

Swedish Allergists' View on the Role of Corticosteroids and the Formulation (Tablets or Self-Dissolving Film) for the Treatment of Acute Allergic Reactions



Hjelmgren J.¹, Värendh M.¹, Tornling G.²

¹ The Swedish Institute for Health Economics (IHE), Lund, Sweden; ² Respiratory Medicine Division, Department of Medicine Solna, Karolinska Institutet, Stockholm, Sweden

ihe.se

- Acute allergic reactions (AARs) are characterised by a gradual onset of symptoms shortly after allergen exposure. Symptom severity vary along a continuum; the highest severity is anaphylactic shock.¹
- Treatments for AARs include antihistamine, systemic corticosteroids (CS; i.e. tablets dissolved in water) and adrenaline.
- Although most health care regions in Sweden have some guidance on how to treat AARs², there are no national recommendations.
- It is unclear how physicians' use and perceive available treatments for AARs, particularly in relation to CS.
- There is a new option for administration of CS by a self-dissolving oral film.
- Physicians' view on the potential advantage of the oral film over tablets is not known.



Oral film with CS (dexamethasone)

OBJECTIVE

To investigate Swedish allergists' view on the following topics:

- AARs in clinical practice: treatments in relation to severity and role of CS
- the patients' situation: treatment conditions and risks
- a self-dissolving oral film with the CS dexamethasone: potential advantages and role

METHODS



Participants: A total of six experienced Swedish allergists were contacted and five agreed to participate. Three of the allergists currently have or have had connections with AcuCort.



Interview period: November 7-30, 2023

Questions: The questions asked to the specialists were based on a pre-distributed questionnaire. The questionnaire covered eight sections:

- How allergy severity is determined
- How treatment is adjusted based on the severity of the allergy
- Risks and consequences of untreated allergies
- Conditions for allergy patients in acute treatment situations Advantages and disadvantages of CS in various forms
- The role of CS in treating severe acute allergic reactions
- The role of an oral film depending on treatment situation
- Advantages and disadvantages of an oral film versus tablets

Process:

- The interviews were conducted by two experienced health economists from IHE, digitally via Microsoft Teams.
- The questionnaire was sent out before the interview and covered questions related to the study objectives (i) to (iii).
- The duration of each interview was approximately one hour. Each interview was recorded to facilitate transcription, which was sent to each expert to correct for any ambiguities and to avoid that any incorrect information was extracted from the interview. Once transcribed, the recordings were deleted.
- In cases where relevant questions outside the scope of the original questionnaire were discussed (e.g., absence of clinical studies on corticosteroid use in acute allergic reactions), follow-up questions were emailed to the other experts, allowing them to provide written responses on the specific issue.

1. Treatment of AARs in Current Clinical Practice

Treatment versus AAR severity

Severity grade	Experts' reaction	Treatment	Proportion
	Most common type involving individuals	Antihistamine if needed	100%
Mild to moderate	with mild and moderate symptoms.	CS	40%
((1)	Reactions too intense for over-the-	Antihistamine and CS simultaneously	80%
Severe and acute	to seek prescriptions from their doctors.	Antihistamine, CS and adrenaline	20%
<u>-</u>	The most extreme situation scenario	Adrenaline, antihistamine/CS and contact health care	80%
Anaphylactic shock	involving life-threatening reactions.	Adrenaline, ambulance	20%

The experts confirmed that severity of allergic reactions is a continuum.

For severe and acute allergic reactions, most experts recommended the use of CS alongside antihistamines and adrenaline to prevent anaphylaxis.

Role of CS

Optimal

Unchanged role of CS in the treatment of AARs

No real-life studies have demonstrated an effect of CS on late reactions

40%

Designing trials for AARs is difficult

• The experts highlighted the importance of CS in severe allergic reactions. Some noted though that their effectiveness in preventing "late reactions" is based on empiric experience and not scientifically proven.

Percent of experts

2. Patient's Situation

Optimal versus non-optimal treatment conditions

• All medications, water and a container for dissolving CS tablets are available. • The patient is supported by people around them • The patient or another person present acts calmly and follows instructions. **Inoptimal** One or more of the following factors apply: • Medications are unavailable.

- Water to dissolve CS tablets is missing
- The patient is alone, stressed/panicked, cannot follow instructions. • The patient has difficulty swallowing during the AAR
- The patient lacks support from people around them

Definitions of the two situations are correct 100% and relevant The inoptimal situation occurs in at least 50% 100% of all AARs Being lonely and stressed is the most common inoptimal situation Forgetting to bring medication is a common situation Having no water available is a common 60% situation

The experts acknowledged that inoptimal treatment situations is most common and significantly impact outcomes for allergy sufferers during acute events.

Risk and consequences of untreated AARs

Different degrees of suffering

death

Risk of injuries and

Anaphylactic shock

Fear and anxiety

 Untreated severe reactions can lead to anaphylaxis and suffering.

3. The Oral Film in Severe and Acute Allergic Reactions

	Oral film vs tables	Tablets vs oral film	Oral film in optimal situation	Oral film in inoptimal situation
Advantages	More convenient 100%	Lower price 60%	Limited advantages 60%	Convenient- easy to carry with you and use anywhere 80 %
	Increased compliance 100%	Individual dose adjustment (8-10 tablets) 40 %	Oral film has advantages in all situations provided it is available 40%	No need for water 40%
Disadvantages	Higher price 40%	Water is needed 60%	-	-
	Unable to dose adjust at AAR 40%	Patients forget to bring tablets 40%	-	-

- Experts favored tablets for cost and dosing, while oral film was found to be more convenient, accessible and to increase compliance.
- They also considered that the oral film would offer limited advantages in optimal situations but significantly improve adherence in inoptimal conditions, particularly for adolescents and disabled individuals, due to its ease of use without needing water.

CONCLUSIONS

- Interviews with allergists in Sweden highlight the significant role of CS in treating severe and acute allergic reactions.
- Factors affecting treatment outcomes in real-life scenarios include patients' lack of access to medication, stress, and the commonality of "inoptimal treatment situations".
- There is a consensus among the experts that a self-dissolving oral film offers advantages over tablets, such as improved adherence and accessibility, despite concerns about its cost and dosing.

References: 1. Dribin TE, et al., Emerg Med Clin North Am. 2022;40(1):1-17; 2. IHE data on file

Financing: This study was financed by AcuCort AB, Sweden; Medical writing support was provided by Karin Wahlberg at The Swedish Institute for Health Economics