Qualitative Insights From RAPIDe-3: Oral Deucrictibant Immediate-Release Capsule for On-Demand Treatment of Hereditary Angioedema Attacks

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Key takeaways

Qualitative in-trial interviews conducted with participants during the RAPIDe-3 trial of deucrictibant for on-demand treatment of hereditary angioedema (HAE) attacks captured high-quality patient experience data, including insights into the experiences of people living with HAE related to their attacks and associated health-related quality of life (HRQoL) impacts.

Activities of daily living (ADL) and work/school

Were most frequently identified by participants as the most important HRQoL domains to improve with treatment

HAE attack-related impacts in RAPIDe-3

Fatigue, emotional wellbeing, and ADL

Were reported to be the top 3 HRQoL domains impacted by HAE attacks during the study

45.7%

Of participants reported that deucrictibant-treated attacks had a lower impact on day-to-day life compared with prior attacks treated with icatibant or C1INH

C1INH, C1 inhibitor.

This presentation includes data for an investigational product not yet approved by regulatory authorities.

Background

- **Hereditary angioedema (HAE):** a bradykinin-mediated condition with painful swelling attacks caused by excess bradykinin-mediated activation of bradykinin B2 receptors that affects multiple locations in the body and negatively impacts health-related quality of life (HRQoL).[1-5]
- **Unmet need:** prior to RAPIDe-3, no qualitative patient experience data had been collected in the setting of Phase 3 clinical trials evaluating on-demand treatments of HAE attacks.[6]
- **Oral deucrictibant:** a selective, bradykinin B2 receptor antagonist under development for both prophylactic and on-demand treatment of bradykinin-mediated angioedema attacks.[7-15]
- **AURORA Delphi consensus:** RAPIDe-3 is the first trial to conform fully with the AURORA Delphi consensus study[16] by including all of the efficacy outcomes recommended to standardize measurements across HAE clinical trials as pre-specified endpoints in the trial protocol.

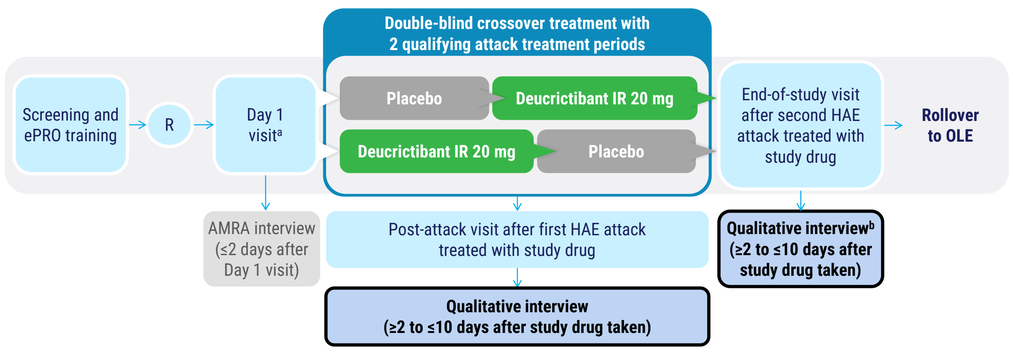
Objective

To characterize the patient experience with HAE attacks in RAPIDe-3, including fatigue and anxiety, impact on daily activities, satisfaction with on-demand treatment with deucrictibant immediate-release (IR) capsule, and overall health status captured through qualitative interviews.

Methods

- **RAPIDe-3 (NCT06343779)*:** a completed, global, Phase 3, randomized, double-blind, placebo-controlled, crossover trial that evaluated the efficacy and safety of deucrictibant IR capsule 20 mg for on-demand treatment of HAE attacks in adolescents and adults.[9]
- **Eligible participants:** aged ≥12 to ≤75 years, living with HAE, with a history of at least two HAE attacks in the last 3 months before screening, and with experience using standard-of-care treatment to manage HAE attacks.

Figure 1. RAPIDe-3 study design



AMRA, Angioedema SyMptom Rating scAle; ePRO, electronic patient-reported outcome; HAE, hereditary angioedema; IR, immediate-release; OLE, open-label extension; R, randomization. [a]Adolescent participants received a non-attack dose for pharmacokinetic sampling at day 1 visit prior to R. [b]The qualitative interview following the second treated attack had to occur before completion of the end-of-study visit.

