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Challenges and experiences of dermatologists in managing chronic urticaria

Kronik ürtiker yönetimi: Dermatologların deneyimleri ve karşılaştıkları zorluklar

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Abstract

Background and Design: Chronic urticaria (CU) is a common inflammatory skin disease that substantially affects patients' quality of life and poses significant challenges for healthcare providers. Although international guidelines provide standardized treatment algorithms, real-world data on the barriers encountered in routine clinical practice remain limited. This study aimed to evaluate dermatologists experiences managing CU, focusing on treatment approaches, perceived challenges, and potential areas for improvement.

Materials and Methods: This descriptive, cross-sectional study was based on a 28-item online survey distributed to dermatologists practicing in Türkiye through professional communication channels between October and December 2024. The questionnaire collected information on demographic characteristics, professional experience, healthcare setting, diagnostic and therapeutic approaches to CU, challenges encountered in daily practice, and suggested system-level improvements.

Results: A total of 251 dermatologists participated in the survey. Most respondents reported using second-generation antihistamines as first-line therapy for CU, and nearly all indicated increasing the dose up to fourfold in patients with inadequate response. Omalizumab was the most frequently preferred treatment option in antihistamine-refractory cases. However, administrative procedures and reimbursement requirements were identified as the primary barriers to prescribing biologic therapy. Additional challenges included limited access to provocation testing for chronic inducible urticaria, insufficient consultation time, and difficulties related to patient education and expectations. A substantial proportion of respondents also reported unmet needs with current treatment options.

Conclusion: Dermatologists face multiple clinical and systemic challenges in managing CU, particularly in accessing advanced therapies and diagnostic resources. Addressing these barriers through healthcare policy adjustments, improved infrastructure, and enhanced patient education strategies may facilitate more effective disease management and improve patient outcomes.

Keywords: Chronic urticaria, guideline, health care surveys, omalizumab, antihistamines

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Öz

Amaç: Kronik ürtiker (KÜ), hastaların yaşam kalitesini önemli ölçüde etkileyen ve sağlık hizmeti sunucuları için çeşitli zorluklar oluşturan yaygın bir enflamatuvar deri hastalığıdır. Uluslararası kılavuzlar standart tedavi algoritmaları sunmasına rağmen, günlük klinik uygulamada karşılaşılan engellere ilişkin gerçek yaşam verileri sınırlıdır. Bu çalışma, dermatologların KÜ yönetimine ilişkin deneyimlerini; tedavi yaklaşımları, karşılaşılan güçlükler ve iyileştirme alanları açısından değerlendirmeyi amaçlamıştır.

Gereç ve Yöntem: Bu tanımlayıcı, kesitsel çalışma Ekim-Aralık 2024 tarihleri arasında Türkiye'de görev yapan dermatologlara mesleki iletişim kanalları aracılığıyla ulaştırılan 28 soruluk çevrim içi bir anket çalışmasına dayanmaktadır. Anket formunda katılımcıların demografik özellikleri, mesleki deneyimleri, çalıştıkları kurum türü, KÜ tanı ve tedavi yaklaşımları, günlük pratikte karşılaşılan zorluklar ve sağlık sistemi düzeyinde iyileştirme önerileri sorgulanmıştır.

Bulgular: Çalışmaya toplam 251 dermatolog katılmıştır. Katılımcıların büyük çoğunluğu KÜ tedavisinde ilk basamak olarak ikinci kuşak antihistaminikleri kullandıklarını ve yetersiz yanıt durumunda dozu dört kata kadar artırdıklarını belirtmiştir. Antihistaminiklere dirençli olgularda en sık tercih edilen tedavi seçeneği omalizumab olmuştur. Bununla birlikte, biyolojik tedavilerin reçetelenmesinde idari süreçler ve geri ödeme koşulları başlıca engeller olarak bildirilmiştir. Kronik indüklenebilir ürtiker için provokasyon testlerine sınırlı erişim, yetersiz muayene süresi ile hasta eğitimi ve beklenti yönetimine ilişkin güçlükler diğer önemli sorunlar arasında yer almıştır. Ayrıca katılımcıların önemli bir kısmı mevcut tedavi seçeneklerinin bazı karşılanmamış ihtiyaçlar barındırdığını ifade etmiştir.

Sonuç: Dermatologlar KÜ yönetiminde, özellikle ileri tedavilere ve tanısal kaynaklara erişim açısından çeşitli klinik ve sistemsel zorluklarla karşılaşmaktadır. Sağlık politikalarında yapılacak düzenlemeler, altyapının güçlendirilmesi ve hasta eğitimine yönelik stratejilerin geliştirilmesi, hastalık yönetiminin daha etkin yürütülmesine ve hasta sonuçlarının iyileştirilmesine katkı sağlayabilir.

Anahtar Kelimeler: Kronik ürtiker, kılavuz, sağlık hizmetleri anketleri, omalizumab, antihistaminikler

Introduction

Chronic urticaria (CU) is defined as recurring wheals, angioedema, or both for over six weeks[1,2]. It predominantly affects adults, is more common in women, and represents a heterogeneous condition with variable clinical presentations and disease courses[1,3-6]. Globally, the lifetime prevalence of CU is estimated at approximately 4.4%, with point prevalence ranging between 0.1% and 1.5%, while pediatric prevalence is considerably lower[7-9].

