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Evaluation and management of chronic urticaria: Updating current guidelines

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EAACI/GA²LEN/EDF/WAO
urticaria guidelines: 2012 revision and update

EAACI/GA²LEN/EDF/WAO
urticaria guidelines: 2012 revision and update
EAACI / GA²LEN / EDF / WAO
Urticaria Guidelines: 2012 Revision and Update

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Urticaria Guideline: 2016 Revision and Update
URTICARIA 2016: Guideline Consensus Conference

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Urticaria Guideline: 2016 Revision and Update

45 Experts / Authors

36 Societies

32 Countries
22 Questions and Recommendations
Nomenclature and classification
1. How should urticaria be classified?

Assessment of patients
2. Which instruments should be used to assess and monitor urticaria patients?

Diagnostic workup
3. Should routine diagnostic measures be performed in acute urticaria?
4. Should routine diagnostic measures be performed in chronic spontaneous urticaria?
5. Should extended diagnostic measures be performed in chronic spontaneous urticaria?
6. Should routine diagnostic measures be performed in inducible, non-spontaneous subtypes of urticaria?

Therapy
7. Should treatment aim at complete symptom control in urticaria?
8. Should modern second generation H1-antihistamines (sgAHs) be used as 1st-line treatment of urticaria?
9. Are modern sgAHs to be preferred over first generation H1-antihistamines for the treatment of urticaria?
10. Is an increase in the dose to 4fold of modern sgAHs useful and to be preferred over other treatments of urticaria (2nd-line treatment)?
11. Should modern sgAHs be taken regularly or as needed?
12. Should different sgAHs be used at the same time?
13. If there is no improvement, should higher than fourfold doses of sgAHs be used?
14. Is omalizumab useful as add-on treatment in patients unresponsive to high doses of sgAHs (3rd-line treatment)?
15. Is cyclosporine A useful as add-on treatment in patients unresponsive to high doses of sgAHs (3rd-line treatment)?
16. Are leukotriene antagonists useful as add-on treatment in patients unresponsive to high doses of sgAHs (3rd-line treatment)?
17. Should oral corticosteroids be used as add-on treatment in the treatment of urticaria?
18. Are pseudoallergen-free diets useful in the treatment of chronic spontaneous urticaria?
19. Could any other treatment options be recommended as third-line treatment in urticaria?
20. Should the same treatment algorithm be used in all subtypes of chronic urticaria?
21. Should the same treatment algorithm be used in children?
22. Should the same treatment algorithm be used in pregnant women and during lactation?
How should urticaria be classified?
Definition of Urticaria

Itchy Wheals and/or Angioedema
Classification of urticarias

Acute Urticaria: < 6 weeks

Chronic Urticaria: > 6 weeks
# Chronic Urticaria

<table>
<thead>
<tr>
<th>Spontaneous Urticaria</th>
<th>Inducible Urticaria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Due to known cause</td>
<td>Physical urticaria</td>
</tr>
<tr>
<td></td>
<td>Symptomatic dermographism</td>
</tr>
<tr>
<td></td>
<td>Cold Urticaria</td>
</tr>
<tr>
<td></td>
<td>Delayed pressure urticaria</td>
</tr>
<tr>
<td></td>
<td>Solar urticaria</td>
</tr>
<tr>
<td></td>
<td>Heat urticaria</td>
</tr>
<tr>
<td>Due to unknown cause</td>
<td>Vibratory angioedema</td>
</tr>
<tr>
<td></td>
<td>Cholinergic urticaria</td>
</tr>
<tr>
<td></td>
<td>Contact urticaria</td>
</tr>
<tr>
<td></td>
<td>Aquagenic urticaria</td>
</tr>
</tbody>
</table>

Should routine diagnostic measures be performed in chronic spontaneous urticaria?

Question / Recommendation #4
Question / Recommendation #1

How should urticaria be classified?

or
Which instruments should be used to assess and monitor urticaria patients?
Which instrument should be used to measure QoL in urticaria?

We recommend using the validated CU-Q2oL and AE-QoL instruments for assessing QoL impairment and to monitor disease activity (strong recommendation/clinical consensus).

Should the current activity score (UAS7) be maintained assessing severity in urticaria?