Interviews

- The trial included 60-minute, semi-structured, blinded, qualitative interviews (up to two) capturing participants' descriptions of living with HAE, their attacks and associated symptoms, physical and emotional impacts of HAE, and fatigue/tiredness.
  - Planned to be conducted remotely by an independent third party ≥2 days to ≤10 days following each of two HAE attacks self-treated with study drug.
  - The interviews captured participants' experiences and satisfaction with conventional on-demand HAE medications, participants' experiences and satisfaction with the study drug, health status, and study experience, including the impacts on HRQoL they experienced after taking the study drug.
  - Herein, we report on participants' treatment experience before enrolling in RAPIDe-3 and their experience with study drug–treated attacks (impact experience) during the trial.

Results

Study population

- A total of 141 interviews post attack (deucrictibant-treated, n=70; placebo-treated, n=71) were conducted with 91 of the 134 RAPIDe-3 participants across 19 countries.
- Of these, 50 participants across 16 countries completed the interviews for both attacks treated according to the crossover sequence; the remaining 41 participants completed an interview for a single attack during the study.
- Interviewed participants had a mean (standard deviation [SD]) age of 36.7 (14.0) years and were predominantly female (n=49/91 [53.8%]) and White (n=71/91 [78.0%]).
- Baseline demographic and clinical characteristics of the interview sample were comparable to those of the total RAPIDe-3 population (**Table 1**).

Table 1. Participant baseline demographics and disease characteristics

Participant characteristics	Interviewed participants (n=91)	All participants (N=134)
Age, mean (SD), years	36.7 (14.0)	39.0 (14.7)
Sex, female, n (%)	49 (53.8)	76 (56.7)
Race, n (%)		
White	71 (78.0)	93 (69.4)
Asian	5 (5.5)	19 (14.2)
Black or African American	5 (5.5)	10 (7.5)
American Indian or Alaska Native	1 (1.1)	1 (0.7)
Other	5 (5.5)	7 (5.2)
Not reported	4 (4.4)	4 (3.0)
Region, n (%)[a]		
Europe	46 (50.5)	56 (41.8)
North America	26 (28.6)	38 (28.4)
Rest of World	19 (20.9)	40 (29.9)
HAE type, n (%)		
Type 1	82 (90.1)	118 (88.1)
Type 2	6 (6.6)	10 (7.5)
Unspecified type 1 or 2	1 (1.1)	2 (1.5)
HAE-nC1INH	2 (2.2)	4 (3.0)
Age at diagnosis, mean (SD), years[b]	19.6 (12.3)	21.8 (14.0)

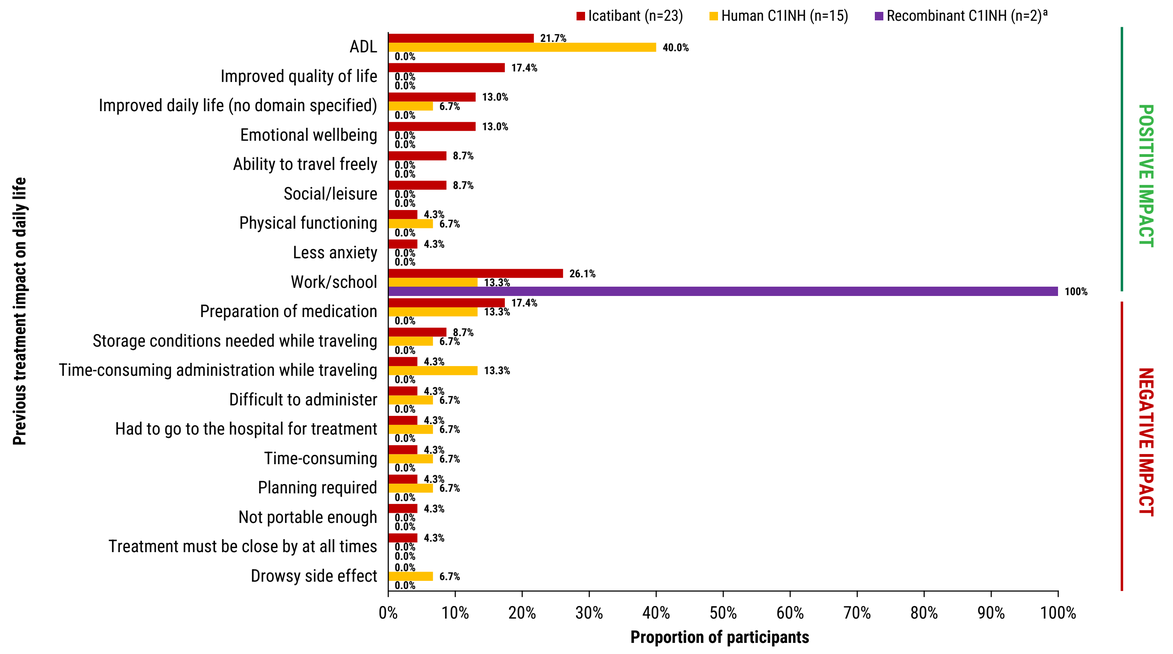
C1INH, C1 inhibitor; HAE, hereditary angioedema; HAE-nC1INH, hereditary angioedema with normal C1 inhibitor; SD, standard deviation. [a]Geographic region of North America included Canada, Puerto Rico, and the United States; Europe included Austria, Bulgaria, Czech Republic, France, Germany, Hungary, Italy, the Netherlands, Poland, Spain, Sweden, and the UK; Rest of World included Argentina, Australia, Brazil, Hong Kong, Japan, Saudi Arabia, South Africa, South Korea, and Turkey. [b]Estimated from year of diagnosis.