Despite its relatively common occurrence, epidemiological and real-world data on CU, particularly regarding disease subtypes and management practices, remain limited in Türkiye. This data gap complicates adapting international recommendations to local clinical realities and healthcare system structures. CU presents significant challenges not only for patients, but also for healthcare providers[10]. Beyond its physical manifestations, it substantially impairs quality of life, work productivity, and psychological well-being, thus imposing a societal burden[11]. In the United States, the annual economic cost of CU exceeds $200 million, largely due to direct healthcare expenditures and indirect costs from lost productivity[12]. A cost-analysis study in Türkiye estimated the national burden of CU at approximately €9.27 million annually-0.06% of the Social Security Institution budget-yet this figure likely underrepresents the true burden when indirect costs and quality-of-life impacts are considered[13]. These findings highlight the relevance of CU as a public health issue in Türkiye and underscore the need for real-world data to better understand how systemic factors and healthcare policies influence disease management and outcomes.

The primary aims of CU management include symptom control, reducing flare-up frequency and severity, and preserving patients' ability to carry out daily activities. However, several factors complicate disease management, including the condition's chronic course, heterogeneity in treatment responses, and difficulty identifying consistent triggers. Consequently, current treatment strategies emphasize patient education, multidisciplinary collaboration, and the use of patient-reported outcome measures (PROMs) to monitor disease activity[2]. Recent Delphi consensus studies show that setting clear treatment goals and monitoring disease control with objective tools significantly improves clinical effectiveness[14]. For antihistamine-refractory CU cases, omalizumab (OMA) is widely recommended as an effective biological therapy[15]. The Global Allergy and Asthma European Network (GA^{2}LEN) Task Force has highlighted that limited or delayed access to effective treatments, including biologic agents, contributes to inadequate disease control, prolonged disease activity, and increased healthcare utilization in patients with chronic spontaneous urticaria (CSU)[16]. Although international guidelines provide standardized algorithms for CU management, limited data are available on the practical barriers dermatologists encounter when implementing these recommendations in Türkiye. In this context, systemic limitations may include restrictive reimbursement policies, administrative approval requirements for advanced therapies, regulatory constraints, and disparities in access to specialized diagnostic tools or biologic treatments. Previous data from Türkiye have shown relatively high rates of sedative antihistamine (26.4%) and systemic corticosteroid (19.1%) use in CU management, suggesting potential gaps between guideline recommendations and real-world practice[10]. Accordingly, there is a critical need to better understand systemic constraints, real-world management practices, and clinical decision-making processes in the Turkish healthcare setting. This study evaluates the challenges dermatologists encounter in managing CU in Türkiye, focusing on treatment approaches, structural barriers, and unmet needs, using a multicenter, comprehensive survey-based methodology.

Materials and Methods

Study Design and Ethics

This multicenter, observational survey evaluated dermatologists' clinical practices and challenges in managing urticaria and angioedema in Türkiye. The survey was conducted between October and December 2024. Participation was voluntary and anonymous, and no personally identifiable information was collected. To minimize duplicate responses, we distributed the survey link through professional channels and instructed participants to complete the questionnaire only once. Because the survey relied on voluntary participation, we could not formally assess sample representativeness. Therefore, the findings may not fully reflect dermatological practice across Türkiye.

The Sakarya University Ethics Committee approved the study (approval number: E-43012747-050.04-399603-42, date: 19.09.2024). The study was conducted in accordance with the Declaration of Helsinki, and electronic informed consent was obtained prior to participation.

Questionnaire

The questionnaire consisted of 28 structured items divided into two main sections:

1. Demographic information (5 items)

2. Challenges in the clinical management of urticaria and angioedema (23 items)

The questionnaire was developed based on current international and national guideline recommendations for CU management, including the Turkish Guideline for the Diagnosis and Management of Urticaria and the International European Academy of Allergy and Clinical Immunology (EAACI)/GA²LEN/EuroGuiDerm/APAAACI guideline[2,17].

The initial draft was reviewed for content validity by three senior dermatologists with recognized expertise in urticaria (E.K., Ö.S.K.B., E.Ş.) and was subsequently pilot-tested with five dermatologists to ensure clarity, relevance, and ease of comprehension. The final questionnaire consisted of 28 structured items and is provided in full, including thematic domains and response formats, in Supplementary Table 1. Most items were structured and closed-ended; selected questions included an "Other (please specify)" option to allow brief additional input. These responses were reviewed descriptively. Participants were categorized by affiliation with Urticaria Centers of Reference and Excellence (UCARE)[17] (affiliated vs. non-affiliated) to assess differences in treatment approaches and PROM utilization between groups. The survey was distributed via Google Forms using the official mailing list of the Turkish Society of Dermatology and professional WhatsApp groups.

Statistical Analysis

Data were analyzed using IBM SPSS Statistics v28.0. Although the primary design of the study was descriptive, a predefined exploratory subgroup analysis based on UCARE affiliation was performed. Descriptive statistics were used. All numerical variables were reported as the mean±standard deviation, median, minimum, maximum, frequency, and percentages. Comparisons between respondents affiliated with UCARE centers with those without were performed using the Pearson chi-squared test. p-values lower than 0.05 were considered significant.