We recommend to use the UAS7 to assess severity (strong recommendation/clinical consensus).
Measure CSU activity and impact

Activity
- UAS7
- AAS

Quality of life
- CU-Q_20L
- AE-QoL

Disease Control
- UCT
Measure CSU activity and impact

Activity
- UAS7
- AAS

Quality of life
- CU-Q_{2oL}
- AE-QoL

Disease Control
- UCT
**Urticaria activity score (UAS7)**

- Once daily; wheal number & and itch intensity (0 – 3 points each)
- Day Score (0 – 6 points)
- Week Score (= UAS7: 0 – 42 points)

<table>
<thead>
<tr>
<th>Points</th>
<th>Number of wheals</th>
<th>Intensity of pruritus</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>none</td>
<td>none</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>some (≤ 20)</td>
<td>mild</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>many (21-50)</td>
<td>moderate</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>a lot (≥ 50)</td>
<td>severe</td>
<td>3</td>
</tr>
</tbody>
</table>
Urticaria activity score (UAS7)

This calendar can help you to monitor the course of your urticaria and to find factors/triggers that induce or aggravate your symptoms. Please indicate once a day and every day 1) how many wheals occurred, 2) how itchy your skin was, 3) whether you had additional symptoms (and if so, how strong they were) and 4) whether (and when) you took your urticaria medication. My urticaria medication*: __________________________

<table>
<thead>
<tr>
<th>Day</th>
<th>Wheals</th>
<th>Itchiness</th>
<th>Symptoms (global evaluation)</th>
<th>Urticaria medication*</th>
<th>Triggers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>For example:</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Stress</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Exercise</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Food</td>
</tr>
<tr>
<td>7</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>8</td>
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<tr>
<td>12</td>
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<tr>
<td>13</td>
<td></td>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>
Measure CSU activity and impact

Activity: UAS7, AAS
Quality of life: CU-QoL, AE-QoL
Disease Control: UCT
Urticaria Control Test

www.moxie-gmbh.de
The Angioedema Activity Score (AAS)
Measure CSU activity and impact

Activity

UAS7

AAS

Quality of life

CU-Q\textsubscript{2}oL

AE-QoL

Disease Control

UCT
Question / Recommendation #4

Should routine diagnostic measures be performed in chronic spontaneous urticaria?
Should routine diagnostic measures be performed in chronic spontaneous urticaria?

We recommend for only very limited routine diagnostic measures in chronic spontaneous urticaria (strong recommendation/clinical consensus).
Rule out severe inflammatory disease

- ESR or CRP
- Differential blood count
Question / Recommendation #5

Should extended diagnostic measures be performed in chronic spontaneous urticaria?
Should extended diagnostic measures be performed in chronic spontaneous urticaria?

We recommend for only limited extended diagnostic measures in chronic spontaneous urticaria based on patient history (strong recommendation/clinical consensus).
# International vs US recommendations

<table>
<thead>
<tr>
<th>EAACI/GA²LEN/EDF/WAO international guidelines</th>
<th>US practice parameters for the diagnosis and management of CU (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Thorough patient history and physical examination</strong></td>
<td></td>
</tr>
<tr>
<td>History includes psychosomatic and psychiatric disease, surgical implantations, and events after surgery</td>
<td>No major differences from international guidelines</td>
</tr>
<tr>
<td><strong>Routine laboratory evaluation</strong></td>
<td></td>
</tr>
<tr>
<td>Very limited routine diagnostic measures (CBC with differential, ESR and/or CRP level)</td>
<td>Testing should be selective. For patients with CU without atypical features consider: CBC with differential, ESR and/or CRP level, liver enzymes, TSH; clinical utility of using these tests routinely has not been established</td>
</tr>
<tr>
<td><strong>Tests for the identification of underlying causes of CSU based on patient history</strong></td>
<td></td>
</tr>
<tr>
<td>Based on patient history (in no preferred order): test for infectious diseases (e.g. <em>Helicobacter pylori</em>), type I allergy, functional autoantibodies, thyroid hormones and autoantibodies, tryptase as indication of severe systemic disease; perform skin tests including physical tests and/or lesional skin biopsy; trial pseudoallergen-free diet for 3 weeks; conduct ASST</td>
<td>Limited laboratory testing, routine testing rarely yields clinically significant findings</td>
</tr>
<tr>
<td><strong>Tests for differential diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Depending on patient history:</td>
<td>Based on patient circumstances, history and physical exam consider:</td>
</tr>
<tr>
<td>- If autoinflammatory disease is strongly suspected, consider: ESR and/or CRP level; testing for paraproteinemia (adults); screening for neutrophil-rich infiltrates in skin biopsy; performing gene mutation analysis for hereditary periodic fever syndromes</td>
<td>- Skin biopsy</td>
</tr>
<tr>
<td>- If HAE is suspected, test for complement C4, C1-INH levels and function, and C1q and C1-INH antibodies</td>
<td>- Physical challenge tests</td>
</tr>
<tr>
<td>- If history suggests HAE and former tests are unremarkable, perform gene mutation analysis</td>
<td>- Complement activity tests</td>
</tr>
<tr>
<td>- If mean wheal duration is &gt;24 h, perform biopsy of lesional skin to assess for signs of urticarial vasculitis (damage to small vessels in the papillary and reticular dermis and/or fibrinoid deposits in perivascular and interstitial locations)</td>
<td>- Stool analysis (ova and parasites)</td>
</tr>
<tr>
<td></td>
<td>- Urinalysis</td>
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<td>- Hepatitis B and C serologies</td>
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<td>- Chest radiography and/or imaging studies</td>
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<td></td>
<td>- Anti-nuclear antibody, rheumatoid factor and/or anti-citrullinated protein</td>
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<td>- Cryoglobulin levels</td>
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<td></td>
<td>- Serologic and/or skin testing for immediate hypersensitivity</td>
</tr>
<tr>
<td></td>
<td>- Thyroid autoantibodies: TSH receptor, thyroglobulin, thyroid peroxidase, and sodium/iodine symporter</td>
</tr>
<tr>
<td></td>
<td>- Serum protein electrophoresis</td>
</tr>
<tr>
<td>Types</td>
<td>Subtypes</td>
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<tr>
<td>----------------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>Spontaneous urticaria</td>
<td>Acute spontaneous urticaria</td>
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<td>Chronic spontaneous urticaria</td>
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<td>Inducible urticaria</td>
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<td>Delayed pressure urticaria</td>
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</tr>
<tr>
<td></td>
<td>Contact urticaria</td>
</tr>
</tbody>
</table>
What is the best approach to treating patients with chronic urticaria?

