Content Validity of the Angioedema Activity Score From the Perspective of Adults with Chronic Spontaneous Urticaria

Sarah Sauchelli[1]; Diane Whalley[1]; Maria-Magdalena Balp[2]; Ravneet Kohli[3]; Panagiotis Orfanos[2]

[1]RTI Health Solutions, Manchester, United Kingdom; [2]Novartis Pharma AG, Basel, Switzerland;
[3]Novartis Healthcare Private Limited, Hyderabad, India

KEY FINDINGS & CONCLUSIONS

- Participants' reported experiences of angioedema and feedback on the AAS confirmed that the aspects of angioedema assessed in the AAS are relevant and important to evaluate in adults with CSU
- Participants found the AAS to be comprehensive, appropriate, clear, and easy to understand, confirming its content validity to assess angioedema activity
- A 1-category change on the PGIS and "a lot better" on the PGIC reflect meaningful improvement in urticaria symptoms from the patient perspective

This study is funded by Novartis Pharma AG
Poster presented at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), Barcelona, Spain, 17-20 November 2024

INTRODUCTION

- The Angioedema Activity Score (AAS) is a 6-item patient-reported diary measure[1]
- The measure has a gateway item on whether angioedema was experienced in the previous 24 hours and, if so, items assessing time(s) of day swelling episode(s) (midnight-8am; 8am-4pm; 4pm-midnight); severity of physical discomfort (no discomfort to severe discomfort); ability to perform daily activities (no restriction to no activities possible); adverse effect on appearance (no to severely); and overall severity of the episode(s) (negligible to severe)

OBJECTIVE

- The study aimed to evaluate the content validity of the AAS in adults with CSU and explore patients' perceptions of meaningful change on Patient Global Impression of Severity (PGIS) and Patient Global Impression of Change (PGIC) items of urticaria symptoms

METHODS

- Cognitive interviews were conducted with 15 English-speaking adults in the United States with physician-confirmed CSU and who self-reported ≥ 1 angioedema episode in the past 3 months, urticaria symptoms at least several times per week in the past 6 weeks, and use of H_1-antihistamines in the past 6 weeks
- A semi-structured interview guide was used to explore experiences of CSU and obtain feedback on the understandability, meaningfulness, and relevance of the AAS, as well as perceptions of meaningful change on a 5-category PGIS (no symptoms to very severe) and a 7-category PGIC (very much better to very much worse)
- Directed content analysis methods were used to summarize interview data