Table 1. Demographic and professional characteristics of dermatologists (n=251)

		n (%)/value
Age	Mean±SD (min-max), median	38.92±9.89 (26-67) 35
Gender	Female	185 (73.7%)
	Male	66 (26.3%)
Years worked as a dermatologist (including residency)	0-5	63 (25.1%)
	5-10	65 (25.9%)
	10-20	65 (25.9%)
	More than 20	58 (23.1%)
Type of current institution	Private university	19 (7.6%)
	State university	62 (24.8%)
	Training and research hospital	68 (27.2%)
	State hospital	48 (19.2%)
	Private hospital	34 (13.6%)
	Private practice	19 (7.6%)
Is there an UCARE* in the institution?	Yes	44 (17.5%)
	No	207 (82.5%)

*UCARE: Urticaria Centers of Reference and Excellence, SD: Standard deviation, min: Minimum, max: Maximum

Results

A total of 251 dermatologists completed the survey. Participants reported the total number of years working as a dermatologist, including residency training. Professional status (dermatology resident vs. board-certified specialist) was not queried separately. Because dermatology residency in Türkiye has a standardized duration of four years, respondents reporting 0-5 years of dermatology practice likely include both dermatology residents and recently certified specialists. Thus, an exact numerical distinction between residents and specialists could not be determined. Regarding professional experience, 25.1% of respondents reported 0-5 years, 25.9% reported 5-10 years, 25.9% reported 10-20 years, and 23.1% reported more than 20 years of dermatology practice (Table 1). While 59.6% of participants were working in tertiary-level healthcare institutions (e.g., university hospitals and training and research hospitals), only 17.5% were affiliated with UCARE (Table 1)[18].

Clinical Approaches and Treatment Preferences

The majority of participants (96.8%) reported prescribing second-generation H1-antihistamines (sgAHs) as the first-line treatment for CU (Table 2). Among antihistamine types, 98.8% of respondents preferred second-generation agents. Unresponsiveness to standard-dose antihistamines was assessed based on physicians routine clinical judgment and referred to insufficient disease control despite the use of licensed doses of sgAHs. The questionnaire imposed no predefined criteria for treatment duration or specific disease-activity thresholds [e.g., Urticaria Activity Score (UAS) or UAS7 scores]. In such cases, 96.8% of respondents reported increasing the antihistamine dosage up to fourfold. The remaining 3.2% did not escalate the dose, citing drug side effects as the primary reason (42.9%). Among these, systemic corticosteroids and combinations with first-generation antihistamines (fgAHs) were the most preferred alternatives.

Antihistamine Resistance, Omalizumab Use, and Treatment Challenges

Participants were asked to evaluate whether the current literature sufficiently supports clinical decision-making in CU management, including treatment algorithms, biologic therapy evidence, and long-term management data. While 43.4% believed that the available literature was sufficient, 26.3% were undecided, and 9.6% explicitly disagreed; the remaining respondents did not express a clear opinion. In antihistamine-resistant cases, defined pragmatically as persistent disease activity despite up-dosing of sgAHs up to fourfold, 86.1% of respondents preferred OMA. No uniform therapy duration or standardized disease-activity threshold was mandated, and antihistamine resistance was classified based on the treating physician's clinical assessment.

However, 20.7% of respondents reported not prescribing OMA, with 76.9% attributing this to difficulties in meeting tertiary-level healthcare institutions (e.g., university hospitals and training and research hospitals) and triple-physician approval requirements (Figure 1). The most commonly reported difficulties in OMA prescription were:

- Requirement of six months of prior antihistamine use (52.5%)
- Mandatory report renewal every three months (44.4%)
- Monthly hospital visits for prescription renewal (33.8%)

Impact of UCARE Affiliation on Treatment Strategies and Outcome Measure Use in CU

Among respondents, 17.5% (n=44) were UCARE-affiliated, and 82.5% (n=207) were not. Preference for sgAHs and prescription of high-dose (fourfold) antihistamines did not differ between groups (p=0.422 and p=0.572, respectively). However, UCARE-affiliated respondents more frequently prescribed OMA 300 mg every 4 weeks (93.2% vs. 76.3%, p=0.012) and were more likely to increase the dose in non-responders (95.5% vs. 76.3%, p=0.004). UCARE-affiliated participants also used PROMs significantly more often (84.1% vs. 34.8%, p<0.001) (Table 3).

Table 2. The preferred treatment options for CSU

What is your first-line treatment option in CSU?	**n**	**%**
Second generation non-sedating antihistamines	243	96.8%
Leukotriene antagonists	1	0.4%
Sedating antihistamines	6	2.4%
Others	1	0.4%
Do you prescribe high-dose (4 times) antihistamine treatment in patients who do not respond to standard single-dose antihistamine therapy?		
Yes	243	96.8%
No	8	3.2%
What is your first treatment option in a patient with antihistamine-resistant chronic urticaria?		
Omalizumab (300 mg/4 wks)	243	96.8%
Cyclosporine	8	3.2%
Systemic steroid	24	9.6%
Combination treatment	1	0.4%
Phototherapy	1	0.4%
Doxapine	1	0.4%
What is your first treatment option in a patient with chronic urticaria resistant to standard dose omalizumab (300 mg every 4 weeks)?		
Omalizumab (300 mg/4 wks) and cyclosporine	17	6.8%
Omalizumab (300 mg/4 wk) and dapsone	3	1.2%
Cyclosporine	22	8.8%
Omalizumab (450 mg/4 wks)	147	58.6%
Omalizumab (600 mg/4 wks)	46	18.3%
Methotrexate	1	0.4%
Others	15	6%

CSU: Chronic spontaneous urticaria

Challenges in Chronic Urticaria Management

Chronic inducible urticaria (CIndU): Management of inducible forms was limited mainly by a lack of equipment for provocation testing (47.2%) and insufficient consultation time (39.2%). Additionally, 31.2% noted the off-label status of OMA in CIndU as a significant barrier (Figure 1).