Cure or protection from signs and symptoms is the best treatment!
Urticaria - Therapeutic strategies

Trigger → Mast cell-activating signal → Mast cell activation → Mast cell mediators → Urticaria reaction

causal

symptomatic
Urticaria - Therapeutic strategies

Trigger

Cause

Mast cell-activating signal → Mast cell activation → Mast cell mediators → Urticaria reaction

causal

symptomatic

Urticaria and Angioedema. Zuberbier T, Grattan C, Maurer M (eds.). Springer 2010
Urticaria - Therapeutic strategies

- Trigger
- Mast cell-activating signal
- Mast cell activation
- Mast cell mediators
- Urticaria reaction

Causal vs. Symptomatic

Urticaria and Angioedema. Zuberbier T, Grattan C, Maurer M (eds.). Springer 2010
**Urticaria - Therapeutic strategies**

- **Trigger**
  - **Cause**
  - **Mast cell-activating signal**
  - **Mast cell activation**
  - **Mast cell mediators**
  - **Urticaria reaction**

**causal**

**symptomatic**
Urticaria - Therapeutic strategies

Trigger

Cause → Mast cell activating signal → Mast cell activation → Mast cell mediators → Urticaria reaction

causal → symptomatic
What is the goal of treating patients with chronic urticaria?

Treat the disease until it is gone!
Are modern second generation H1-antihistamines first line treatment in urticaria and to be preferred against other licensed medication?

We recommend that modern second generation H1-antihistamines are to be used as first line treatment of urticaria (strong recommendation/high level of evidence).
Second-generation H\textsubscript{1}-Antihistamine (sgAH)

Increase sgAH dose (up to 4x)

If symptoms persist after 2 weeks

Add Omalizumab, Cyclosporine A, or Leukotrieneantagonist

If symptoms persist after 1-4 weeks

Short course systemic corticosteroid may be tried for exacerbations
International vs US recommendations

**First-line:**
- Modern second-generation antihistamines

If symptoms persist after 2 weeks

**Second-line:**
- Increase dosage up to four-fold of modern second-generation antihistamines

If symptoms persist after 1–4 further weeks

**Third-line:**
- Add on to second-line*: omalizumab or cyclosporine A or montelukast
- Short course (maximum 10 days) of corticosteroids may also be used at all times if exacerbations demand this

**STEP 1**
- Monotherapy with second-generation antihistamine
- Avoidance of triggers (e.g. NSAIDs) and relevant physical factors if physical urticaria/angioedema syndrome is present

**STEP 2**
One or more of the following:
- Dose advancement of second-generation antihistamine used in Step 1
- Add another second-generation antihistamine
- Add H₂-antagonist
- Add leukotriene-modifying agents
- Add first-generation antihistamine to be taken at bedtime

**STEP 3**
- Dose advancement of sedating first-generation antihistamine (e.g. hydroxyzine or doxepin) as tolerated

**STEP 4**
- Add an alternative agent:
  - Omalizumab or cyclosporine
  - Other anti-inflammatory agents, immunosuppressants, or biologics
Question / Recommendation #10

Is an increase in the dose to 4fold of modern sgAHs useful and to be preferred over other treatments of urticaria (2nd-line treatment)?
Is an increase in the dose to fourfold of modern second generation H1-antihistamines useful as second line treatment and to be preferred over other treatments in urticaria?

We recommend a trial of up to fourfold dose of modern second generation H1-antihistamines as second-line in the algorithm of treatment.
Second-generation H₁-Antihistamine (sgAH)
The first line therapy in urticaria are second-generation H$_1$-Antihistamines.