Results

Treatment experience before study enrollment

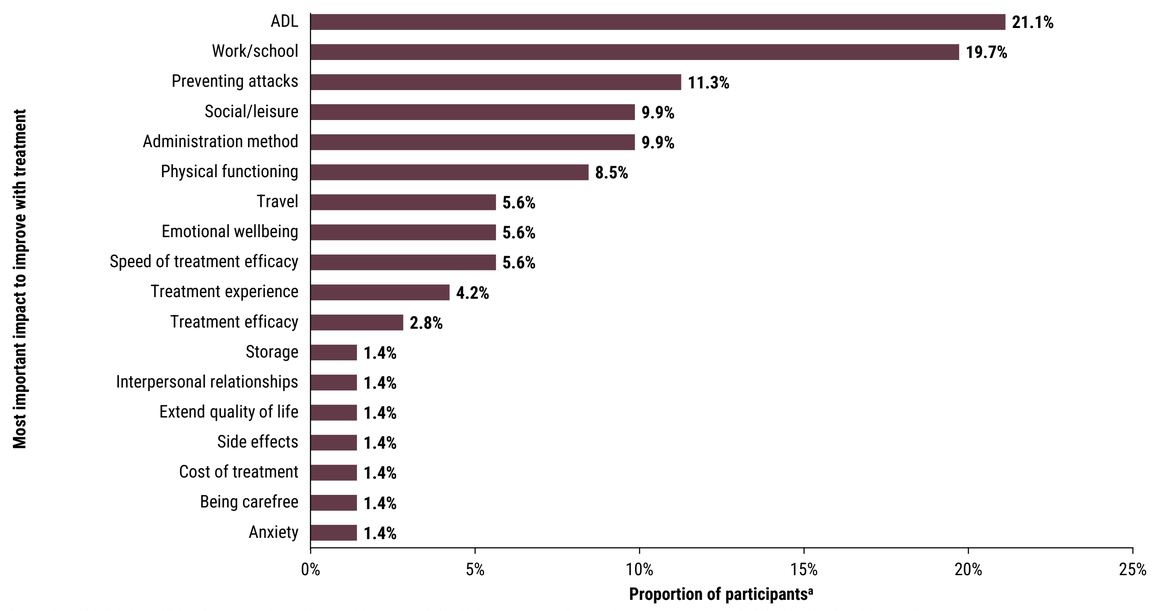
- All participants were asked about previous on-demand treatments used to treat HAE attacks before participating in RAPIDe-3: n=66/91 (72.5%) had used icatibant, n=41/91 (45.1%) human C1 inhibitor (C1INH), and n=7/91 (7.7%) recombinant C1INH.
- Participants (icatibant, n=23; human C1INH, n=15; recombinant C1INH, n=2) reported a total of 19 positive and negative impacts of previous HAE treatments on daily life (**Figure 2**).
- When participants (n=71) were asked to choose the most important aspect of their daily life they would have wanted to see improved with HAE treatment, 15/71 (21.1%) identified activities of daily living (ADL) and 14/71 (19.7%) said work/school (**Figure 3**).

Figure 2. Overview of previous treatment-related positive and negative impact on daily life



ADL, activities of daily living; C1INH, C1 inhibitor. Some participants provided multiple responses, so the sum of proportions may exceed 100%. [a]Both participants only reported negative impacts on work/school with previous recombinant C1INH.