Disease activity monitoring PROMs: Only 43.4% of respondents used PROMs. The most commonly used tools were the UAS7 (92.7%), Urticaria Control Test (UCT, 54.1%), and Dermatology Life Quality Index (37.6%) (Figure 1). Among those not using PROMs, the main reason was lack of time (63.6%).

Patient expectations and communication barriers: Participants reported challenges such as high expectations for treatment response (43.5%), unnecessary diagnostic test requests (45.5%), and difficulty providing sufficient information within limited consultation time (52.4%). Additionally, patients commonly reported a lack of trust in treating physicians (45.2%) and frequent physician switching (Figure 2).

Patient application profiles and treatment history: Most patients had a history of standard-dose antihistamine use (84.4%), while 42% had received systemic corticosteroids. Fourfold antihistamine use was reported in 15.6% of cases, leukotriene antagonists in 14%, and OMA in only 2.8%.

Mismanagement in emergency departments: A significant proportion (77.8%) reported that acute urticaria cases were frequently misdiagnosed as anaphylaxis in emergency settings, leading to unnecessary administration of adrenaline. Physician awareness and therapeutic limitations: Approximately 60.6% of participants indicated a need for novel treatment options for patients inadequately controlled by current guidelines. Additionally, 44.6% believed clinician awareness and knowledge of CU management were insufficient.

Recommendations for Improving Chronic Urticaria Management

Health Policy and Reimbursement: Participants suggested including fourfold antihistamine treatment in the reimbursement system (62.1%), making OMA accessible at the second-line treatment level (45.5%), and providing a 3-month dose of OMA (43.2%). Many also emphasized the need to increase the number of specialized urticaria clinics (Figure 2).

Educational needs and knowledge gaps: Only 35.1% of CU patients reported being aware that treatment needs to be sustained over time. Key areas of knowledge gaps included treatment in special populations (48%) and the lack of comparative studies across different urticaria subtypes (44.6%) (Figure 2).

Discussion

This multicenter study comprehensively evaluated dermatologists' clinical approaches to managing CU, the challenges encountered in daily practice, and healthcare system-related barriers. While treatment strategies generally aligned with international guidelines, notable limitations emerged, particularly regarding access to second-line therapies, patient follow-up, and systemic regulations.

Table 3. Differences in therapeutic approaches and PROM utilization between UCARE-affiliated and non-affiliated centers

In the treatment of chronic urticaria, which AH group do you most frequently prefer?	**Respondents affiliated with UCARE %, (n) 17.5% (44)**	**Respondents without UCARE affiliation %, (n) 82.5% (207)**	**p**
First generation AHs	0	1.4% (3)	0.422
Second generation AHs	100% (44)	98.6% (204)	
Do you prescribe high-dose (4 times) AH treatment?			
Yes	95.5% (42)	97.1% (201)	0.572
Do you prescribe omalizumab 300 mg every 4 weeks?			
Yes	93.2% (41)	76.3% (158)	0.012
In patients who do not respond to standard-dose omalizumab (300 mg every 4 weeks), do you increase the omalizumab dose?			
Yes	95.5% (42)	76.3% (158)	0.004
Do you use patient-reported outcome measures in the initial and follow-up visits of patients with CU?			
Yes	84.1% (37)	34.8% (72)	p<0.001

PROM: Patient-reported outcome measure, AH: Antihistamine, CU: Chronic urticaria, UCARE: Urticaria Centers of Reference and Excellence

Antihistamine Use and Compliance with Guideline Practices

The majority of participants (96.8%) reported prescribing sgAHs as first-line therapy for CU. In cases unresponsive to standard doses, dose escalation up to fourfold was widely adopted, in line with national and EAACI/GA²LEN/European Dermatology Forum/World Allergy Organization 2022 guideline recommendations[2,17]. Supporting evidence from the literature reinforces these findings. In a retrospective study, van den Elzen et al[19]. showed that antihistamine updosing beyond fourfold achieved adequate symptom control in nearly half of treatment-resistant patients, with only a low rate of mild, tolerable adverse effects, mainly sedation and anticholinergic symptoms[19]. Combination therapy was reported less frequently but may remain relevant in selected clinical scenarios. Supporting this, a study from Türkiye by Ayse Ornek et al.[20] reported remission rates of 35.8%, 37.5%, and 25% in patients treated with combinations of two different sgAHs, sgAH plus fgAHs, and sgAH combined with a leukotriene receptor antagonist (LTRA), respectively. Although these regimens may improve symptom control compared with sgAH monotherapy, they remain less effective than increasing the dose of the same sgAH to achieve optimal disease control. Similarly, Türk et al.[21] demonstrated that complete response to antihistamine therapy in CSU was associated with lower baseline disease activity, highlighting the importance of individualized treatment strategies. The questionnaire did not include items on switching between sgAHs or adding a LTRA after failure of fourfold antihistamine up-dosing, as these strategies are not routinely emphasized in the current EAACI/GA²LEN-based treatment algorithm. Therefore, the present data could not support conclusions about these approaches[17].