**But:**
This is effective in only < 50% of patients!
Second-generation H₁-Antihistamine (sgAH)

If symptoms persist after 2 weeks

Increase sgAH dose (up to 4x)
Patients sufficiently treated with antihistamines

Patients (in %)

- ns-AH (regular dose): 45%
- ns-AH (high dose): 65%
International vs US recommendations

**First-line:**
- Modern second-generation antihistamines

If symptoms persist after 2 weeks

**Second-line:**
- Increase dosage up to four-fold of modern second-generation antihistamines

If symptoms persist after 1–4 further weeks

**Third-line:**
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  - Add leukotriene-modifying agents
  - Add first-generation antihistamine to be taken at bedtime

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**STEP 4**
- Add an alternative agent:
  - Omalizumab or cyclosporine
  - Other anti-inflammatory agents, immunosuppressants, or biologics
Adverse effects of first generation antihistamines
sgAH Combination vs. Updosing

Pruritus reduction (in %)

- **Combination**
  - 2 x 2: 16
  - 3 x 2: 38
- **Updosing**
  - 4 x 1: 13

**Schulz et al., Hautarzt 2009**

- Desloratadine 2-0-2
- Levocetirizine 1-0-1
- Fexofenadine 1-0-1
- Azelastine 1-0-1
Second-generation H₁-Antihistamine (sgAH)

If symptoms persist after 2 weeks

Increase sgAH dose (up to 4x)

EAACI / GA²LEN / EDF / WAO
Urticaria Guidelines: 2012 Revision and Update
Is omalizumab useful as add-on treatment in patients unresponsive to high doses of sgAHs (3rd-line treatment)?
Is omalizumab useful in the treatment of patients unresponsive to high doses of H1-antihistamines as third-line treatment?

We recommend a trial of omalizumab as add on therapy to modern second generation H1-antihistamines as third-line in the algorithm of treatment of urticaria (strong recommendation/high level of evidence).
GLACIAL – Results

Itch Score

Week

Treatment

Placebo

Omalizumab 300 mg

X-ACT study: OMA 300mg improves QoL in CSU patients with angioedema

Mean CU-QoL Score

Baseline | Week 4 | Week 12 | Week 20 | Week 28 | Follow up

Omalizumab 300 mg

Placebo

*** = Treatment

Staubach et al., Allergy 2016
X-ACT study: OMA 300mg angioedema in CSU patients

**Angioedema Activity Score (AAS)**

- Baseline
- Week 4
- Week 12
- Week 20
- Week 28
- Follow-up

**AE-QoL Total Score**

- Baseline
- Week 4
- Week 12
- Week 20
- Week 28
- Follow-up

Graphs showing the decrease in angioedema activity score and AE-QoL total score over time with Omalizumab 300 mg compared to Placebo.

Staubach et al., Allergy 2016
Omalizumab for the treatment of chronic spontaneous urticaria: a meta-analysis of randomized clinical trials

Omalizumab works in Symptomatic Dermographism

Change in CFTs (FricTest)

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>150 mg</th>
<th>300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>0</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-1</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>-2</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>-3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Maurer et al., under review
Omalizumab works in Symptomatic Dermographism

Maurer et al., under review
Omalizumab works in Cold Urticaria

Change in CTT (in °C)

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>150 mg</th>
<th>300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omalizumab</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Metz et al., under review
Omalizumab works in Cold Urticaria

Placebo

150 mg Omalizumab

300 mg Omalizumab

Temperature threshold (°C)

Baseline

Week 10

Baseline

Week 10

Baseline

Week 10

Metz et al., under review
Omalizumab and CSU

- Safe and well tolerated
- Very effective, in standard and high dose AH-resistant patients
- Quick response
- Relapse
Is cyclosporine A useful as add-on treatment in patients unresponsive to high doses of sgAHs (3rd-line treatment)?
Is ciclosporin A useful as add on treatment in patients unresponsive to high doses of H1-antihistamines as third-line treatment?

We recommend a trial of ciclosporin A as add on therapy to modern second generation H1-antihistamines as third-line in the algorithm of treatment of urticaria (strong recommendation/high level of evidence).
Are leukotriene antagonists useful as add-on treatment in patients unresponsive to high doses of sgAHs (3rd-line treatment)?
Should leukotriene antagonists be used in the third line treatment of urticaria?

We suggest a trial of montelukast as add on therapy to modern second generation H1-antihistamines as third-line in the treatment of urticaria (weak recommendation/low level of evidence).
Second-generation H₁-Antihistamine (sgAH)

If symptoms persist after 2 weeks

Increase sgAH dose (up to 4x)

If symptoms persist after 1-4 weeks

Add Omalizumab, Cyclosporine A, or Leukotrieneantagonist

Short course systemic corticosteroid may be tried for exacerbations
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