Figure 3. Overview of the most important aspect of daily life that participants would have wanted to see improved with HAE treatment

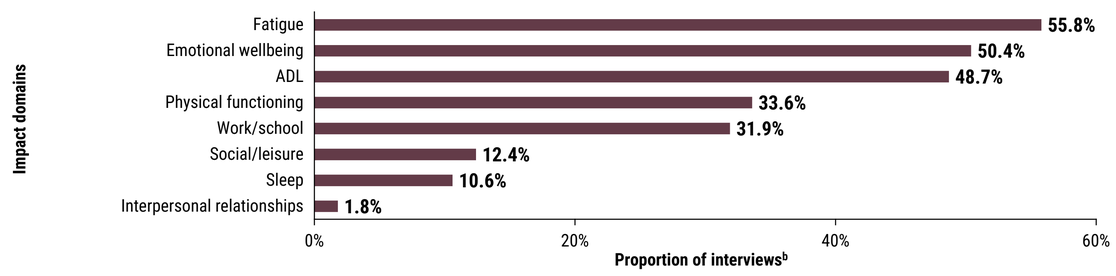


ADL, activities of daily living; HAE, hereditary angioedema. Some participants provided multiple responses, so the sum of proportions may exceed 100%. [a]Number of participants = 71.

Impact on HRQoL related to HAE attacks

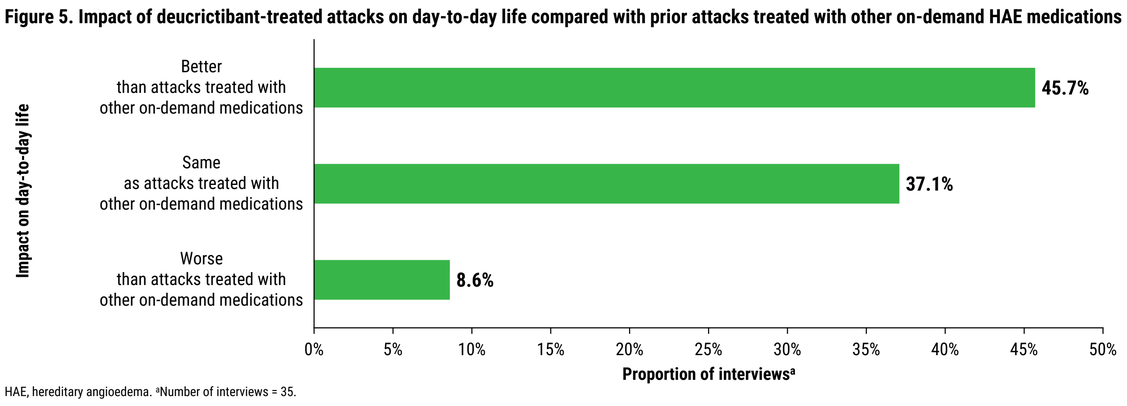
- Overall, participants reported experiencing eight negative HRQoL impacts with HAE attacks during the study, prior to the treatment with the study drug, in 113 interviews; the most frequently reported were fatigue (n=63/113 [55.8%]), emotional wellbeing (n=57/113 [50.4%]), and ADL (n=55/113 [48.7%]) (**Figure 4**).
- Despite using effective and well-tolerated HAE treatments in the past, 16/35 (45.7%) participants reported that deucrictibant-treated attacks had a lower negative impact on day-to-day life compared with prior attacks treated with other HAE treatments (**Figure 5**).

Figure 4. Negative impacts of study HAE attacks prior to treatment with the study drug across treatment periods[a]



ADL, activities of daily living; HAE, hereditary angioedema. [a]Fatigue and anxiety (within the emotional wellbeing domain) were specifically probed upon in the interviews, potentially explaining the high number of reports for their associated domains. Other domains were not specifically probed. [b]Number of interviews = 113.

Figure 5. Impact of deucrictibant-treated attacks on day-to-day life compared with prior attacks treated with other on-demand HAE medications



HAE, hereditary angioedema. [a]Number of interviews = 35.

On-study treatment experience with deucrictibant

- When asked about their overall preference for taking deucrictibant versus their usual treatment, most participants (n=31/32 [96.7%]) reported that they would use deucrictibant instead of their usual treatment if it was available outside of the study.
- Most participants (n=36/39 [92.3%]) reported that the ease of taking deucrictibant was better than taking their usual treatment.
  - Among those who provided a reason for their response, preferring oral administration to injections was reported as the reason most participants (n=22/27 [81.5%]) considered deucrictibant as better than their usual treatment.

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