OMA Use and Access Barriers

OMA was the most frequently preferred second-line treatment for patients with CU unresponsive to antihistamines, with 86.1% of dermatologists in our study reporting its use. This represents a marked increase compared with the 35% usage rate reported in a 2017 study from Türkiye, suggesting growing clinical familiarity and confidence in OMA therapy. Beyond standard dosing, previous studies have also demonstrated that uptitration of OMA (300-600 mg/month) can improve disease control in patients with refractory CSU[10,22].

Despite this positive trend, structural barriers continue to hinder timely and equitable access to OMA significantly. Participants reported multiple limiting factors, including the mandatory use of antihistamines for at least 24 weeks before prescription, the requirement for report renewal every three months, and the necessity for monthly patient visits to healthcare institutions to obtain the medication. Similar barriers have been highlighted internationally. The GA²LEN Task Force emphasized that complex reimbursement procedures frequently delay treatment initiation[16]. At the same time, Rubeiz et al.[23] reported that insurance restrictions, referral requirements, and logistical challenges continue to limit equitable access to biologics, particularly in low- and middle-income countries. Compared with many European countries and the United States, reimbursement policies in Türkiye impose additional administrative requirements that may further delay treatment and disproportionately affect patients managed in secondary-care settings[23]. These findings indicate a need for policy-level reforms, including expanding prescribing authority to secondary-care institutions, simplifying reimbursement procedures, reducing the frequency of report renewals, and permitting multi-month prescriptions for eligible patients. These measures may improve equitable access to biologics, reduce treatment delays, and better align national practice with international recommendations.

Management of CU in Settings with Limited Access to Biologics

While international guidelines advocate a stepwise approach to achieving complete symptom control in CU, real-world practice in many countries-including Türkiye-is shaped more by reimbursement restrictions and administrative barriers than by evidence-based algorithms alone. Global surveys and real-world analyses have consistently shown that high cost, restricted formularies, and complex approval processes are the main barriers to prescribing biologic therapies such as OMA[16,23,24]. In biologic-restricted settings, clinicians frequently rely on pragmatic alternative strategies. These include sequential switching between