RESULTS

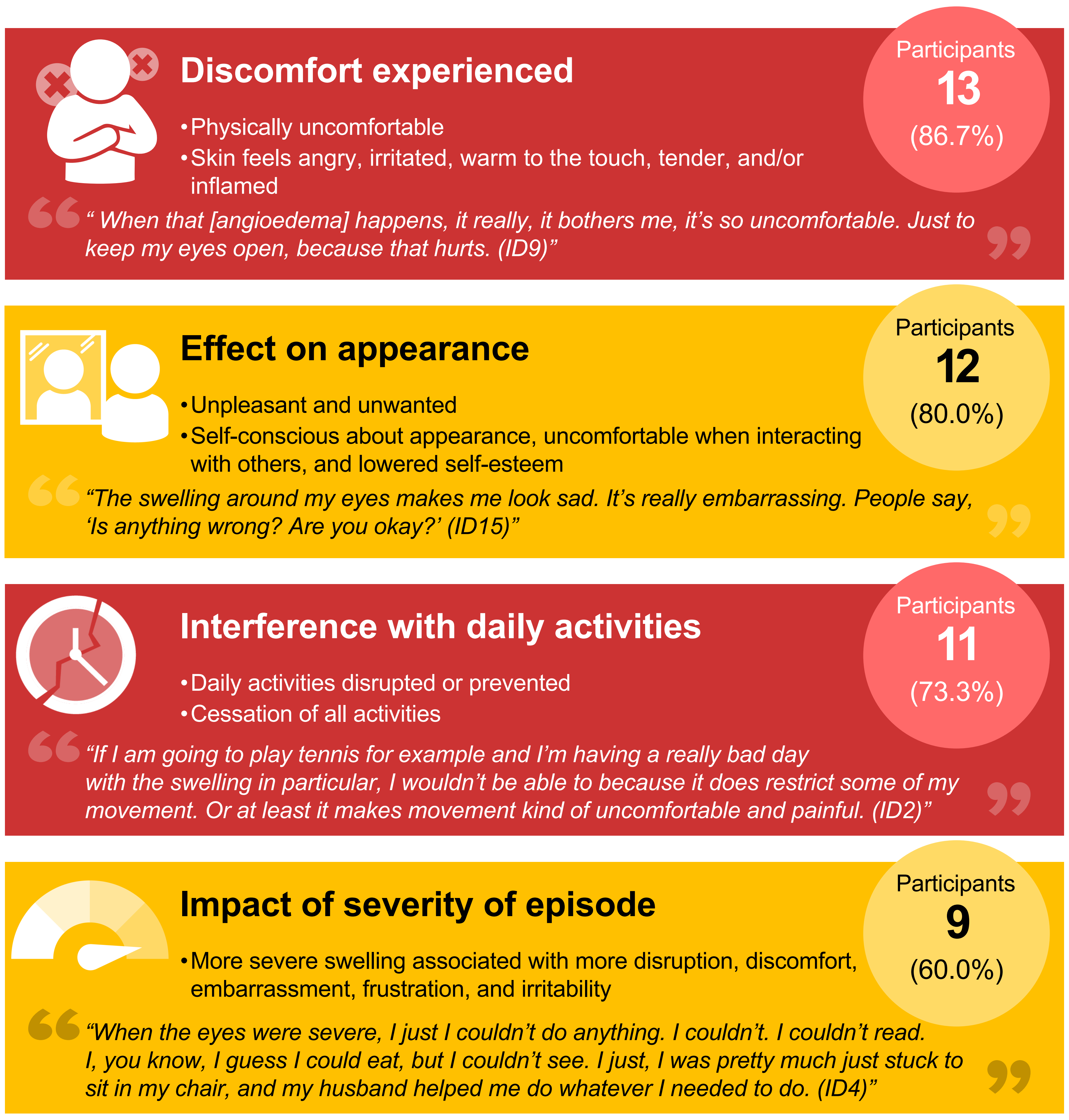
Interview Sample

- Fifteen adults of whom 10 were female, participated in the interview. The participants' age ranged from 21 to 66 years, with a mean age of 45.4 years and standard deviation of 12.2 years
- Eight participants identified as White and seven were in full-time employment. The participants' educational backgrounds varied from high school diploma or equivalent (n = 4) to advanced or professional degree (n = 3)

Experiences of Angioedema

- Key aspects of angioedema described by participants aligned with concepts captured in the AAS (**Figure 1**)
- Additional issues were reported in personal care (n = 7), emotions (n = 7), relationships (n = 5), physical function (n = 4), and cognitive function (n = 4)

Figure 1. Participants' Descriptions and Illustrative Quotes for Angioedema Experiences (N = 15)



Discomfort experienced

Participants
13
(86.7%)

- Physically uncomfortable
- Skin feels angry, irritated, warm to the touch, tender, and/or inflamed

" When that [angioedema] happens, it really, it bothers me, it's so uncomfortable. Just to keep my eyes open, because that hurts. (ID9)"

Effect on appearance

Participants
12
(80.0%)

- Unpleasant and unwanted
- Self-conscious about appearance, uncomfortable when interacting with others, and lowered self-esteem

"The swelling around my eyes makes me look sad. It's really embarrassing. People say, 'Is anything wrong? Are you okay?' (ID15)"

Interference with daily activities

Participants
11
(73.3%)

- Daily activities disrupted or prevented
- Cessation of all activities

"If I am going to play tennis for example and I'm having a really bad day with the swelling in particular, I wouldn't be able to because it does restrict some of my movement. Or at least it makes movement kind of uncomfortable and painful. (ID2)"

Impact of severity of episode

Participants
9
(60.0%)

- More severe swelling associated with more disruption, discomfort, embarrassment, frustration, and irritability

"When the eyes were severe, I just I couldn't do anything. I couldn't. I couldn't read. I, you know, I guess I could eat, but I couldn't see. I just, I was pretty much just stuck to sit in my chair, and my husband helped me do whatever I needed to do. (ID4)"

Feedback on the AAS

Items and Response Options

- All or almost all participants (n ≥ 14) interpreted the items as intended and most (n ≥ 11) considered them relevant to their own experience of angioedema or were aware of the issue among people with CSU
- All participants were able to answer all items, even if the issue was not experienced
- Participants generally found the response categories appropriate and were able to make meaningful distinctions between response categories

Recall Period

- All participants found it easy to recall their experiences of angioedema during the previous 24 hours; 1 participant highlighted that administration over 7 days would capture the unpredictability of angioedema

Comprehensiveness

- Participants considered the AAS to capture the key aspects of angioedema (n = 15), with no important issues missed (n = 12)

> ***"I think it does a really good job of identifying episodes, having me gauge the severity of the episodes and categorizes them well. " (ID3).***

Meaningful Change on PGIS and PGIC

- Most participants considered a 1-point improvement on the PGIS to reflect meaningful improvement in CSU symptoms (**Table 1**), with benefits in the level of discomfort experienced, ability to participate in daily activities, and feelings of self-consciousness
- Several participants needed to see a 2-point or 3-point change from very severe for the improvement to be meaningful (**Table 1**)
- Most participants considered "a lot better" on the PGIC to be the smallest meaningful improvement (**Table 2**), being sufficient to generate meaningful improvements in how bothersome the symptoms were and how much they interfered with daily life

Table 1. Smallest Meaningful Improvement on the PGIS

Starting PGIS category	n	Smallest improvement on PGIS considered meaningful, n (%)		
		1-point improvement	2-point improvement	3-point improvement
Mild	6[a]	5 (83.3)	N/A	N/A
Moderate	13	12 (92.3)	1 (7.7)	N/A
Severe	13	11 (84.6)	2 (15.4)	0 (0.0)
Very severe	13	6 (46.2)	5 (38.5)	2 (15.4)

N/A: not applicable; PGIS: Patient Global Impression of Severity.

[a]One participant reported that they would not consider a change from "mild" to "no symptoms" as meaningful because they were used to tolerating mild symptoms

Table 2. Smallest Meaningful Improvement on the PGIC

N	Smallest improvement on PGIC considered meaningful, n (%)		
	"A little better"	"A lot better"	"Very much better"
14	3 (21.4)	11 (78.6)	0 (0.0)

PGIC: Patient Global Impression of Change

References

1. Weller K, Groffik A, Magerl M, Tohme N, Martus P, Krause K, et al. Development, validation, and initial results of the Angioedema Activity Score. Allergy. 2013 Sep;68(9):1185-92.

Acknowledgements

The authors acknowledge Mukhtar Ahmad Dar (Novartis Healthcare Private Limited, Hyderabad) for editorial and medical writing support. The final responsibility for the content lies with the authors

Disclosures

This study is funded by Novartis Pharma AG, Basel, Switzerland

Scan to obtain:
Poster

https://www.medicalcongressposters.com//Default.aspx?doc=7a68e