and the UCT score of the study group (after acupuncture therapy) and the control group is presented in **Table 3**.

According to the Mann-Whitney U test, the mean scores of free time, falling asleep, waking up at night, tiredness, concentration, limit foods, embarrassing by signs of the disease, embarrassing in public, cosmetics, limiting clothing choices, and sports were not significantly between groups ( $P=0.118$ ,  $P=0.158$ ,  $P=0.157$ ,  $P=0.232$ ,  $P=0.109$ ,  $P=0.095$ ,  $P=0.612$ ,  $P=0.132$ ,  $P=0.79$ ,  $P=0.705$ , and  $P=0.677$ , respectively). However, all other scores of the CU-QoL questionnaire (pruritis, wheals, eyes swelling, lip swelling, work, physical activities, sleep, social relationships, eating, nervousness, bad mood, and medication adverse effects) were significantly lower in the acupuncture group compared to the control group ( $P=0.001$ ,  $P<0.001$ ,  $P=0.027$ ,  $P=0.006$ ,  $P=0.013$ ,  $P=0.025$ ,  $P=0.011$ ,  $P=0.009$ ,  $P=0.011$ ,  $P=0.042$ , respectively). Additionally, the mean total CU-QoL score was significantly lower ( $P=0.006$ ) and the mean UCT score was significantly higher ( $P<0.001$ ) in the acupuncture group than in the control group.

## Discussion

Chronic urticaria (CU) presents a significant challenge for physicians due to its complex pathogenesis and varied treatment responses. While numerous treatment modalities exist, acupuncture, the oldest healthcare system globally, offers a potential complementary approach. In this study, we investigated the efficacy of acupuncture as an adjunctive therapy in patients with CU receiving omalizumab. We employed the validated CU-QoL questionnaire and UCT to evaluate the impact of acupuncture therapy. Our findings demonstrated a significant decrease in total CU-QoL scores and a substantial increase in UCT scores after acupuncture compared to baseline in the omalizumab-treated group. Additionally, compared to the control group receiving only omalizumab, the combined omalizumab and acupuncture group exhibited significantly lower CU-QoL scores and higher UCT scores.

The exact mechanisms underlying CU pathogenesis remain unclear, although various mediators and cytokines are likely involved in triggering sensory nerve fibers, vasodilation, and plasma extravasation, leading to urticarial lesions [20]. This lack of definitive etiology underscores the need for diverse treatment options, especially considering the significant impact of CU on patient quality of life [13]. Therefore, we hypothesized that acupuncture could potentially improve the quality of life and control the disease in patients with refractory CU.

Previous studies have explored the potential benefits of acupuncture in managing both acute and chronic urticaria [21]. Notably, Iraj et al reported a significant reduction in the frequency and duration of CU episodes within 3 weeks of acupuncture therapy [22]. Additionally, Zhao suggested that acupuncture could even serve as an alternative to antihistamines, demonstrating superior efficacy in clearing wheals compared to oral antihistamines [23]. Furthermore, prior research documented complete wheal clearance in 25.8% of patients receiving acupuncture, along with extended periods between relapses [24]. Our study compared the effects of combined omalizumab and acupuncture therapy with both the control group and the pre-acupuncture scores within the omalizumab group. The results revealed significantly lower mean total CU-QoL scores and significantly higher mean UCT scores in the combined therapy group compared to both control and pre-acupuncture groups. These findings suggest that acupuncture therapy can significantly improve the quality of life for patients with CU. Although the mean UCT score was slightly below 11 ( $10.9 \pm 3.84$ ), many patients had an UCT over 11, showing that acupuncture therapy made a notable contribution to control of the disease.

Brain-derived neurotransmitters and metabolites can influence skin function by interacting with the hypothalamic-

pituitary-adrenal axis. Dysregulation of the axis can trigger mast cell activation and histamine release, which are key factors in CSU. Additionally, these neural mediators can contribute to or exacerbate skin inflammation [25]. While the precise mechanisms by which acupuncture exerts its effects in CU remain under investigation, previous studies have reported increases in adrenal corticosteroid production and serum cortisol levels following acupuncture treatment [26,27]. This suggests that acupuncture stimulates the hypothalamus-pituitary-adrenal axis, leading to increased glucocorticoid secretion and potentially suppressing the immunological basis of urticaria [27]. Additionally, acupuncture may interfere with the transmission of pain and itch signals, stimulate the release of endomorphin-like substances, modulate the immune system, and suppress allergic responses [28]. Therefore, the observed improvements in CU following acupuncture therapy may be associated with elevated in-vivo corticosteroid levels. However, although previous studies have proposed various mechanisms underlying the effects of acupuncture, the exact mechanisms remain poorly understood. Consequently, additional research is required to gain a more comprehensive understanding of how acupuncture works.

A noteworthy limitation of this study is the relatively small sample size. The limited popularity of acupuncture among chronic urticaria patients and the extended treatment duration pose challenges in recruiting larger study populations. Despite this limitation, our findings provide valuable insights and pave the way for further prospective studies exploring the efficacy of acupuncture in CU and in various other dermatological conditions. While the present study provides valuable insights, a larger sample size in future studies could bolster the statistical significance of the findings and improve the generalizability of the results, paving the way for a stronger evidence base for acupuncture's use in chronic urticaria and beyond.

## Conclusions

This study suggests that acupuncture therapy may be a beneficial adjunctive treatment for patients with chronic urticaria (CU) receiving omalizumab therapy. We found significant improvements in both quality of life and disease control as measured by CU-QoL and UCT scores in the combined therapy group compared to both the control and pre-acupuncture groups.

While the study has limitations, including a relatively small sample size and short follow-up period, the observed improvements highlight the potential value of acupuncture in managing CU. Further research with larger patient populations and longer-term follow-up is warranted to confirm these findings and establish the role of acupuncture as a standard treatment option for CU.

## Ethical Statement

This research was reviewed and approved by the Institutional Ethics Committee (IEC) of Balikesir University (Registration number: 2021/177). Informed consent was obtained from all participants.

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## Data Availability

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