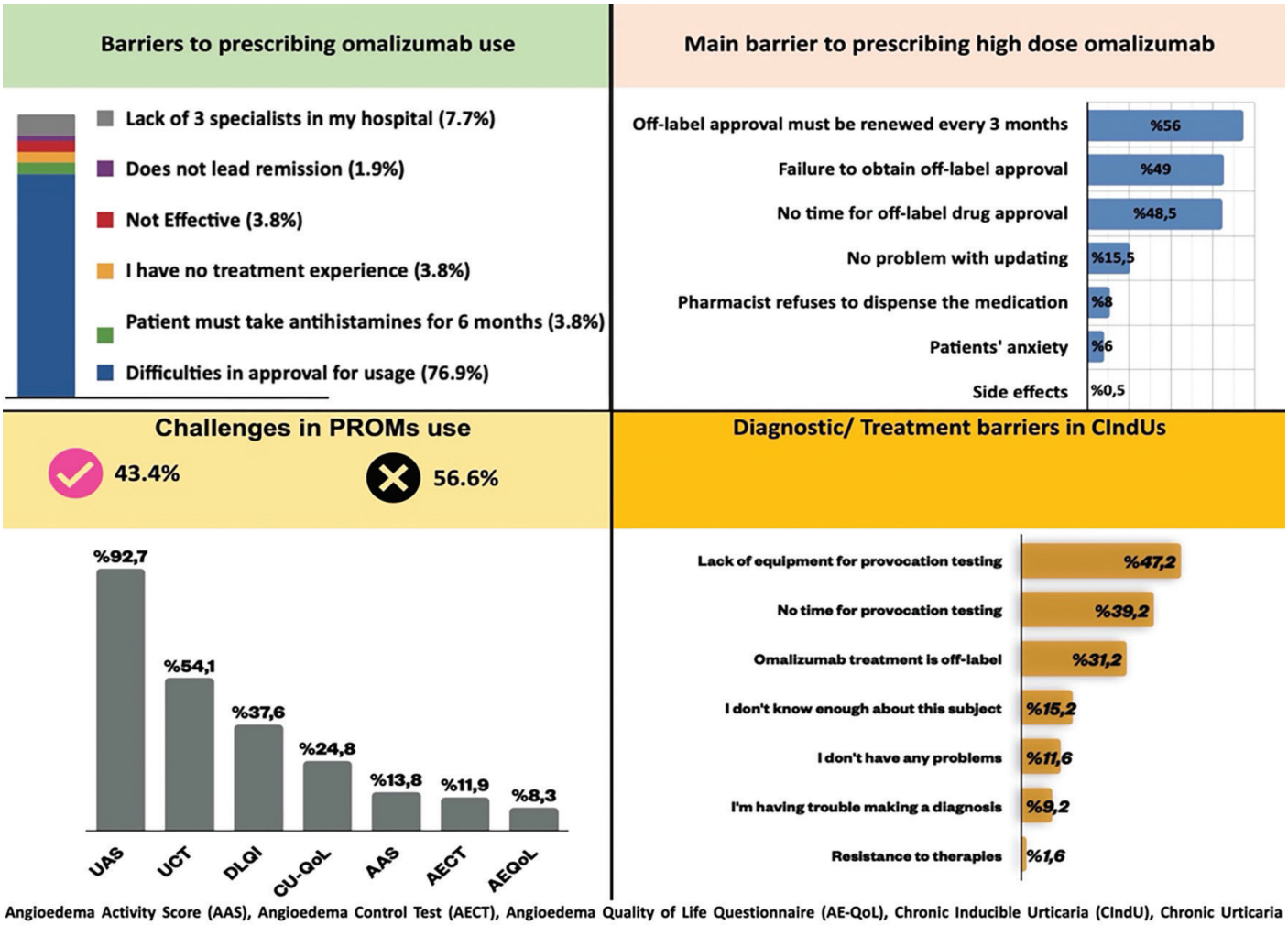


Figure 1. Barriers to prescribing (standard and high dose) omalizumab, PROMs and treatment challenges in CIndUs
AAS: Angioedema activity score, AECT: Angioedema control test, AE-QoL: Angioedema quality of life questionnaire, CIndU: Chronic inducible urticaria, CU-Q2oL: Chronic urticaria quality of life questionnaire, DLQI: Dermatology life quality index, PROMs: Patient-reported outcome measures, UAS: Urticaria activity score, UCT: Urticaria control test

different sgAHs, adjunctive use of LTRA nists such as montelukast, or combination regimens involving sgAHs with fgAHs, despite the limited high-quality evidence supporting their long-term efficacy[20]. Up-dosing of the same sgAH up to fourfold remains the most consistently recommended approach before escalation and is firmly endorsed by international guidelines[17,19]. Short-term systemic corticosteroids may be used as rescue therapy during acute exacerbations; however, long-term use is strongly discouraged due to safety concerns[17]. Reports from international networks such as GA²LEN and UCARE highlight substantial heterogeneity in access to biologic therapies worldwide. While biologics are more readily available in Western Europe and North America, access remains highly restricted in many low- and middle-income countries, resulting in marked inequities in disease control and quality of life[16,17,23]. Importantly, these non-biologic strategies should be regarded as interim or compensatory measures rather than true alternatives to biologic therapy. Prolonged reliance on suboptimal treatment regimens is associated with persistent symptom burden, impaired quality of life, and increased healthcare utilization[24,25]. In settings with limited access to biologics, an individualized and stepwise management approach that maximizes tolerated antihistamine strategies and selectively incorporates adjunctive therapies remains essential. However, these approaches should not delay efforts to improve equitable access to licensed biologic therapies such as OMA and emerging disease-modifying treatment options currently under investigation[26]. Policy reforms, simplified reimbursement pathways, and expanded specialist care networks are critical to narrowing the gap between guideline recommendations and real-world outcomes in managing CU[16,24].

Role of OMA Biosimilars in Improving Access

Recent regulatory approvals of OMA biosimilars, including OMA-igec, by the European Medicines Agency and the U.S. Food and Drug Administration may offer an important opportunity to improve access to biologic therapy for CU. Biosimilars could substantially reduce drug acquisition costs and ease budgetary pressures that currently limit biologic use in many healthcare systems. Emerging evidence suggests

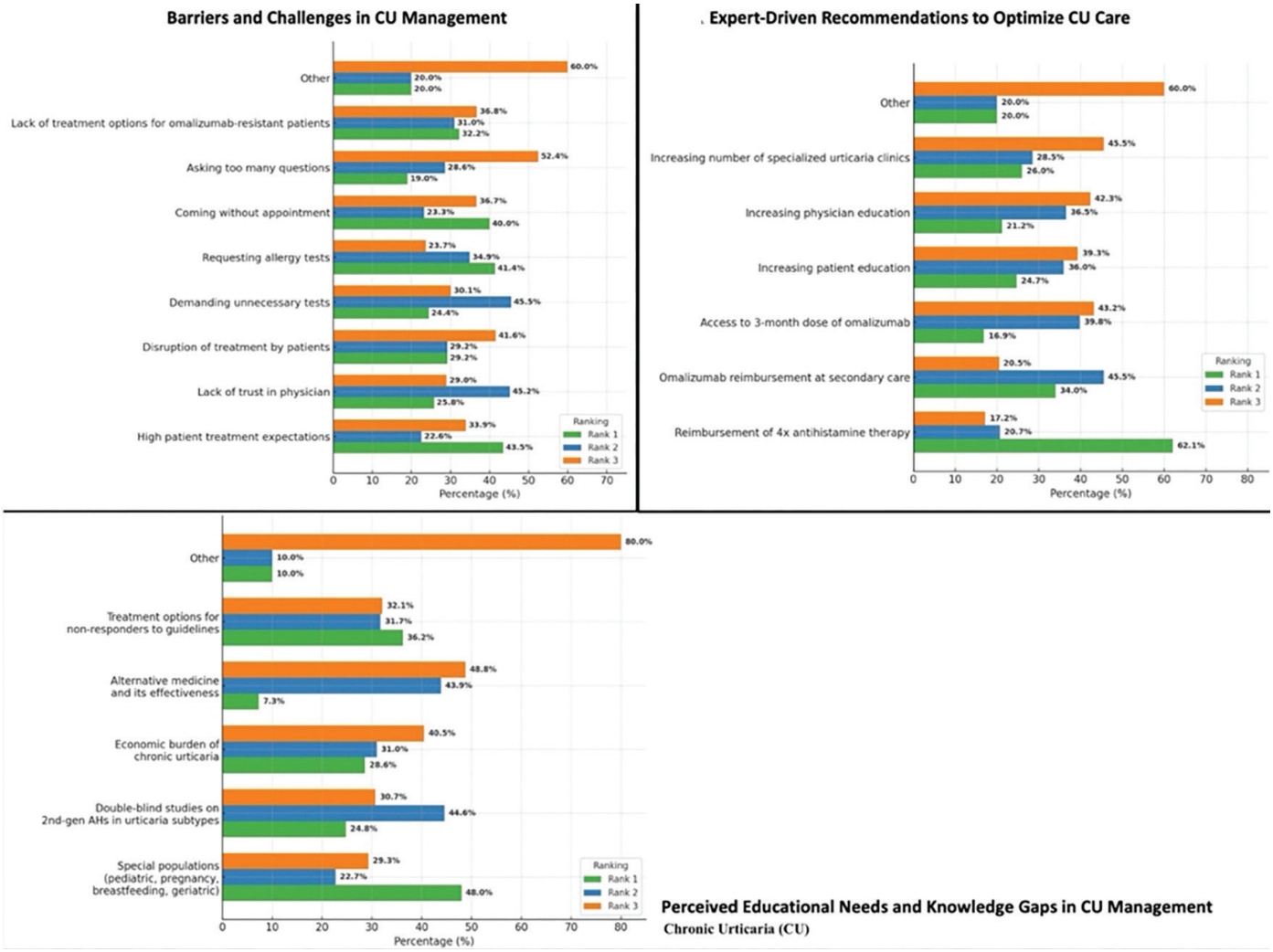


Figure 2. Physician-reported barriers, recommendations, and educational needs in the management of chronic urticaria
CU: Chronic urticaria

that introducing OMA biosimilars could significantly lower healthcare expenditures while maintaining clinical efficacy and safety comparable to the reference product[27]. Health economic analyses further support this perspective. A recent budget impact model evaluating the introduction of an OMA biosimilar across 23 European countries projected meaningful national cost savings, with the potential to expand patient eligibility and facilitate earlier access to biologic therapy[28]. In biologic-restricted settings such as Türkiye, where reimbursement constraints and administrative requirements remain major barriers, biosimilars may offer a pragmatic pathway to align real-world practice more closely with international guideline recommendations. Nevertheless, the successful integration of biosimilars into CU management will depend not only on regulatory approval, but also on clinician confidence, pharmacovigilance frameworks, and reimbursement policies that actively support their use. Future real-world studies evaluating clinical outcomes, physician acceptance, and long-term cost-effectiveness of OMA biosimilars in CU are warranted.

CındU and Diagnostic Limitations

For CIndU, one of the most frequently reported challenges was the underuse of provocation testing, primarily due to insufficient access to standardized diagnostic tools and time constraints in routine clinical practice. These barriers not only hinder guideline-based assessment but also contribute to the misclassification of CIndU as CSU, ultimately leading to suboptimal treatment outcomes and delayed disease control[29,30]. Although international guidelines provide structured diagnostic algorithms, some recommended procedures require specialized equipment and are time-consuming, limiting their feasibility in many outpatient settings. Turkish studies have also demonstrated that CIndU significantly impairs patients quality of life and can exacerbate disease burden when coexisting with CSU[31-33]. Although international guidelines provide structured diagnostic algorithms, some recommended procedures require specialized equipment and are time-consuming, limiting their feasibility in many outpatient settings. Improving access to standardized diagnostic methods, together with

hands-on educational initiatives such as workshops and practical training programs, may facilitate earlier diagnosis and better implementation of guideline-based management. Incorporating CIndU-focused education into undergraduate and continuing medical education programs could further strengthen physicians ability to distinguish CIndU from other urticaria subtypes and optimize patient care.

Use of PROMs and Treatment Targets

In our study, only 43.4% of physicians reported using PROMs to follow up CU. The most commonly used criteria were the UAS7 and the UCT[31]. The main barriers to their use were lack of time and the perception that these tools were impractical. Nevertheless, PROMs provide standardized assessment of disease activity, treatment response, disease control, and quality of life. Similarly, Cherrez-Ojeda et al.[34] reported that PROMs remain underused worldwide in CU management despite their recognized clinical value. In that multinational study, 80% of physicians reported needing additional training. At the same time, time constraints, limited integration into clinical workflows, and concerns about patient adherence were identified as the major barriers to routine implementation[28]. International expert consensus also strongly supports routine use, with more than 95% agreement[14].

Notably, UCARE-affiliated respondents in our study reported significantly higher PROM utilization than non-affiliated centers. As UCARE centers promote standardized, guideline-based care and systematic disease monitoring[18], this finding suggests that specialized reference networks may facilitate the broader implementation of PROMs in routine practice. Similarly, regarding treatment targets, 91.4% of experts in the Delphi study stated that "complete control" (UAS7=0 and/or UCT=16) was the ideal treatment target[14]. In our study, 53.2% of physicians aimed for complete symptom control, and 46% aimed to keep symptoms at tolerable levels, indicating that clinical practice adopts a patient-centered approach.

Health Policies and Need for New Therapies

A substantial proportion of participants emphasized the need for health policy reforms. The most frequently proposed changes included reimbursement for fourfold antihistamine treatment, enabling reimbursement and prescribing of OMA at the secondary-care level, and providing three-month treatment packages. Supporting these recommendations, Mak et al.[24] demonstrated that reimbursement access was associated with greater OMA use and improved disease control, highlighting the critical role of drug accessibility in clinical outcomes. Likewise, Nochaiwong et al.[25] reported that OMA is a cost-effective treatment because it reduces work productivity loss.

Despite these proposed policy changes, more than 60% of dermatologists in our study reported an unmet need for additional therapeutic options in patients who remain inadequately controlled with current treatment algorithms. Accordingly, increasing access to existing therapies should be accompanied by the development of novel disease-modifying therapies that target mechanisms beyond mast cell activation[26]. Such therapies could modify the natural course of CSU, promote long-term remission, and further reduce both the individual and societal burden of disease[26].

Patient Education and Knowledge Gaps

While time constraints were a major barrier to routine PROMs use, participants also highlighted broader gaps in patient education and awareness. Only 35.1% of dermatologists reported that their patients were aware of the long-term nature of CU treatment, and knowledge regarding disease management-especially in special populations (48%) and across different urticaria subtypes (44.6%)-was generally low. These gaps may reduce treatment adherence, continuity of follow-up, and patient expectations in routine clinical practice. Collectively, these findings indicate that patient education should be considered an integral component of CU management. Practical strategies to facilitate PROMs, such as integrating them into routine clinical workflows or digital platforms, may help overcome time-related barriers and improve longitudinal disease monitoring. Digital tools such as the CRUSE® mobile application and patient-centered online resources may further support patient engagement and treatment adherence, particularly in settings with limited consultation time[35,36]. Dermatology practice conditions also vary considerably across healthcare settings. Dermatologists working in high-volume public hospitals often face greater time constraints, whereas university hospitals and UCARE-affiliated centers generally have broader access to diagnostic resources and biologic therapies. Consistent with this, UCARE-affiliated respondents demonstrated greater adherence to guideline-recommended OMA use and more frequent implementation of PROMs, suggesting that specialized reference networks may facilitate more standardized and guideline-concordant care[18]. Although our study included participants from a wide range of institution types, the uneven distribution of participants across broader institutional categories (e.g., public vs. private or academic vs. non-academic settings) prevented robust comparisons by hospital type. Future studies employing stratified sampling and predefined subgroup analyses are warranted to explore institutional differences in CU management more precisely.

Study Limitations

This study has several limitations. First, the data were self-reported, which may introduce response bias. Second, the survey was primarily distributed through professional dermatology networks, which may have skewed the sample toward tertiary-level healthcare institutions (e.g., university hospitals and training and research hospitals) or academic institutions. Although the questionnaire included an item asking whether participants were affiliated with a UCARE center, UCARE centers in Türkiye function as designated reference institutions and are therefore fewer than general dermatology clinics. Additionally, the questionnaire was not specifically designed to differentiate clinical practices between public and private institutions or academic and non-academic environments. Consequently, we could not robustly perform subgroup analyses exploring institutional differences beyond UCARE affiliation. The uneven distribution of participants across healthcare settings and the absence of predefined stratified analyses further limited the exploration of institution-specific practices. Although we conducted an exploratory subgroup comparison by UCARE affiliation, the study was not powered for comprehensive inferential analyses, so interpret these findings with caution. Overall, these limitations highlight the need for future studies incorporating stratified sampling designs, adequately

powered inferential statistical analyses, and institution-focused comparisons to provide more granular insights into CU management.

Conclusion

This study highlights the gap between guideline recommendations and real-world CU management. Improving access to biologic therapies, strengthening diagnostic infrastructure, promoting routine use of PROMs, and enhancing patient education may support more effective and standardized care. Future efforts should focus on reducing implementation barriers and facilitating evidence-based management in daily clinical practice.

Ethics

Ethics Committee Approval: The Sakarya University Ethics Committee approved the study (approval number: E-43012747-050.04-399603-42, date: 19.09.2024).

Informed Consent: Electronic informed consent was obtained prior to participation.

Footnotes

Authorship Contributions

Concept: R.Ö.K., P.K.C., Ö.S.K.B., E.K., Design: R.Ö.K., P.K.C., Ö.S.K.B., E.K., Data Collection or Processing: R.Ö.K., P.K.C., Ö.S.K.B., E.Ş., B.Ö.K., Ö.S.K.B., E.K., Analysis or Interpretation: R.Ö.K., P.K.C., Ö.S.K.B., E.Ş., B.Ö.K., Ö.S.K.B., E.K., Literature Search: R.Ö.K., P.K.C., Ö.S.K.B., E.K., Writing: R.Ö.K., P.K.C., Ö.S.K.B., E.Ş., B.Ö.K., Ö.S.K.B., E.K.G.

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Supplementary Table: https://d2v96fxpocvxx.cloudfront.net/13b035c5-551c-4fd4-a824-19a1febb0519/content-images/81472d48-b277-43a4-99ca-c99e8f07aabe.pdf

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